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

DEPARTMENT OF ENERGY

10 CFR Part 433

[EERE–2022–BT–STD–0012]

RIN 1904–AE44

Baseline Energy Efficiency Standards Update for New Federal Commercial and Multi-Family High-Rise Residential Buildings

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE) is publishing this final rule to implement provisions in the Energy Conservation and Production Act (ECPA) that require DOE to update the baseline Federal energy efficiency performance standards for the construction of new Federal commercial and multi-family high-rise residential buildings. This rule updates the baseline Federal commercial standard to the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Standard 90.1–2019.

DATES: This rule is effective June 6, 2022.

The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of June 6, 2022. The incorporation by reference of certain other material listed in this rule was approved by the Director of the Federal Register through January 5, 2016.

All Federal agencies shall design new Federal buildings that are commercial and multi-family high-rise residential buildings, for which design for construction began on or after April 7, 2023, using ASHRAE Standard 90.1–2019 as the baseline standard for 10 CFR part 433.

ADDRESSES: The docket, which includes this **Federal Register** notice and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

This rulemaking can be identified by docket number EERE–2022–BT–STD–0012 and/or RIN number 1904–AE44. A link to the docket web page can be found at *www.energy.gov/eere/femp/notices-and-rules-related-federal-energy-management.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

For technical issues: Nicolas Baker, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Federal Energy Management Program, Mailstop EE–5F, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–8215, Email: *nicolas.baker@ee.doe.gov.*

For legal issues: Matthew Ring, U.S. Department of Energy, Office of the General Counsel, Forrestal Building, GC–33, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2555, Email: *matthew.ring@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE maintains a previously approved incorporation by reference and incorporates by reference the following standard into 10 CFR part 433:

ANSI/ASHRAE/IES Standard 90.1–2013, Energy Standard for Buildings Except Low-Rise Residential Buildings, I–P Edition, Copyright 2013.

ANSI/ASHRAE/IES Standard 90.1–2019, Energy Standard for Buildings Except Low-Rise Residential Buildings, I–P Edition, Copyright 2019.

Copies of ANSI/ASHRAE/IES Standards 90.1–2013 and 2019 can be obtained from ASHRAE, Inc., 1791 Tullie Circle, NE, Atlanta, GA 30329, or *www.ashrae.org.*

For a further discussion of these standards, see section VII.N of this document.

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I. Summary of the Final Rule

Section 305 of ECPA, as amended, requires DOE to determine whether the energy efficiency standards for new Federal buildings [1] should be updated to reflect revisions to ASHRAE Standard 90.1 based on the cost-effectiveness of the revisions. (42 U.S.C. 6834(a)(3)(B)) Accordingly, DOE conducted a cost-effectiveness analysis that found ASHRAE Standard 90.1–2019 to be cost-effective for new Federal commercial and multi-family high-rise residential buildings. DOE's assumptions and methodology for the cost-effectiveness of this rule are based on DOE's State building energy codes program's cost-effectiveness analysis of ASHRAE Standard 90.1–2016 and ASHRAE Standard 90.1–2019.[2] These assumptions and methodology also provide the basis for the environmental assessment (EA) for this rulemaking. Therefore, in this final rule, DOE updates the energy efficiency standards for new Federal buildings to ASHRAE Standard 90.1–2019 for buildings for which design for construction begins on or after one year after this rule is published in the **Federal Register**. (42 U.S.C. 6834(a)(3)(A))

To ensure consistency with ASHRAE Standard 90.1–2019, this final rule also limits the types of process and receptacle loads that may be excluded from the calculation of the 30 percent improvement beyond ASHRAE Standard 90.1 by revising 10 CFR 433.101(b) to require Federal agencies to include unregulated energy use (*i.e.,* process loads and receptacle loads not within the scope of ASHRAE Standard 90.1) when calculating the 30 percent improvement beyond ASHRAE Standard 90.1, except for energy-intensive process loads that are: (i) Driven by mission and operational requirements, not necessarily buildings, and (ii) not influenced by conventional building energy conservation measures.

This final rule also amends the definition for ''new Federal buildings'' in 10 CFR 433.2 to include buildings leased by Federal agencies and privatized military housing in accordance with amendments to the underlying statutory definition of this term made by the Energy Independence and Security Act (EISA) 2007.[3] This final rule also makes technical amendments to the definitions in 10 CFR 433.2 for consistency with the materials incorporated by reference in 10 CFR 433.3.

Additionally, in the discussion of final rule, DOE clarifies and reiterates several programmatic principles related to agencies' implementation of ASHRAE Standard 90.1. These clarifications do not represent changes to the regulations in 10 CFR part 433. However, DOE frequently receives repeat questions from Federal agencies expressing confusion over particular aspects of implementing ASHRAE Standard 90.1. Accordingly, DOE wishes to reduce agencies' confusion by clarifying several important principles of implementing ASHRAE Standard 90.1 in the discussion of final rule.

II. Introduction

A. Energy Conservation and Production Act Requirements

ECPA, as amended, requires DOE to establish building energy efficiency standards for all new Federal buildings. (42 U.S.C. 6834(a)(1)) The standards established under section 305(a)(1) of ECPA must contain energy efficiency measures that are technologically feasible, economically justified, and meet the energy efficiency levels in the applicable voluntary consensus energy codes specified in section 305. (42 U.S.C. 6834(a)(1)–(3)) Section 306(a) of ECPA further provides that each Federal agency and the Architect of the Capitol must adopt procedures to ensure that new Federal buildings will meet or exceed the Federal building energy efficiency standards established under section 305. (42 U.S.C. 6835(a)) ECPA Section 306(b) bars the head of a Federal agency from expending Federal funds for the construction of a new Federal building unless the building meets or exceeds the applicable baseline Federal building energy standards established under section 305. (42 U.S.C. 6835(b))

Under section 305 of ECPA, the referenced voluntary consensus code for new Federal commercial buildings (including multi-family high rise residential buildings) is ASHRAE Standard 90.1. (42 U.S.C. 6834(a)(2)(A)) DOE codified this referenced code as the baseline Federal building standard in its existing energy efficiency standards found in 10 CFR part 433. Also pursuant to section 305 of ECPA, DOE must establish, by rule, Federal building energy efficiency performance standards for new Federal buildings that require such buildings be designed to achieve energy consumption levels that are at least 30 percent below the levels established in the referenced code (baseline Federal building standard), if life-cycle cost (LCC) effective. (42 U.S.C. 6834(a)(3)(A)(i)(I)) These requirements do not extend to renovations or modifications to existing buildings.

Additionally, under section 305 of ECPA, not later than one year after the date of approval of each subsequent revision of the ASHRAE Standard or the International Energy Conservation Code (IECC), DOE must determine whether to amend the baseline Federal building standards with the revised voluntary standard based on the cost-effectiveness of the revised voluntary standard. (42 U.S.C. 6834(a)(3)(B)) It is this requirement that this rulemaking addresses. ASHRAE has updated Standard 90.1 from the version currently referenced in DOE's regulations at 10 CFR part 433. In this rule, DOE revises the latest baseline Federal building standard for 10 CFR part 433 from ASHRAE Standard 90.1–2013 to ASHRAE Standard 90.1–2019. DOE notes that although ASHRAE published an update to ASHRAE Standard 90.1 in 2016, this rule updates 10 CFR part 433 to ASHRAE Standard 90.1–2019 directly, without requiring agencies to comply with ASHRAE Standard 90.1–2016. DOE notes however that because development of ASHRAE Standard 90.1 is incremental from version to version, ASHRAE Standard 90.1–2019 does include all content in ASHRAE Standard 90.1–2016 that was not specifically removed or modified during the development of ASHRAE Standard 90.1–2019.

B. ASHRAE Standard 90.1

Standard 90.1 is recognized by the U.S. Congress as the national model energy code for commercial buildings under the ECPA. Standard 90.1 is developed under ANSI-approved consensus procedures and is under continuous maintenance by a Standing Standard Project Committee (commonly referenced as SSPC 90.1). Updates to

[1] For the purposes of discussion in this document, all references to ''Federal buildings'' subject to 10 CFR part 433 will include commercial and multi-family high-rise residential unless otherwise noted.

[2] See DOE's State building energy codes program analyses of the cost savings of the 2016 and 2019 ASHRAE 90.1 Standards at *www.energycodes.gov/sites/default/files/2020-07/90.1-2016_National_Cost-Effectiveness.pdf* and *www.energycodes.gov/sites/default/files/2021-07/90.1-2019_National_Cost-Effectiveness.pdf,* respectively.

[3] See section 433(b) of EISA 2007, Public Law 110–140, 121 Stat. 1614 (Dec. 19, 2007).

Standard 90.1 are published every three years in order for the Standard to be included in model building energy codes.

Standard 90.1 includes several paths for compliance in order to provide flexibility to users of the Standard. The prescriptive path, which is widely considered the most traditional, establishes criteria for energy-related characteristics of individual building components such as minimum insulation levels, maximum lighting power, and controls for lighting and heating, ventilation, air conditioning, and refrigeration (HVAC&R) systems. Some of those requirements are considered ''mandatory,'' meaning that they must be met even when one of the other optional paths are utilized (*e.g.,* performance path).

In addition to the prescriptive path, Standard 90.1 includes two optional whole building performance paths. The first, known as the Energy Cost Budget (ECB) method, provides flexibility in allowing a designer to ''trade-off'' compliance among various requirements of Standard 90.1. This effectively allows a designer to not meet a given prescriptive requirement if the impact on energy cost is offset by exceeding other prescriptive requirements, as demonstrated through established energy modeling protocols. A building is deemed in compliance when the annual energy cost of the proposed design is no greater than the annual energy cost of the reference building design (baseline). Additionally, Standard 90.1 includes a second performance approach, the Performance Rating Method in Appendix G of the Standard. Traditionally, Appendix G has been used to rate the performance of buildings that exceed the requirements of Standard 90.1 for ''beyond code'' programs, including the Leadership in Energy and Environmental Design (LEED) Rating System, Green Globes, ASHRAE Standard 189.1, the International Green Construction Code (IgCC), the National Green Building Standard (NGBS), and other above-code programs.

C. Regulatory Requirements of 10 CFR Part 433

The energy efficiency standards for the design and construction of new Federal commercial and multi-family high rise buildings required by section 305 of ECPA were established by DOE under 10 CFR part 433.[4] As required by section 305 of ECPA, the standards in 10 CFR part 433 require Federal buildings be designed to achieve energy consumption levels that are at least 30 percent below the levels set by the most recently adopted version of ASHRAE Standard 90.1. When it is not LCC effective to design new Federal buildings to exceed ASHRAE Standard 90.1 performance levels by 30 percent, new Federal buildings must be designed to exceed the ASHRAE Standard 90.1 performance levels up to the percentage that is LCC effective. (10 CFR 433.100(c)). Furthermore, new Federal buildings must, at minimum, be designed to achieve the baseline standards established in ASHRAE Standard 90.1. (10 CFR 433.100(a)(1)–(4), (c)).

To determine if achieving energy consumption at least 30 percent lower than the levels of ASHRAE Standard 90.1 is LCC effective, Federal agencies must use the life-cycle-cost-effectiveness procedures set out in subpart A of 10 CFR part 436. (10 CFR 433.8) A Federal agency may choose to use one of four methods to determine LCC effectiveness: Lower LCC (10 CFR 436.19), positive net savings (10 CFR 436.20), savings-to-investment ratio estimated to be greater than one (10 CFR 436.21), and an adjusted internal rate of return estimated to be greater than the discount rate as listed in OMB Circular Number A–94 ''Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs'' (10 CFR 436.22).

To determine if a proposed building's energy consumption levels are at least 30 percent better than ASHRAE Standard 90.1, Federal agencies must use the Performance Rating Method found in Appendix G of ASHRAE Standard 90.1, subject to the DOE-specific formula found in 10 CFR 433.101. *See* 10 CFR 433.101(a)(1)–(4). This requires the use of a whole building simulation tool and model for every new Federal building design. Similarly, if it is LCC effective for a proposed building's energy consumption levels to be at a percentage better than ASHRAE Standard 90.1, but less than 30 percent, Federal agencies must use the Performance Rating Method in Appendix G of ASHRAE Standard 90.1 to determine this percentage. However, Federal agencies may use the prescriptive or ECB methods in lieu of the Performance Rating Method when determining whether a proposed building's energy consumption levels comply with, or meet, the energy consumption levels of ASHRAE Standard 90.1.

Currently, for the purposes of calculating the 30 percent savings requirements in 10 CFR 433.100, Federal agencies must include energy consumption levels associated with the building envelope and energy consuming systems normally specified as part of the building design by ASHRAE Standard 90.1, such as space heating, space cooling, ventilation, service water heating (SWH), and lighting, but must not include receptacle and process loads not within the scope of ASHRAE Standard 90.1, such as specialized medical or research equipment and equipment used in manufacturing processes.[5] (10 CFR 433.101(b)) However, due to a change made by ASHRAE in Standard 90.1–2016, and retained in ASHRAE Standard 90.1–2019, unregulated process and receptacle loads must be accounted for in the whole building analysis to determine whether a Federal building design complies with, or meets, ASHRAE Standard 90.1–2019, and in the whole building simulation used to establish the baseline for applying the Appendix G Performance Rating Method. See section III.B for a more detailed discussion.

D. Synopsis of Changes to ASHRAE Standard 90.1 Between ASHRAE Standard 90.1–2013 and ASHRAE Standard 90.1–2019

Under its building energy codes program, DOE evaluated ASHRAE Standard 90.1–2016 and 90.1–2019 and determined that each version would improve energy efficiency in commercial buildings subject to the code relative to the previous version of the Standard. (*See* 83 FR 8463 and 86 FR 40543) The summaries of the changes between each version of the Standard in the following sections are taken directly from DOE's determinations and supporting analyses for ASHRAE Standard 90.1–2016 and ASHRAE Standard 90.1–2019.[6] Section

[4] For the purposes of discussion in this document, all references to ''Federal buildings'' subject to 10 CFR part 433 will include commercial and multi-family high-rise residential unless otherwise noted.

[5] ''Process load'' means the load on a building resulting from energy consumed in support of a manufacturing, industrial, or commercial process. Process loads do not include energy consumed maintaining comfort and amenities for the occupants of the building (including space conditioning for human comfort). ''Receptacle load,'' also known as ''plug load,'' means the load on a building resulting from energy consumed by any equipment plugged into electrical outlets. (10 CFR 433.2)

[6] See determinations for the 2016 and 2019 ASHRAE 90.1 Standards at *www.regulations.gov/document/EERE-2017-BT-DET-0046-0008* and *www.regulations.gov/document/EERE-2020-BT-DET-0017-0010*. See analysis of energy savings for the 2016 and 2019 ASHRAE 90.1 Standards at *www.energycodes.gov/sites/default/files/2021-07/02202018_Standard_90.1-2016_Determination_TSD.pdf* and *www.energycodes.gov/sites/default/files/2021-07/Standard_90.1-2019_Final_Determination_TSD.pdf*.

II.D.1 describes the changes between ASHRAE Standard 90.1–2013 and ASHRAE Standard 90.1–2016, and section II.D.2 describes the changes between ASHRAE Standard 90.1–2016 and ASHRAE Standard 90.1–2019.

1. Changes in ASHRAE From Standard 90.1–2013 to Standard 90.1–2016

ASHRAE publishes changes to Standard 90.1 as individual addenda to the preceding Standard, and then bundles them together to form the next published edition. In creating the 2016 edition, ASHRAE published 121 addenda in total (listed in Appendix H of Standard 90.1–2016). DOE characterized the individual addenda into four categories:

(1) Addenda that are clarifications, administrative, or update references to other documents;
(2) Addenda that modify prescriptive and mandatory design and construction requirements for the envelope, HVAC, SWH, power, lighting, and other equipment sections of the standard;
(3) Addenda that modify the performance path options for compliance (the energy cost budget, building envelope trade-off option, and performance rating method sections of Standard 90.1); or
(4) Addenda that modify normative references.

DOE analyzed these addenda in preliminary and final energy savings analyses in making its determination that changes in ASHRAE Standard 90.1–2016 would lead to improved overall energy efficiency in buildings subject to the code compared to the 2013 edition of the Standard. (*See* 83 FR 8463) A more detailed discussion of the individual addenda may be found in DOE's energy savings analysis technical support document (TSD) for the final determination, which may be accessed at *www.energycodes.gov/determinations.*

For the purposes of this final rule, the most significant changes in ASHRAE Standard 90.1–2016 and beyond are to the Appendix G Performance Rating Method. The changes include: moving to a fixed baseline for calculating baseline building costs in the Performance Rating Method, adjustments to the associated equation for demonstrating compliance with the Performance Rating Method, and the application of a second equation that includes selecting building type and climate zone from a new table included in the revision. These changes are discussed in more detail in this section. However, as before, the calculations in the Appendix G Performance Rating Method are expressed in terms of energy costs.

Another significant change is that the new Appendix G Performance Rating Method may now be used to demonstrate compliance with ASHRAE Standard 90.1. In previous versions of the Standard, the Appendix G Performance Rating Method could only be used to make ''beyond code'' determinations of a proposed building's energy efficiency improvement beyond ASHRAE Standard 90.1. To demonstrate compliance, users were required to use either the prescriptive path or the ECB model to determine compliance. With the changes to the Appendix G Performance Rating Method formula, users may now use the Performance Rating Method to determine compliance with ASHRAE Standard 90.1.

a. Fixed Baseline

In Standard 90.1–2016, Appendix G was redesigned to have a consistent baseline across future versions for purposes of calculating baseline building energy costs, as opposed to having a baseline based on the prescriptive requirements of each new Standard. The new baseline for the Appendix G Performance Rating Method is now fixed at a level of performance approximately equal to the requirements in ASHRAE Standard 90.1–2004. That baseline is then used in a new formula found in Section 4.2.1.1 of ASHRAE Standard 90.1–2016 to set a compliance baseline for buildings designed under ASHRAE Standard 90.1–2016. The formula uses factors for different building types and climate zones, the building performance factors (BPFs) which are established in ASHRAE Standard 90.1–2016, and will be updated in each subsequent version. The BPFs are based upon the percent improvement in energy cost savings that is required by each successive ASHRAE Standard 90.1 compared to the fixed baseline. The resulting target represents the increase in energy cost savings beyond the fixed baseline that is required in each successive ASHRAE Standard 90.1 for each building type and climate zone.

The intent of these changes is to encourage the development of software tools that implement the Appendix G Performance Rating Method by providing a consistent baseline for Standard 90.1–2016 and future versions. This would allow software developers to more easily update programs to account for subsequent versions of the Standard by simply updating the BPFs used in the subsequent Standard. These efforts could have significant value to Federal agencies because the software tools envisioned would perform both the baseline and proposed building performance calculations and keep track of the relationships between the baseline building performance and proposed building performance, as noted in Table G3.1 of the Appendix G Performance Rating Method in ASHRAE Standard 90.1–2016. While these tools do not currently exist, it is expected that adhering to a consistent baseline will encourage software development.

b. Revisions and Additions to the Formula for Demonstrating Compliance With the Appendix G Performance Rating Method

To accommodate the new baseline, and because ASHRAE Standard 90.1 prescriptive requirements are now significantly more stringent than that baseline, ASHRAE revised the formula for demonstrating compliance with, and improvement beyond, the Appendix G Performance Rating Method in Standard 90.1–2016. The new formula requires the user to determine a metric first established in ASHRAE Standard 90.1–2016, the Performance Cost Index (PCI), which is calculated as follows:

Performance Cost Index = proposed building performance/baseline building performance

To determine compliance with, or improvement beyond, ASHRAE Standard 90.1, the user must then compare the PCI with a PCI Target (PCI_t). The PCI_t is the energy cost value that a proposed building must meet in order to comply with ASHRAE Standard 90.1 and, as noted above, it represents the increase in energy cost savings beyond the fixed baseline that is required in new versions of ASHRAE Standard 90.1 for that specific building type and climate zone. Accordingly, where $PCI \leq PCI_t$ the proposed building design complies with ASHRAE Standard 90.1.

To calculate PCI_t, users must use the formula in Section 4.2.1.1, first established in ASHRAE Standard 90.1–2016 and repeated in Standard 90.1–2019, which is quoted below:

''When using Appendix G, the Performance Cost Index (PCI) shall be less than or equal to the Performance Cost Index Target (PCI_t) when calculated in accordance with the following:

$$PCI_t = [BBUEC + (BPF \times BBREC)]/BBP$$

Where:

PCI = Performance Cost Index calculated in accordance with section G1.2.
BBUEC = Baseline Building Unregulated Energy Cost, the portion of the annual energy cost of a baseline building design that is due to unregulated energy use.
BBREC = Baseline Building Regulated Energy Cost, the portion of the annual energy cost of a baseline building design that is due to regulated energy use.

BPF = Building Performance Factor from Table 4.2.1.1. For building area types not listed in Table 4.2.1.1, use ''all others.'' Where a building has multiple building area types, the required BPF shall be equal to the area-weighted average of the building area types.
BBP = Baseline Building Performance.''

This formula is used in conjunction with Table 4.2.1.1, which provides BPFs for 9 building area types: Multifamily, Healthcare/Hospital, Hotel/Motel, Office, Restaurant, Retail, School, Warehouse, and All Others. BPFs are also provided for 17 climate zones: 0A and 1A, 0B and 1B, 2A, 2B, 3A, 3B, 3C, 4A, 4B, 4C, 5A, 5B, 5C, 6A, 6B, 7, and 8. Table 4.2.1.1 may be viewed in the online read-only version of ASHRAE Standard 90.1–2019.[7]

Definitions of Regulated and Unregulated Energy Use

As noted previously, there are two key terms used in the formula in Section 4.2.1.1 of ASHRAE Standard 90.1: ''regulated energy use'' and ''unregulated energy use.'' ASHRAE defines ''regulated energy use'' as ''energy used by building systems and components with requirements prescribed in sections 5 through 10. This includes energy used by HVAC, lighting, SWH, motors, transformers, vertical transportation, refrigeration equipment, computer-room cooling equipment, and other building systems, components, and processes with requirements in sections 5 through 10.'' ASHRAE defines ''unregulated energy use'' as ''energy used by building systems and components that is not regulated energy use (see regulated energy use).'' For purposes of clarity, DOE notes that the definition of ''regulated energy use'' should include SWH used for pools, both interior lighting and exterior lighting, and service water pressure booster systems.

DOE also notes that in ASHRAE Standard 90.1–2016, ASHRAE considered plug loads such as computers, printers, copiers, and other electronic devices to be ''unregulated energy use'' for purposes of ASHRAE Standard 90.1. While automatic receptacle control[8] for plug loads is required by Section 8.4.2 of ASHRAE Standard 90.1, the actual plug loads themselves are not regulated. DOE also notes that cooking equipment other than refrigeration equipment should be considered ''unregulated energy use'' as well. DOE notes that both plug loads and cooking equipment are covered by Federal energy efficient product procurement requirements in 10 CFR part 436.

2. Changes in ASHRAE From Standard 90.1–2016 to Standard 90.1–2019

In creating Standard 90.1–2019, ASHRAE published 88 addenda in total, of which:

- 29 are expected to decrease energy use (*i.e.,* increased energy savings);
- none are expected to increase energy use (*i.e.,* decreased energy savings), and;
- 59 are expected to have no direct impact on energy savings (such as administrative or clarifications or changes to alternative compliance paths).

DOE analyzed these addenda in preliminary and final energy savings analyses in making its determination that changes in ASHRAE Standard 90.1–2019 will lead to improved overall energy efficiency in buildings subject to the code compared to the 2016 edition of the Standard. (*See* 86 FR 20674 (April 21, 2021) and 86 FR 40543 (July 28, 2021)) A more detailed discussion of the individual addenda may be found in DOE's energy savings analysis TSD for the final determination, which may be accessed at *www.energycodes.gov/determinations.*

The 29 changes considered that are expected to decrease energy use are:

(1) Modified exceptions to exhaust air energy recovery requirements.

(2) Changes the term ''ventilation air'' to ''outdoor air'' in multiple locations. Adds an exception to allow systems intended to operate continuously not to install motorized outdoor air dampers. Changes return air dampers to require low leakage ratings.

(3) Provides a definition of ''occupied-standby mode'' and adds new ventilation air requirements for zones served in occupied-standby mode.

(4) Clarifies that exhaust air energy recovery ventilators (ERVs) should be sized to meet both heating and cooling design conditions unless one mode is specifically excluded by existing exceptions.

(5) Revises the exception to demand control ventilation (DCV) requirements to clarify that the exception only applies to systems with ERV required to meet section 6.5.6.1.

(6) Revises the definition of ''networked guest room control system'' and aligns HVAC and lighting time-out periods for guest rooms.

(7) Expands the exterior lighting power density (LPD) application table to cover additional exterior spaces that are not in the exterior LPD table.

(8) Adds heat recovery for the space conditioning requirement targeted specifically at in-patient hospitals.

(9) Restructures commissioning and functional testing requirements in all sections of Standard 90.1 to require verification or testing for smaller and simpler buildings and commissioning for larger and more complex buildings.

(10) Adds indoor pool dehumidifier energy recovery requirement.

(11) Implements Federal clean water pump requirements.

(12) Replaces Fan Energy Grade metric with Fan Energy Index metric.

(13) Revises supply air temperature reset controls.

(14) Eliminates the requirement that zones with direct digital control (DDC) have air flow rates that are no more than 20 percent of the zone design peak flow rate.

(15) Revises the prescriptive fenestration U-factor and solar heat gain coefficient (SHGC) requirements and makes them material neutral.

(16) Provides separate requirements for non-transient dwelling unit exhaust air energy recovery.

(17) Changes the interior LPD requirements for many space types.

(18) Adds a new chiller table for heat pump and heat recovery chillers.

(19) Revises the computer room air conditioner (CRAC) requirements to clarify these are for floor mounted units and adds a new table for ceiling mounted units.

(20) Adds a definition of Standby Power Mode Consumption. Increases the furnace efficiency requirements.

(21) Adds a new Table F–5 to specify DOE-covered residential water boiler efficiency requirements and notes that requirements in Table 6.8.1–6 apply only to products used outside the United States. Adds standby mode and improved efficiency as of January 15, 2021.

(22) Adds dry cooler efficiency requirements and slightly increases efficiency requirements for evaporative condensers.

(23) Combines the commercial refrigerator and freezer table with the refrigerated casework table into a single table. Increases efficiency requirements.

(24) Revises LPDs using the Building Area Method.

(25) Makes a similar change to the variable air volume (VAV) box minimums as Addendum *au* to 90.1–2016, but in exception 1 to section 6.5.2.1 where the same 20 percent requirement still existed.

(26) Cleans up the outdated language regarding walk-in cooler and walk-in freezer

[7] Table 4.2.1.1 of Standard 90.1–2019 is copyrighted by ASHRAE and is not included in this rule. However, a read-only copy of ANSI/ASHRAE/IES Standard 90.1–2019 may be found on the ASHRAE website at *www.ashrae.org/technical-resources/standards-and-guidelines* by scrolling down to ''Preview ASHRAE Standards and Guidelines'' and selecting ''Standard 90.1–2019 (I–P).'' Table 4.2.1.1 is found in Section 4 on page 47.

[8] ASHRAE Standard 90.1 uses the term ''automatic receptacle control'' without a specific definition, indicating that the common usage of this term should be used. However, ASHRAE Standard 90.1 does use the term ''automatic control device'' in conjunction with the term ''automatic receptacle control.'' The definition of ''automatic control device'' in ASHRAE Standard 90.1 is ''a device capable of automatically turning loads off and on without manual intervention.'' This definition implies that an ''automatic receptacle control'' is a device capable of automatically turning loads *plugged into a receptacle* off and on without manual intervention.

requirements and makes the requirements consistent with current Federal regulations.

(27) Adds new normative references and updates existing ones with new effective dates, including several addenda to ASHRAE Standard 62.1–2016.

(28) Updates the lighting control requirements for parking garages in section 9.4.1.2.

(29) Changes the daylight responsive requirements from continuous dimming or stepped control to continuous dimming required for all spaces and adds a definition of continuous dimming.

The remaining 59 changes were considered administrative in nature or were determined to not be energy related. These changes are discussed in more detail in Appendix A of Preliminary Energy Savings Analysis: ANSI/ASHRAE/IES Standard 90.1–2019.[9] One change that is considered administrative in DOE's determination but is significant to this rulemaking is that ASHRAE updated the BPFs in Table 4.2.1.1 that are used in the Performance Rating Method in Standard 90.1–2019. This change reflects the increased performance of buildings designed to Standard 90.1–2019. The changes made to the Performance Rating Method that are discussed previously in section II.D.1 were carried over from ASHRAE Standard 90.1–2016 and included in ASHRAE Standard 90.1–2019.

III. Discussion of the Final Rule

DOE is issuing this action as a final rule. As indicated previously, DOE must determine whether the energy efficiency standards for new Federal buildings should be updated to reflect revisions to ASHRAE Standard 90.1 based on the cost-effectiveness of the revisions. (42 U.S.C. 6834(a)(3)(B)). In this final rule, DOE determines that the energy efficiency standards for new Federal buildings should be updated to reflect the 2019 revisions to ASHRAE Standard 90.1 based on the cost-effectiveness of the revisions. This final rule amends 10 CFR part 433 to update the referenced baseline Federal energy efficiency performance standards and provides a formula for Federal agencies to use when implementing the Appendix G Performance Rating Method based on the changes in ASHRAE Standard 90.1–2016, detailed in section II.D.1, that were carried over into ASHRAE Standard 90.1–2019. These amendments are described in sections II.D.1. and II.D.2. of this document. Additionally, DOE clarifies and reiterates several programmatic principles for Federal agencies implementing ASHRAE Standard 90.1 based on frequently asked questions received by DOE.

DOE also notes that there are a number of energy management requirements for Federal buildings found in statutory provisions, regulations, Executive Orders, and associated guidance, including, but not limited to the National Energy Conservation Policy Act, as amended (42 U.S.C. 8253–8258); the Energy Policy Act (EPAct) of 2005 (42 U.S.C. 15852); 10 CFR parts 433 and 435; and Executive Order 13834 (83 FR 23771 (May 22, 2018)). This final rule supports and does not supplant other legal requirements governing energy consumption in new Federal buildings. For example, by designing buildings to meet the ASHRAE Standard 90.1–2019 baseline, Federal agencies also help achieve the energy intensity reductions mandated under 42 U.S.C. 8253(a).

A. DOE's Analysis of the Cost-Effectiveness of ASHRAE Standard 90.1 as Applied to New Federal Buildings

DOE has determined that the energy efficiency standards for new Federal buildings should be updated to reflect the 2019 revisions to ASHRAE Standard 90.1 because these revisions are cost-effective for the Federal government. DOE's determination that the revisions to ASHRAE Standard 90.1 are cost effective for new Federal buildings is based on several forms of analysis.

DOE is required by ECPA section 304(b) to determine whether revisions to ASHRAE Standard 90.1 would improve energy efficiency in commercial buildings and must publish notice of its determination in the **Federal Register**. (42 U.S.C. 6833(b)(2)(A)). Although DOE's review of ASHRAE Standard 90.1 is required for the activities of DOE's State building energy codes program, DOE also uses the analysis as part of its review for purposes of the baseline standard update for new Federal buildings. Accordingly, DOE first compared ASHRAE Standard 90.1–2016 to the 2013 version of the standard and found that the revisions in the 2016 version achieved greater energy efficiency. (*See* 82 FR 34513 (July 25, 2017)). This determination was subject to notice and comment. (*See* 83 FR 8463 (Feb. 27, 2018)). In that determination, DOE found that the 2016 version of Standard 90.1 would have energy cost, source energy, and site energy savings of 8.3, 7.9, and 6.8 percent, respectively, compared to the 2013 version of Standard 90.1. Similarly, DOE compared ASHRAE Standard 90.1–2019 to the 2016 version of the standard and found that the revisions in the 2019 version would achieve greater energy efficiency. (*See* 86 FR 20674 (April 21, 2021)) This determination was subject to notice and comment. (*See* 86 FR 40543; July 28, 2021). In that determination, DOE found that the 2019 version of Standard 90.1 would have energy cost, source energy, and site energy savings of 4.3, 4.3, and 4.7 percent, respectively, compared to the 2016 version of Standard 90.1. DOE also conducted an independent, supplemental analysis of the updated ASHRAE Standard 90.1 as applied to the Federal sector, and found that the 2019 version of Standard 90.1 would have energy cost, source energy, and site energy savings of 11.3, 11.3, and 11.2 percent, respectively, compared to the 2013 version of Standard 90.1.

Second, DOE conducted an analysis of the cost-effectiveness of the updated ASHRAE Standard 90.1 as part of DOE's required activities for its building energy codes program and found the updated version to be cost-effective. DOE determines the cost effectiveness of revisions to ASHRAE Standard 90.1 as part of DOE's participation in the code development process. Section 307(b) of ECPA requires DOE to participate in the ASHRAE code development process and to assist in determining the cost-effectiveness of the voluntary standards. (42 U.S.C. 6836). DOE is required to periodically review the economic basis of the voluntary building energy codes and participate in the industry process for review and modification, including seeking adoption of all technologically feasible and economically justified energy efficiency measures. (42 U.S.C. 6836(b)).

Finally, DOE conducted an independent, supplemental analysis of ASHRAE Standard 90.1–2019 as applied to the Federal sector (baseline ASHRAE Standard 90.1–2013), and found that the energy efficiency gains resulted in $161.9 million annual life-cycle-cost net savings overall for an assumed 19.54 million square feet of annual new Federal construction, with a cumulative net present value (NPV) of total benefits of $1.66 billion (at a 7-percent discount rate) and $3.48 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating cost savings minus the estimated increased building costs for new Federal construction for 2022–2051 with a 30-year lifetime, along with monetized estimates of climate and health benefits. As part of the development of this rule, for the purpose of complying with the requirements of Executive Order 12866, DOE considered the estimated monetary benefits from the reduced emissions of CO_2, CH_4, N_2O, NO_X, and SO_2 that are

[9] *www.energycodes.gov/sites/default/files/2021-07/20210407_Standard_90.1-2019_Determination_TSD.pdf.*

expected to result from this rule. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law. These results are discussed in greater detail in section IV of this document.

DOE's assumptions and methodology for the supplemental review cost-effectiveness of this rule are based on the cost-effectiveness analysis of ASHRAE Standard 90.1–2016 and ASHRAE Standard 90.1–2019 conducted by DOE's State building energy codes program. These assumptions and methodology also provide the basis for the EA for this rulemaking. In this supplemental review, DOE recognized differences in Federal sector building types and attempted to address these differences by drawing functional equivalencies among building types that were analyzed in the cost-effectiveness analysis described above. DOE also calculated the weighted average incremental costs for the 14 Federal building types that most closely matched the prototypes analyzed in DOE's cost-effectiveness analysis of Standard 90.1–2019. These Federal building types comprise 79.3 percent of estimated Federal construction. DOE assumes that all other Federal building types are represented by the average of the Federal buildings that were mapped to DOE's cost-effectiveness analysis building types. The results of this supplemental review are discussed in detail in section IV of this document.

Accordingly, based on these analyses, DOE has determined that the energy efficiency standards for new Federal buildings should be updated to reflect the 2019 revisions to ASHRAE Standard 90.1 based on the cost-effectiveness of the revisions.

B. Federal Agency Implementation of Changes to the Appendix G Performance Rating Method in ASHRAE Standard 90.1–2016 and ASHRAE Standard 90.1–2019

As previously discussed, ASHRAE Standard 90.1–2016 was the first version of Standard 90.1 in which the Appendix G Performance Rating Method may be used to demonstrate compliance with Standard 90.1. In previous versions, Appendix G was limited to demonstrating the percentage improvement above Standard 90.1. Federal agencies can now use Appendix G for both compliance and demonstrating the percentage improvement better than ASHRAE Standard 90.1–2019. Federal agencies may also choose to use one of the other compliance methods (the prescriptive path or the ECB method) to demonstrate compliance with Standard 90.1–2019. However, Federal agencies can only use the Appendix G Performance Rating Method for calculating the 30 percent improvement beyond ASHRAE Standard 90.1 as required in 10 CFR 433.100 and 433.101.

DOE notes that not all Federal building types are explicitly covered by the BPFs listed in Table 4.2.1.1 of ASHRAE Standard 90.1–2019. DOE plans to work with Federal agencies to define the most appropriate building area type for various types of buildings constructed in the Federal sector, such as courthouses, barracks, and industrial type facilities.

To calculate the percent improvement beyond ASHRAE Standard 90.1–2019, Federal agencies must use the formula in new 10 CFR 433.101(a)(5). The formula is as follows:

Percent improvement beyond code = $100 \times ((PCIt—PCI)/PCIt)$

Where

PCI = Performance Cost Index, as defined in Appendix G of ASHRAE Standard 90.1–2019, and

PCI_t = Performance Cost Index Target, as calculated in Section 4.2.1.1 of ASHRAE Standard 90.1–2019

This formula differs from previous formulas that DOE has required in 10 CFR 433.101 due to the new ASHRAE requirement to calculate PCI_t to determine whether a proposed building design exceeds the energy costs savings of ASHRAE Standard 90.1–2019.

Importantly, section 4.2.1.1 requires that the Baseline Building Unregulated Energy Consumption (BBUEC) be included in the calculation of a building's PCI_t. DOE notes that Federal agencies have always been required to include energy consumption that has generally been ''unregulated'' by ASHRAE Standard 90.1 (*i.e.,* certain process loads and receptacle loads) for purposes of determining compliance with ASHRAE Standard 90.1. Additionally, Federal agencies are required to include such unregulated energy use to conduct the required whole building simulation to establish the baseline for applying the Appendix G Performance Rating Method.

However, Federal agencies are currently required to exclude unregulated energy use not within the scope of ASHRAE Standard 90.1 when determining whether a design has met the required 30 percent improvement below ASHRAE Standard 90.1. (10 CFR 433.101(b)) In the initial promulgation of the energy efficiency standards for Federal commercial and multi-family high rises, DOE stated that such an exclusion for process loads was warranted because process loads in government facilities typically involve specialized equipment for which improvements in energy efficiency may affect the functionality of the equipment or where improvements are not available at all. Additionally, some Federal buildings use most of their energy serving process loads, and application of the energy savings requirement to these buildings would likely place an undue burden on the rest of the building if the 30 percent savings is to be achieved. (*See* 72 FR 72565, 72567–72568 (Dec. 21, 2007)). With respect to receptacle loads, DOE stated that it is often not possible to identify all receptacle loads when a building is designed or constructed as the occupants will to some degree establish what is plugged in, and that as equipment is replaced over time the initial savings from receptacle loads may diminish. (*See* 72 FR 72567–72568) Moreover, DOE stated that the energy efficiency of many receptacle loads was addressed in section 104 of EPAct 2005 (Pub. L. 109–58), which requires Federal agencies to purchase energy efficient appliances and equipment. (42 U.S.C 8259b).

However, due to ASHRAE's explicit inclusion of unregulated energy use in the PCI_t equation, in this final rule, DOE limits the types of unregulated loads that may be excluded from the calculation of the 30 percent improvement beyond ASHRAE Standard 90.1. This final rule revises 10 CFR 433.101(b) to require Federal agencies to include unregulated energy use (*i.e.,* process loads and receptacle loads not within the scope of ASHRAE Standard 90.1) in agencies'

determination of PCI_t when calculating the 30 percent improvement beyond ASHRAE Standard 90.1, except for energy-intensive process loads that are (i) driven by mission and operational requirements, not necessarily buildings, and (ii) not influenced by conventional building energy conservation measures. Examples would include training simulators, health-care equipment, facilities which generate and/or transmit electricity or steam, waterway shipping locks, and transmitters and other types of electronic installations. This exception aligns with DOE's exception for certain assumed exclusions of structures and processes under the Federal energy performance and reporting requirements of section 543 of the National Energy Conservation Policy Act (NECPA), as amended by EPAct.[10] (*See* 42 U.S.C. 8253(a)) This final rule also removes paragraph (b) from 10 CFR 433.100, as this paragraph is duplicative of the current paragraph (b) in 10 CFR 433.101, and is not reflective of the changes in this final rule. Moreover, the content in this paragraph, how to incorporate process and receptacle loads in the calculation of the 30 percent improvement, is best placed in 10 CFR 433.101, which prescribes the equations for the 30 percent improvement calculation.

DOE acknowledges that the inclusion of unregulated loads into the 30 percent or more determination is a change from prior practice. However, the changes in this final rule ensure consistency between ASHRAE Standard 90.1–2019 and the application of the Standard to Federal buildings, as required by section 305 of ECPA, while still providing agencies the flexibility to exclude unique mission-focused, energy-intensive process loads from the 30 percent improvement calculation so that the functionality of such loads is not jeopardized and an undue burden is not placed on the rest of the building if the 30 percent savings is to be achieved. The inclusion of unregulated energy, particularly receptacle loads, into the 30 percent improvement calculation may mean that fewer building designs will meet the 30 percent threshold, where such designs would otherwise meet that threshold if unregulated energy loads were excluded from the calculation. However, DOE believes that the inclusion of unregulated energy use into this calculation is more consistent with the text of section 305 of EPAct 2005, which requires that Federal buildings be designed to achieve energy savings of 30 percent or more below ASHRAE Standard 90.1, without reference to or exception for process or receptacle loads. Moreover, DOE notes that such buildings consume the same amount of energy, regardless of whether unregulated energy is included in the 30 percent or more calculation. Additionally, DOE reiterates that a building design is compliant with 10 CFR 433.100 even if the design does not meet the 30 percent or more threshold, provided the design obtains the most energy savings below ASHRAE Standard 90.1 that is cost-effective, in accordance with 10 CFR 433.100(c) (now section 433.100(b)).

C. Definition of ''New Federal Building''

The definition of ''New Federal building'' in 10 CFR part 433 has not previously been updated to match what is found in 42 U.S.C. 6832(6). EISA 2007 (Pub. L. 110–140, 121 Stat. 1614 (Dec. 19, 2007)) updated the definition of ''Federal building'' to include privatized military family housing and leased buildings. Accordingly, in order to bring 10 CFR part 433 into agreement with 42 U.S.C. 6832(6), DOE is updating the definition of ''New Federal building'' to mean '' any new building (including a complete replacement of an existing building from the foundation up) to be constructed by, or for the use of, any Federal agency. Such term shall include new buildings (including a complete replacement of an existing building from the foundation up) built for the purpose of being leased by a Federal agency, and privatized military housing.''

D. Programmatic Clarifications for Implementing ASHRAE Standard 90.1

As noted previously, DOE is clarifying and reiterating several programmatic principles regarding implementation of ASHRAE Standard 90.1–2019 in the preamble of final rule. The clarifications and reiterations are not changes to the regulatory text. Instead, DOE is taking this opportunity to provide answers and clarifications for frequent questions that DOE receives from Federal agencies in order to reduce confusion over agencies' implementation of ASHRAE Standard 90.1.

1. Whole Building Simulation and Model for Appendix G Performance Rating Method

Based on frequent questions regarding the issue, DOE reiterates that the use of the ASHRAE Standard 90.1 Appendix G Performance Rating Method requires the consideration of the building envelope and the use of a whole-building simulation tool and simulation model for the chosen tool of the proposed building design. As noted previously, Federal agencies must use the Performance Rating Method when determining if their proposed buildings are 30 percent or better beyond ASHRAE Standard 90.1. Since all Federal agencies must determine if they can meet the 30 percent or more threshold, this means that all Federal agencies must use a whole building simulation tool and a building model for every new Federal building design. Additionally, where a Federal agency uses the Performance Rating Method to determine compliance with ASHRAE Standard 90.1–2019, the agency must use a whole building simulation tool and whole building model.

2. DOE and Agency Roles When Applying ASHRAE Standard 90.1

DOE has often received questions regarding enforcement of the energy efficiency standards for Federal commercial and multi-family high rise buildings, including for situations when agencies may seek exceptions to particular aspects of ASHRAE Standard 90.1. Specifically, agencies have asked whether DOE is the ''authority having jurisdiction'' referenced in ASHRAE Standard 90.1, and whether DOE is the ''authority having jurisdiction'' for purposes of granting exceptions to aspects of the Standard for Federal agencies. As with prior versions of ASHRAE Standard 90.1, Standard 90.1–2019 provides some flexibility to building designers based upon the type of code requirement at issue. Standard 90.1 contains ''prescriptive requirements,'' which may have exceptions to them or may be ''traded off'' in the Performance Rating Method if designers are unable or choose not to meet a specific prescriptive requirement. Such an approach means that another building component would need to be improved beyond what was required prescriptively by the Standard for that component, or else the overall score of the building design under the Performance Rating Method will be lowered. Standard 90.1 also contains ''mandatory requirements,'' which may not be traded off with other requirements. However, Standard 90.1

[10] Section 543 of NECPA requires agencies to meet specific energy reduction targets, report progress towards such targets, perform periodic energy consumption evaluations, and implement periodic energy conservation measures where feasible. (42 U.S.C. 8253). Section 543(c)(3) of NECPA requires DOE to issue guidelines that establish criteria for exclusions to these performance and reporting requirements. These exclusions are outlined in ''Guidelines Establishing Criteria for Excluding Buildings from the Energy Performance Requirements of Section 543 of the National Energy Conservation Policy Act as Amended by the Energy Policy Act of 2005,'' (Jan. 27, 2006), available at: *www.energy.gov/eere/femp/downloads/guidelines-establishing-criteria-excluding-buildings-energy-performance.*

allows building designs to be excepted from meeting certain mandatory requirements in certain situations if allowed by the ''authority having jurisdiction,'' ''building code official,'' and/or ''code official.'' For example, the ''authority having jurisdiction'' or ''code official'' is the person who authorizes the use of alternative materials, methods of construction, or design (see, *e.g.,* section 4.1.3 of Standard 90.1–2019), and is also the person charged with determining if there is a conflict between the Standard and other laws or requirements and how to address such conflict (see section 4.1.5 of Standard 90.1–2019).

For the purposes of the energy efficiency standards for Federal buildings, DOE does not have authority to grant exceptions to the Standard for any Federal agency. The statute does not provide a specific enforcement authority beyond the statutory requirements, but section 548(a) of NEPCA (42 U.S.C. 8258(a)) requires Federal agencies to submit to DOE an annual report that describes activities to meet the energy management requirements of section 543 of NECPA (42 U.S.C. 8253). This submittal includes a list of all new Federal buildings owned, operated, or controlled by the Federal agency, for which designs were started since the beginning of FY 2007 (begun since October 1, 2006), and a statement specifying whether the Federal buildings are expected to meet or exceed the Federal building efficiency standards in 10 CFR part 433, as applicable. (See *www.energy.gov/eere/femp/downloads/annual-energy-management-data-report*). The DOE Annual Energy Management Data Report Reporting workbook and associated guidance can be found on the DOE Federal Energy Management Program (FEMP) website.[11] Federal agencies themselves are responsible for implementing the energy efficiency standards for Federal buildings and meeting any applicable statutory and regulatory requirements. Accordingly, where the terms are used in ASHRAE Standard 90.1, Federal agencies are their own ''authority having jurisdiction,'' ''building official,'' and/or ''code official,'' and may use their own best judgment in determining whether to exempt a proposed Federal building from aspects of the Standard or seek an alternative energy conservation measure to meet a particular aspect of the Standard where such exceptions or alternatives are permitted by the Standard. However, agencies must still comply with all relevant Federal energy efficiency statutes and regulations, including 10 CFR part 433. DOE notes that, as a general rule, any prescriptive requirement in ASHRAE Standard 90.1–2019 can be ''traded off'' in the Performance Rating Method if agencies are unable or choose not to meet a specific prescriptive requirement. Such an approach means that another building component would need to be improved beyond what was required prescriptively by the Standard for that component, or else the overall score of the building design under the Performance Rating Method will be lowered. With respect to mandatory requirements in the Standard, DOE notes that, as the ''authority having jurisdiction,'' ''building official,'' or ''code official,'' agencies should only be making exceptions to mandatory requirements where the Standard allows for the ''authority having jurisdiction,'' ''building official,'' and/or ''code official'' to make exceptions to such requirements. DOE welcomes Federal agencies' questions and requests for assistance in implementing the energy efficiency standards for Federal buildings, and DOE will provide guidance and assistance upon request.

IV. Methodology, Analytical Results, and Conclusion

A. Cost-Effectiveness

DOE's assumptions and methodology for the cost-effectiveness of this rule are based on cost-effectiveness analysis of ASHRAE Standard 90.1–2016 and ASHRAE Standard 90.1–2019 conducted by DOE's State building energy codes program,[12] as well as DOE's EA for this rulemaking.[13] As described in the EA, DOE identified a rate of new Federal commercial construction of 19.54 million square feet per year with a distribution of building types as shown in Table IV.1. The distribution of building types is based on an extraction of the latest 10 years of new construction data entered into the Federal Real Property Portfolio Management System (FRPP MS).[14] Table IV.1 also shows the prototype buildings incorporated into computer simulations that are used to estimate energy use in each building type. DOE derived these prototype buildings from 16 building types in 17 climate zones [15] using its Commercial Prototype Building models.[16] Of the 16 prototype buildings, DOE developed costs for 6 prototype buildings to determine the cost effectiveness of ASHRAE Standard 90.1–2016 and ASHRAE Standard 90.1–2019. DOE then extracted the cost-effectiveness information for those prototype buildings and weighted those values as appropriate to obtain an average cost effectiveness value for building types found in the Federal commercial sector.

TABLE IV.1—NEW FEDERAL COMMERCIAL AND HIGH-RISE MULTI-FAMILY CONSTRUCTION VOLUME BY BUILDING TYPE

Building type	Fraction of Federal construction volume (by floor area) (%)	Assumed BECP prototypes for energy savings	Assumed BECP prototypes for cost effectiveness
Office	20.74	Small Office, Medium Office, Large Office	Small Office, Large Office.
Dormitories and Barracks	14.85	Small Hotel, Mid-rise Apartment, High-rise Apartment.	Small Hotel, Mid-rise Apartment.

[11] Federal Comprehensive Annual Energy Reporting Requirements *www.energy.gov/eere/femp/federal-facility-consolidated-annual-reporting-requirements.*

[12] See DOE's analysis of the cost savings of the 2016 and 2019 ASHRAE 90.1 Standards at *www.energycodes.gov/sites/default/files/2020-07/90.1-2016_National_Cost-Effectiveness.pdf* and *www.energycodes.gov/sites/default/files/2021-07/90.1-2019_National_Cost-Effectiveness.pdf*, respectively.

[13] The Environmental Assessment (EA) (DOE/EA–2165) is entitled, ''Environmental Assessment for Final Rule, 10 CFR part 433, 'Energy Efficiency Standards for New Federal Commercial and Multi-Family High-Rise Residential Buildings' Baseline Standards Update''. The EA may be found in the docket for this rulemaking and at *www.energy.gov/nepa/doeea-2165-energy-efficiency-standards-new-federal-commercial-and-multi-family-high-rise.*

[14] See *www.realpropertyprofile.gov/FRPPMS/FRPP_Login.*

[15] Briggs, R.S., R.G. Lucas, and Z.T. Taylor. 2003. ''Climate classification for building energy codes and standards: Part 1—Development Process.'' ASHRAE Transactions 109(1): 109:121. American Society of Heating, Refrigerating and Air-Conditioning Engineers. Atlanta, Georgia.

[16] DOE's prototype buildings are described at *www.energycodes.gov/prototype-building-models.*

TABLE IV.1—NEW FEDERAL COMMERCIAL AND HIGH-RISE MULTI-FAMILY CONSTRUCTION VOLUME BY BUILDING TYPE—Continued

Building type	Fraction of Federal construction volume (by floor area) (%)	Assumed BECP prototypes for energy savings	Assumed BECP prototypes for cost effectiveness
School	14.33	Secondary School	Primary School.
Service	13.31	Stand-alone Retail, Non-refrigerated Warehouse	Stand-alone Retail.
Other Institutional Uses	5.90	None *	None.
Hospital	5.57	Hospital	Small Office, Large Office.
Warehouses	5.37	Non-Refrigerated Warehouse	None.
Laboratories	4.37	Medium Office, Hospital	Small Office, Large Office.
All Other	3.45	None	None.
Outpatient Healthcare Facility	3.35	Outpatient Healthcare	Small Office.
Industrial	2.36	None	None.
Child Care Center	1.18	Primary School	Primary School.
Communications Systems	1.11	None	None.
Prisons and Detention Centers	1.01	None	None.
Family Housing	0.68	Mid-rise Apartment	Mid-rise Apartment.
Navigation and Traffic Aids	0.53	None	None.
Land Port of Entry	0.53	Non-refrigerated Warehouse	None.
Border/Inspection Station	0.49	Small Office, Non-refrigerated Warehouse	Small Office.
Facility Security	0.31	Small Office	Small Office.
Data Centers	0.23	None	None.
Museum	0.19	None	None.
Comfort Station/Restrooms	0.07	Non-refrigerated Warehouse	None.
Public Facing Facility	0.05	Stand-alone Retail	Stand-alone Retail.
Aviation Security Related	0.01	Small Office	Small Office.
Post Office	0.01	Stand-alone Retail	Stand-alone Retail.

* Note that energy savings and cost-effectiveness mapping are not available for a number of Federal building types, with other institutional uses, warehouses, and all other being the largest Federal building types with no reliable mapping. As described in this section, DOE considered energy savings and costs for these unmapped Federal building types to be equivalent to the weighted energy savings and cost for the mapped Federal building types.

DOE has determined incremental construction first cost information for the building types and climate zones analyzed for ASHRAE Standard 90.1–2016 versus ASHRAE Standard 90.1–2013 (see Table IV.2),[17] ASHRAE Standard 90.1–2019 versus ASHRAE Standard 90.1–2016 (see Table IV.3), and for ASHRAE Standard 90.1–2019 versus ASHRAE Standard 90.1–2013 (see Table IV.4).

TABLE IV.2—INCREMENTAL CONSTRUCTION FIRST COST (2020$) FOR ASHRAE STANDARD 90.1–2016 VS. ASHRAE STANDARD 90.1–2013

Prototype	Value	ASHRAE climate zone *				
		2A	3A	3B	4A	5A
Small Office	First Cost	$673	$584	$515	$1,666	$641
	$/ft2	0.12	0.11	0.09	0.30	0.12
Large Office	First Cost	261,781	268,194	196,408	354,808	223,553
	$/ft2	0.52	0.54	0.39	0.71	0.45
Stand-alone Retail	First Cost	19,608	20,240	19,740	21,563	19,363
	$/ft2	0.79	0.82	0.80	0.87	0.78
Primary School	First Cost	(126,946)	(121,994)	(116,139)	(94,722)	(122,894)
	$/ft2	(1.72)	(1.65)	(1.57)	(1.28)	(1.66)
Small Hotel	First Cost	(104,866)	(104,624)	(104,396)	(101,194)	(103,044)
	$/ft2	(2.43)	(2.42)	(2.42)	(2.34)	(2.38)
Mid-rise Apartment	First Cost	(18,343)	(17,490)	(18,113)	(12,445)	(25,126)
	$/ft2	(0.54)	(0.52)	(0.54)	(0.37)	(0.74)

* Negative costs (shown in parentheses) indicate a reduction in cost due to changes in the code, usually due to reduced HVAC capacity. In this particular transition from ASHRAE Standard 90.1–2013 to ASHRAE Standard 90.1–2016, the cost reduction was mainly because of smaller and less expensive HVAC equipment since the building HVAC load had decreased. This cost reduction is part of the first cost calculation. Note that in addition to reduced equipment costs, there is reduced ductwork or piping costs as well.

[17] Note that the values in Table VI.2 have been adjusted to reflect 2020$ from the table that appears in DOE's determination of energy savings for Standard 90.1–2016, which were in 2018$. This adjustment was made using the GDP deflator value to correct for inflation between 2018 and 2020. Organization for Economic Co-operation and Development, GDP Implicit Price Deflator in United States, retrieved from FRED, Federal Reserve Bank of St. Louis; *fred.stlouisfed.org/series/USAGDPDEFAISMEI*, Updated February 17, 2021. These values have also been adjusted to reflect the same underlying economic assumptions as the 2019 version, and sales tax has also been removed.

TABLE IV.3—INCREMENTAL CONSTRUCTION FIRST COST (2020$) FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2016

Prototype	Value	ASHRAE climate zone*				
		2A	3A	3B	4A	5A
Small Office	First Cost	($9,527)	($9,787)	($9,890)	($9,521)	($9,563)
	$/ft2	(1.73)	(1.78)	(1.80)	(1.73)	(1.74)
Large Office	First Cost	(989,010)	(976,327)	(930,667)	(1,037,775)	(997,955)
	$/ft2	(1.98)	(1.96)	(1.87)	(2.08)	(2.00)
Stand-alone Retail	First Cost	(33,532)	(33,999)	(34,505)	(34,348)	(34,957)
	$/ft2	(1.36)	(1.38)	(1.40)	(1.39)	(1.42)
Primary School	First Cost	(156,050)	(141,073)	(153,621)	(149,787)	(151,492)
	$/ft2	(2.11)	(1.91)	(2.08)	(2.03)	(2.05)
Small Hotel	First Cost	26,805	26,218	26,335	26,078	25,616
	$/ft2	0.62	0.61	0.61	0.60	0.59
Mid-rise Apartment	First Cost	(12,251)	(12,645)	(13,894)	(8,127)	(7,839)
	$/ft2	(0.36)	(0.37)	(0.41)	(0.24)	(0.23)

*Negative costs (shown in parentheses) indicate a reduction in cost due to changes in the code, usually due to reduced HVAC capacity. In this particular transition from ASHRAE Standard 90.1–2016 to ASHRAE Standard 90.1–2019, the cost reduction was mainly because of smaller and less expensive HVAC equipment since the building HVAC load had decreased. This cost reduction is part of the first cost calculation.

Table IV.4 combines the incremental first costs associated with the 2016 and 2019 versions of ASHRAE Standard 90.1. The 2016 analysis was adjusted to use the same underlying economic assumptions as the 2019 version, including fuel prices, fuel price escalations, and labor and material costs. Additionally, the underlying calculations for both the 2016 and 2019 versions were adjusted to remove sales tax, as Federal building construction may be exempt from State sales tax, depending on the State.

TABLE IV.4—INCREMENTAL CONSTRUCTION FIRST COST (2020$) FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2013

Prototype	Value	ASHRAE climate zone*				
		2A	3A	3B	4A	5A
Small Office	First Cost	($8,854)	($9,204)	($9,375)	($7,855)	($8,922)
	$/ft2	(1.61)	(1.67)	(1.70)	(1.43)	(1.62)
Large Office	First Cost	(727,229)	(708,133)	(734,259)	(682,967)	(774,402)
	$/ft2	(1.46)	(1.42)	(1.47)	(1.37)	(1.55)
Stand-alone Retail	First Cost	(13,924)	(13,759)	(14,765)	(12,785)	(15,593)
	$/ft2	(0.56)	(0.56)	(0.60)	(0.52)	(0.63)
Primary School	First Cost	(282,996)	(263,067)	(269,760)	(244,509)	(274,386)
	$/ft2	(3.83)	(3.56)	(3.65)	(3.31)	(3.71)
Small Hotel	First Cost	(78,060)	(78,406)	(78,061)	(75,117)	(77,428)
	$/ft2	(1.81)	(1.81)	(1.81)	(1.74)	(1.79)
Mid-rise Apartment	First Cost	(30,594)	(30,136)	(32,007)	(20,571)	(32,965)
	$/ft2	(0.91)	(0.89)	(0.95)	(0.61)	(0.98)

*Negative costs (shown in parentheses) indicate a reduction in cost due to changes in the code, usually due to reduced HVAC capacity. In this particular transition from ASHRAE Standard 90.1–2013 to ASHRAE Standard 90.1–2019, the cost reduction was mainly because of smaller and less expensive HVAC equipment since the building load had decreased. This cost reduction is part of the first cost calculation. Note that in addition to reduced equipment costs, there may be reduced ductwork or piping costs as well.

DOE used data from Table IV.1 and Table IV.4 to calculate preliminary values for overall incremental first cost of construction for Federal commercial and high-rise, multi-family residential buildings. DOE calculated the incremental first cost of the Federal building types based on the DOE cost prototypes shown in the far-right column of Table IV.1 of this document. DOE then calculated the weighted average incremental cost for mapped Federal building types based on their corresponding BECP prototypes, which represent an estimated 79.3 percent of new Federal construction. This weighted incremental cost was assigned to un-mapped Federal building types, and a total weighted incremental cost was calculated by multiplying the incremental cost for each Federal building type by the fraction of Federal construction shown in Table IV.1 of this document.

The national incremental first cost for building types was developed by multiplying the average (across climate zones) incremental first cost of the prototypes (determined from the DOE State building energy codes program ASHRAE Standard 90.1 cost-effectiveness analysis) by the fraction of the Federal sector construction volume shown in Table IV.1, and then multiplying that by the total estimate of Federal new construction floorspace.[18] DOE estimates that total first cost outlays for new Federal buildings will be less under ASHRAE Standard 90.1–2019 than ASHRAE Standard 90.1–2013, primarily due to lower HVAC equipment costs for some building types (See Table IV.2). The resulting total incremental first cost estimate is a savings of $32.67 million per year. The average first cost decrease is $1.67 per square foot.

DOE also analyzed the relative impact of the final rule on the first cost of new constructed Federal buildings as a percentage of the overall annual cost of newly constructed Federal commercial and high-rise buildings. In order to estimate the total cost of construction for new Federal buildings, DOE obtained estimated construction costs for new Federal commercial and high-rise multifamily buildings were

[18] For the Federal office building, the small and large office prototype first costs were averaged. For the Federal education building, the primary school prototype first cost was used. For the Federal dormitories/barracks building type, the small hotel and mid-rise apartment prototype first costs were averaged.

obtained from RS Means (2020) [19] for the six building types analyzed in DOE's cost-effectiveness report. These new construction costs were weighted by the percent of Federal floorspace to develop an average cost of a new Federal building of $198 per square foot, as shown in Table IV.5. This average construction cost may be multiplied by the 19.54 million square feet of new Federal construction per year used in this rulemaking to estimate the annual total cost of new Federal commercial and high-rise multi-family construction of $3.86 billion. As previously noted, first cost savings associated with this rulemaking are estimated at $32.67 million per year, indicating a potential cost reduction in new Federal construction costs of 0.85 percent ($32.67 million divided by $3.86 billion).

TABLE IV.5—FIRST COST OF TYPICAL NEW FEDERAL BUILDING IN $/ft2

Federal building type	Weight (%)	First cost * ($)	Weighted cost ($)
Office	20.74	210	43.51
Barracks and Dormitories	14.85	217	32.18
School	14.33	225	32.25
Service	13.31	116	15.44
Hospital	5.57	200	11.14
Laboratories	4.37	200	8.73
Outpatient Healthcare Facility	3.35	220	7.38
Child Care Center	1.18	225	2.67
Family Housing >3 Stories	0.68	218	1.48
Border/Inspection Station	0.49	220	1.07
Facility Security	0.31	220	0.69
Aviation Security Related	0.01	220	0.02
Public Facing Facility	0.05	116	0.06
Post Office	0.01	116	0.01
Remaining Federal Stock	20.75	198	41.00
Federal Average	100.00	198	197.62

* All building first cost data from RS Means 2020.

For annual average (first year) energy cost savings, DOE used a similar approach to that used for incremental first cost. That is, DOE developed the national first year energy cost savings [20] for building types by multiplying the average (across climate zones) energy cost savings (determined from the DOE ASHRAE Standard 90.1 cost-effectiveness analysis) by the fraction of the Federal sector construction volume shown in Table IV.1, and then multiplying that by the total estimate of Federal new construction floorspace.[21] Table IV.6 [22] and Table IV.7 show annual energy cost savings by prototype buildings for ASHRAE Standard 90.1–2016 compared to ASHRAE Standard 90.1–2013 and for ASHRAE Standard 90.1–2019 compared to ASHRAE Standard 90.1–2016 respectively, and Table IV.8 shows the combined energy cost savings associated with the 2016 and 2019 versions of ASHRAE Standard 90.1. As was done for the incremental cost analysis, the 2016 energy cost savings analysis was adjusted to use the same underlying economic assumptions as the 2019 version, including fuel prices, fuel price escalations, labor and material costs, and the removal of sales tax. The resulting total annual energy cost savings for 19.54 million square feet of annual construction was estimated to be $3.4 million. The average annual energy savings in year 1 was estimated to be $0.17 per square foot. Note the annual energy cost savings are for one year of Federal commercial and high-rise multi-family residential construction and that those savings would accumulate over the evaluation period.

TABLE IV.6—AVERAGE FIRST YEAR ENERGY COST SAVINGS (2020$) FOR ASHRAE STANDARD 90.1–2016 VS. ASHRAE STANDARD 90.1–2013

Prototype	Value	ASHRAE climate zone *				
		2A	3A	3B	4A	5A
Small Office	First Cost	$597	$583	$589	$557	$591
	$/ft2	0.11	0.11	0.11	0.10	0.11
Large Office	First Cost	37,492	39,844	19,652	49,019	45,108
	$/ft2	0.08	0.08	0.04	0.10	0.09

[19] RS Means. 2020. RS Means Building Construction Cost Data, 78th Ed. Construction Publishers & Consultants. Norwell, MA.

[20] The energy costs used were the national average energy costs used by ASHRAE in the development of Standard 90.1–2019. To quote the cost-effectiveness analysis report ''Energy rates used to calculate the energy costs from the modeled energy usage were $0.98/therm for fossil fuel and $0.1063/kWh for electricity. These rates were used for the 90.1–2019 energy analysis and derived from the EIA data. These were the values approved by the SSPC 90.1 for cost-effectiveness for the evaluation of individual addenda during the development of 90.1–2019.''

[21] For the Federal office building, the small and large office prototype LCCs were weighted by estimated fraction of small and large offices observed in the FRPP MS database over the past 10 years of construction. For the Federal education building, the primary school prototype LCC was used. For the Federal dorm/barracks building type, the small office, small hotel and mid-rise apartment prototype LCCs were averaged.

[22] Note that the values in Table VI.6 have been adjusted to reflect 2020$ from the table that appears in DOE's determination of energy savings for Standard 90.1–2016, which were in 2018$. This adjustment was made using the GDP deflator value to correct for inflation between 2018 and 2020. Organization for Economic Co- operation and Development, GDP Implicit Price Deflator in United States, retrieved from FRED, Federal Reserve Bank of St. Louis; *fred.stlouisfed.org/series/USAGDPDEFAISMEI*, Updated February 17, 2021. These values have also been adjusted to reflect the same underlying economic assumptions as the 2019 version.

TABLE IV.6—AVERAGE FIRST YEAR ENERGY COST SAVINGS (2020$) FOR ASHRAE STANDARD 90.1–2016 VS. ASHRAE STANDARD 90.1–2013—Continued

Prototype	Value	ASHRAE climate zone*				
		2A	3A	3B	4A	5A
Stand-alone Retail	First Cost	3,324	3,214	2,895	3,075	2,778
	$/ft2	0.13	0.13	0.12	0.12	0.11
Primary School	First Cost	15,245	16,130	11,841	15,560	16,377
	$/ft2	0.21	0.22	0.16	0.21	0.22
Small Hotel	First Cost	6,964	6,594	6,025	7,193	8,019
	$/ft2	0.16	0.15	0.14	0.17	0.19
Mid-rise Apartment	First Cost	1,715	1,615	1,649	1,461	1,881
	$/ft2	0.05	0.05	0.05	0.04	0.06

TABLE IV.7—AVERAGE FIRST YEAR ENERGY COST SAVINGS (2020$) FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2016

Prototype	Value	ASHRAE climate zone*				
		2A	3A	3B	4A	5A
Small Office	First Cost	$278	$259	$271	$237	$235
	$/ft2	0.05	0.05	0.05	0.04	0.04
Large Office	First Cost	36,020	36,525	29,947	29,898	31,038
	$/ft2	0.07	0.07	0.06	0.06	0.06
Stand-alone Retail	First Cost	2,674	2,309	2,395	2,035	1,927
	$/ft2	0.11	0.09	0.10	0.08	0.08
Primary School	First Cost	6,320	6,085	6,945	5,411	5,439
	$/ft2	0.09	0.08	0.09	0.07	0.07
Small Hotel	First Cost	4,002	3,754	3,833	3,364	3,203
	$/ft2	0.09	0.09	0.09	0.08	0.07
Mid-rise Apartment	First Cost	1,747	1,581	732	542	522
	$/ft2	0.05	0.05	0.02	0.02	0.02

TABLE IV.8—AVERAGE FIRST YEAR ENERGY COST SAVINGS (2020$) FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2013

Prototype	Value	ASHRAE climate zone*				
		2A	3A	3B	4A	5A
Small Office	First Cost	$874	$842	$860	$794	$826
	$/ft2	0.16	0.15	0.16	0.14	0.15
Large Office	First Cost	73,512	76,369	49,598	78,917	76,146
	$/ft2	0.15	0.15	0.10	0.16	0.15
Stand-alone Retail	First Cost	5,998	5,522	5,290	5,111	4,705
	$/ft2	0.24	0.22	0.21	0.21	0.19
Primary School	First Cost	21,565	22,215	18,786	20,971	21,816
	$/ft2	0.29	0.30	0.25	0.28	0.29
Small Hotel	First Cost	10,966	10,348	9,858	10,557	11,222
	$/ft2	0.25	0.24	0.23	0.24	0.26
Mid-rise Apartment	First Cost	3,462	3,196	2,381	2,003	2,403
	$/ft2	0.10	0.09	0.07	0.06	0.07

For LCC net savings, DOE used a similar approach to that used for incremental first cost and first year energy cost savings. That is, DOE developed the national annual LCC net savings [23] for building types by multiplying the average (across climate zones) LCC net savings (determined from the DOE ASHRAE Standard 90.1 cost-effectiveness analysis) by the fraction of the Federal sector construction volume shown in Table IV.1, and then multiplying that by the total estimate of Federal new construction floorspace.[24] Table IV.9 [25] and Table IV.10 show annual LCC net savings by prototype buildings for ASHRAE Standard 90.1–2016 compared to ASHRAE Standard 90.1–2013 and for ASHRAE Standard 90.1–2019 compared to ASHRAE Standard 90.1–2016 respectively, and Table IV.11 shows the combined LCC associated with the 2016 and 2019 versions of ASHRAE Standard 90.1. As was done for the incremental cost analysis, the 2016 LCC analysis was adjusted to use the same underlying

[23] The energy costs used were the national average energy costs used by ASHRAE in the development of Standard 90.1–2019. To quote the cost-effectiveness analysis report ''Energy rates used to calculate the energy costs from the modeled energy usage were $0.98/therm for fossil fuel and $0.1063/kWh for electricity. These rates were used for the 90.1–2019 energy analysis and derived from the EIA data. These were the values approved by the SSPC 90.1 for cost-effectiveness for the evaluation of individual addenda during the development of 90.1–2019.''

[24] For the Federal office building, the small and large office prototype LCCs were weighted by estimated fraction of small and large offices observed in the FRPP MS database over the past 10 years of construction. For the Federal education building, the primary school prototype LCC was used. For the Federal dorm/barracks building type, the small office, small hotel and mid-rise apartment prototype LCCs were averaged.

[25] Note that the values in Table IV.9 have been adjusted to reflect 2020$ from the table that appears in DOE's determination of energy savings for Standard 90.1–2016, which were in 2018$. This adjustment was made using the GDP deflator value to correct for inflation between 2018 and 2020. Organization for Economic Co-operation and Development, GDP Implicit Price Deflator in United States, retrieved from FRED, Federal Reserve Bank of St. Louis; *fred.stlouisfed.org/series/USAGDPDEFAISMEI*, Updated February 17, 2021. These values have also been adjusted to reflect the same underlying economic assumptions as the 2019 version, and sales tax has also been removed.

economic assumptions as the 2019 version, including fuel prices, fuel price escalations, labor and material costs, and the removal of sales tax. The resulting total LCC net savings for 19.54 million square feet of annual construction was estimated to be $161.9 million. The average LCC net savings in year 1 was estimated to be $8.29 per square foot. Note the annual LCC savings are for one year of Federal commercial and high-rise multi-family residential construction and that those savings would accumulate over the LCC evaluation period. For the purpose of this analysis, DOE relied on a 30-year period.[26]

TABLE IV.9—ANNUAL LIFE-CYCLE COST (LCC) NET SAVINGS (2020$) FOR ASHRAE STANDARD 90.1–2016 VS. ASHRAE STANDARD 90.1–2013

Prototype	ASHRAE climate zone				
	Value				
	2A	3A	3B	4A	5A
Small Office:					
Total	$11,545	$11,362	$11,605	$9,814	$11,502
$/ft²	2.10	2.07	2.11	1.78	2.09
Large Office:					
Total	393,008	459,357	166,387	584,969	722,155
$/ft²	0.79	0.92	0.33	1.17	1.45
Stand-alone Retail:					
Total	297,938	294,578	289,116	290,447	287,461
$/ft²	12.07	11.93	11.71	11.76	11.64
Primary School:					
Total	383,418	394,371	299,407	349,720	402,682
$/ft²	5.18	5.33	4.05	4.73	5.44
Small Hotel:					
Total	244,166	236,409	225,204	244,098	261,430
$/ft²	5.65	5.47	5.21	5.65	6.05
Mid-rise Apartment:					
Total	67,323	63,971	65,950	54,724	83,693
$/ft²	2.00	1.90	1.95	1.62	2.48

TABLE IV.10—ANNUAL LIFE-CYCLE COST (LCC) NET SAVINGS (2020$) FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2016

Prototype	ASHRAE climate zone				
	Value				
	2A	3A	3B	4A	5A
Small Office:					
Total	$22,458	$22,257	$22,670	$21,425	$21,303
$/ft²	4.08	4.05	4.12	3.89	3.87
Large Office:					
Total	2,140,166	2,137,734	1,907,461	2,083,232	2,054,131
$/ft²	4.29	4.29	3.83	4.18	4.12
Stand-alone Retail:					
Total	120,306	113,599	117,007	108,246	106,638
$/ft²	4.87	4.60	4.74	4.38	4.32
Primary School:					
Total	395,974	370,009	398,497	367,937	372,306
$/ft²	5.35	5.00	5.39	4.97	5.03
Small Hotel:					
Total	604,477	600,247	601,537	592,772	590,215
$/ft²	13.99	13.89	13.92	13.72	13.66
Mid-rise Apartment:					
Total	88,940	89,183	73,209	57,750	56,579
$/ft²	2.64	2.64	2.17	1.71	1.68

TABLE IV.11—ANNUAL LIFE-CYCLE COST (LCC) NET SAVINGS (2020$) FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2013

Prototype	ASHRAE climate zone				
	Value				
	2A	3A	3B	4A	5A
Small Office:					
Total	$34,003	$33,620	$34,274	$31,238	$32,805
$/ft²	6.18	6.11	6.23	5.68	5.96
Large Office:					
Total	2,533,174	2,597,090	2,073,848	2,668,200	2,776,287
$/ft²	5.08	5.21	4.16	5.35	5.57
Stand-alone Retail:					

[26] Lavappa, P. and J. Kneifel. 2021. Energy Price Indices and Discount Factors for Life-Cycle Cost Analysis-2021 Annual Supplement to NIST Handbook 135.

TABLE IV.11—ANNUAL LIFE-CYCLE COST (LCC) NET SAVINGS (2020$) FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2013—Continued

Prototype	ASHRAE climate zone				
	Value				
	2A	3A	3B	4A	5A
Total	418,244	408,176	406,123	398,693	394,099
$/ft²	16.94	16.53	16.45	16.15	15.96
Primary School:					
Total	779,392	764,380	697,904	717,657	774,987
$/ft²	10.54	10.33	9.44	9.70	10.48
Small Hotel:					
Total	848,643	836,656	826,742	836,871	851,646
$/ft²	19.64	19.37	19.14	19.37	19.71
Mid-rise Apartment:					
Total	156,263	153,154	139,159	112,474	140,271
$/ft²	4.63	4.54	4.12	3.33	4.16

DOE determined that the total incremental first cost estimate for Federal buildings (as mapped to the prototype buildings in Table IV.1) is a savings of $32.67 million per year, with an average first cost decrease of $1.67 per square foot. DOE determined that the total first year energy cost estimate is a savings of $3.4 million per year, with an average first year energy cost savings of $0.17 per square foot. DOE estimated $161.9 million in annual LCC net savings for the entire Federal commercial and multi-family high-rise buildings sector with an average LCC net savings of $8.29 per square foot.

DOE also conducted a net benefits and costs analysis using a 30-year analysis period and an assumed building lifetime of 30 years. The building lifetime assumption was made to correspond with availability of underlying data from the cost-effectiveness analysis conducted by DOE's State building energy codes program.

DOE calculated the net present value (NPV) of the change in equipment cost and reduced operating cost associated with the difference between ASHRAE 90.1–2013 and ASHRAE 90.1–2019. The NPV is the value in the present of a time-series of costs and savings, equal to the present value of savings in operating cost minus the present value of the increased total equipment cost to consumers.

DOE determined the total increased equipment cost for each year of the analysis period (2022–2051) using the incremental construction cost described previously. DOE determined the present value of operating cost savings for each year from the beginning of the analysis period to the year when all Federal buildings constructed by 2051 have been retired, assuming a 30-year lifetime of the building.

The average annual operating cost includes the costs for energy, repair or replacement of building components (*e.g.,* heating and cooling equipment, lighting, and envelope measures), and maintenance of the building. DOE determined the per-unit annual savings in operating cost based on the savings in energy costs plus replacement and maintenance cost savings, which were calculated in the underlying cost-effectiveness analysis by DOE's State building energy codes program. While DOE used the methodology and prices described above to calculate first year energy cost savings and LCC net savings, for the NPV calculations, DOE determined the per-unit annual savings in operating cost by multiplying the per square foot annual electricity and natural gas savings in energy consumption by the appropriate energy price from EIA's *AEO2021*.[27] DOE forecasted energy prices based on projected average annual price changes in EIA's *AEO2021* to develop the operating cost savings through the analysis period.

DOE uses national discount rates to calculate national NPV. DOE estimated NPV using both a 3-percent and a 7-percent real discount rate, in accordance with the Office of Management and Budget's guidance to Federal agencies on the development of regulatory analysis, particularly section E therein: *Identifying and Measuring Benefits and Costs.*[28] The NPV is the sum over time of the discounted net savings.

The present value of increased equipment costs is the annual total cost increase in each year (the difference between ASHRAE 90.1–2019 and ASHRAE 90.1–2013), discounted to the present, and summed throughout the analysis period (2022 through 2051). Because new construction is held constant through the analysis period, the installed cost is constant.

The present value of savings in operating cost is the annual savings in operating cost (the difference between ASHRAE 90.1–2019 and ASHRAE 90.1–2013), discounted to the present and summed through the analysis period (2022 through 2051). Savings are decreases in operating cost associated with the higher energy efficiency associated with buildings designed to ASHRAE 90.1–2019 compared to ASHRAE 90.1–2013. Total annual savings in operating cost are the savings per square foot multiplied by the number of square feet that survive in a particular year through the lifetime of the buildings constructed in the last year of the analysis period.

B. Monetization of Emissions Reduction Benefits

As part of the development of this rule, for the purpose of complying with the requirements of Executive Order 12866, DOE considered the estimated monetary benefits from the reduced emissions of CO_2, CH_4, N_2O, NO_X, and SO_2 that are expected to result from this rule. In order to make this calculation analogous to the calculation of the NPV of consumer benefit, DOE considered the reduced emissions expected to result over the lifetime of buildings constructed in the analysis period. This section summarizes the basis for the values used for monetizing the emissions benefits and presents the values considered in this rule.

On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–

[27] DOE—U.S. Department of Energy. 2021. Annual Energy Outlook 2021 with Projections to 2050. Washington, DC Available at *www.eia.gov/outlooks/aeo/.*

[28] Office of Management and Budget. OMB Circular A–4, Regulatory Analysis. 2003. OMB: Washington, DC September 17, 2003. *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.*

JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

1. Monetization of Greenhouse Gas Emissions

For the purpose of complying with the requirements of Executive Order 12866, DOE estimates the monetized benefits of the reductions in emissions of CO_2, CH_4, and N_2O by using a measure of the social cost (''SC'') of each pollutant (*e.g.,* SC–GHGs). These estimates represent the monetary value of the net harm to society associated with a marginal increase in emissions of these pollutants in a given year, or the benefit of avoiding that increase. These estimates are intended to include (but are not limited to) climate-change-related changes in net agricultural productivity, human health, property damages from increased flood risk, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. DOE exercises its own judgment in presenting monetized climate benefits as recommended by applicable Executive Orders and guidance, and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases. DOE exercises its own judgment in presenting monetized climate benefits as recommended by applicable Executive Orders, and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases.

DOE estimated the global social benefits of CO_2, CH_4, and N_2O reductions (*i.e.,* SC–GHGs) using the estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG) (IWG, 2021).[29] The SC–GHGs is the monetary value of the net harm to society associated with a marginal increase in emissions in a given year, or the benefit of avoiding that increase. In principle, SC–GHGs includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk and natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. The SC–GHGs therefore, reflects the societal value of reducing emissions of the gas in question by one metric ton. The SC–GHGs is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect CO_2, N_2O and CH_4 emissions. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD), the DOE agrees that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG until revised estimates have been developed reflecting the latest, peer-reviewed science.

The SC–GHGs estimates presented here were developed over many years, using transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. Specifically, in 2009, an interagency working group (IWG) that included the DOE and other executive branch agencies and offices was established to ensure that agencies were using the best available science and to promote consistency in the social cost of carbon (SC–CO_2) values used across agencies. The IWG published SC–CO_2 estimates in 2010 that were developed from an ensemble of three widely cited integrated assessment models (IAMs) that estimate global climate damages using highly aggregated representations of climate processes and the global economy combined into a single modeling framework. The three IAMs were run using a common set of input assumptions in each model for future population, economic, and CO_2 emissions growth, as well as equilibrium climate sensitivity (ECS)—a measure of the globally averaged temperature response to increased atmospheric CO_2 concentrations. These estimates were updated in 2013 based on new versions of each IAM. In August 2016 the IWG published estimates of the social cost of methane (SC–CH_4) and nitrous oxide (SC–N_2O) using methodologies that are consistent with the methodology underlying the SC–CO_2 estimates. The modeling approach that extends the IWG SC–CO_2 methodology to non-CO_2 GHGs has undergone multiple stages of peer review. The SC–CH_4 and SC–N_2O estimates were developed by Marten et al. (2015) and underwent a standard double-blind peer review process prior to journal publication. In 2015, as part of the response to public comments received to a 2013 solicitation for comments on the SC–CO_2 estimates, the IWG announced a National Academies of Sciences, Engineering, and Medicine review of the SC–CO_2 estimates to offer advice on how to approach future updates to ensure that the estimates continue to reflect the best available science and methodologies. In January 2017, the National Academies released their final report, Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide, and recommended specific criteria for future updates to the SC–CO_2 estimates, a modeling framework to satisfy the specified criteria, and both near-term updates and longer-term research needs pertaining to various components of the estimation process (National Academies, 2017).[30] Shortly thereafter, in March 2017, President Trump issued Executive Order 13783, which disbanded the IWG, withdrew the previous TSDs, and directed agencies to ensure SC–CO_2 estimates used in regulatory analyses are consistent with the guidance contained in OMB's Circular A–4, ''including with respect to the consideration of domestic versus international impacts and the consideration of appropriate discount rates'' (E.O. 13783, Section 5(c)).

On January 20, 2021, President Biden issued Executive Order 13990, which re-established the IWG and directed it to ensure that the U.S. Government's estimates of the social cost of carbon and other greenhouse gases reflect the

[29] See Interagency Working Group on Social Cost of Greenhouse Gases, Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990, Washington, DC, February 2021. Available at: *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf* (last accessed March 17, 2021).

[30] See National Academies of Sciences, Engineering, and Medicine. 2017. Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide. Washington, DC: The National Academies Press. *doi.org/10.17226/24651*.

best available science and the recommendations of the National Academies (2017). The IWG was tasked with first reviewing the SC–GHG estimates currently used in Federal analyses and publishing interim estimates within 30 days of the E.O. that reflect the full impact of GHG emissions, including by taking global damages into account. The interim SC–GHG estimates published in February 2021, specifically the SC–CH_4 estimates, are used here to estimate the climate benefits for this rule. The E.O. instructs the IWG to undertake a fuller update of the SC–GHG estimates by January 2022 that takes into consideration the advice of the National Academies (2017) and other recent scientific literature.

The February 2021 SC–GHG TSD provides a complete discussion of the IWG's initial review conducted under E.O. 13990. In particular, the IWG found that the SC–GHG estimates used under E.O. 13783 fail to reflect the full impact of GHG emissions in multiple ways. First, the IWG found that a global perspective is essential for SC–GHG estimates because it fully captures climate impacts that affect the United States and which have been omitted from prior U.S.-specific estimates due to methodological constraints. Examples of omitted effects include direct effects on U.S. citizens, assets, and investments located abroad, supply chains, and tourism, and spillover pathways such as economic and political destabilization and global migration. In addition, assessing the benefits of U.S. GHG mitigation activities requires consideration of how those actions may affect mitigation activities by other countries, as those international mitigation actions will provide a benefit to U.S. citizens and residents by mitigating climate impacts that affect U.S. citizens and residents. If the United States does not consider impacts on other countries, it is difficult to convince other countries to consider the impacts of their emissions on the United States. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with this assessment and, therefore, in this rule DOE centers attention on a global measure of SC–GHG. This approach is the same as that taken in DOE regulatory analyses from 2012 through 2016. Prior to that, in 2008 DOE presented Social Cost of Carbon (SCC) estimates based on values the Intergovernmental Panel on Climate Change (IPCC) identified in literature at that time. As noted in the February 2021 SC–GHG TSD, the IWG will continue to review developments in the literature, including more robust methodologies for estimating a U.S.-specific SC–GHG value, and explore ways to better inform the public of the full range of carbon impacts. As a member of the IWG, DOE will continue to follow developments in the literature pertaining to this issue.

Second, the IWG found that the use of the social rate of return on capital (7 percent under current OMB Circular A–4 guidance) to discount the future benefits of reducing GHG emissions inappropriately underestimates the impacts of climate change for the purposes of estimating the SC–GHG. Consistent with the findings of the National Academies (2017) and the economic literature, the IWG continued to conclude that the consumption rate of interest is the theoretically appropriate discount rate in an intergenerational context (IWG 2010, 2013, 2016a, 2016b), and recommended that discount rate uncertainty and relevant aspects of intergenerational ethical considerations be accounted for in selecting future discount rates. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with this assessment and will continue to follow developments in the literature pertaining to this issue.

While the IWG works to assess how best to incorporate the latest, peer reviewed science to develop an updated set of SC–GHG estimates, it set the interim estimates to be the most recent estimates developed by the IWG prior to the group being disbanded in 2017. The estimates rely on the same models and harmonized inputs and are calculated using a range of discount rates. As explained in the February 2021 SC–GHG TSD, the IWG has recommended that agencies to revert to the same set of four values drawn from the SC–GHG distributions based on three discount rates as were used in regulatory analyses between 2010 and 2016 and subject to public comment. For each discount rate, the IWG combined the distributions across models and socioeconomic emissions scenarios (applying equal weight to each) and then selected a set of four values recommended for use in benefit-cost analyses: An average value resulting from the model runs for each of three discount rates (2.5 percent, 3 percent, and 5 percent), plus a fourth value, selected as the 95th percentile of estimates based on a 3 percent discount rate. The fourth value was included to provide information on potentially higher-than-expected economic impacts from climate change. As explained in the February 2021 SC–GHG TSD, and DOE agrees, this update reflects the immediate need to have an operational SC–GHG for use in regulatory benefit-cost analyses and other applications that was developed using a transparent process, peer-reviewed methodologies, and the science available at the time of that process. Those estimates were subject to public comment in the context of dozens of proposed rulemakings as well as in a dedicated public comment period in 2013.

DOE's derivations of the SC–GHGs (*i.e.,* SC–CO_2, SC–N_2O, and SC–CH_4) values used for this rule are discussed in the following sections, and the results of DOE's analyses estimating the benefits of the reductions in emissions of these pollutants are presented in section VII.A of this document.

a. Social Cost of Carbon

The SC–CO_2 values used for this rule were generated using the values presented in the 2021 update from the IWG's February 2021 TSD. Table IV.12 shows the updated sets of SC–CO_2 estimates from the latest interagency update in 5-year increments from 2020 to 2050. For purposes of capturing the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate include all four sets of SC–CO_2 values, as recommended by the IWG.[31]

[31] For example, the February 2021 TSD discusses how the understanding of discounting approaches suggests that discount rates appropriate for intergenerational analysis in the context of climate change may be lower than 3 percent.

TABLE IV.12—ANNUAL SC–CO_2 VALUES FROM 2021 INTERAGENCY UPDATE, 2020–2050

[2020$ per metric ton CO_2]

Year	Discount rate			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
2020	14	51	76	152
2025	17	56	83	169
2030	19	62	89	187
2035	22	67	96	206
2040	25	73	103	225
2045	28	79	110	242
2050	32	85	116	260

In calculating the potential global benefits resulting from reduced CO_2 emissions, DOE used the values from the 2021 interagency report, adjusted to 2020$ using the implicit price deflator for gross domestic product (''GDP'') from the Bureau of Economic Analysis. For each of the four sets of SC–CO_2 cases specified, the values for emissions in 2020 were $14, $51, $76, and $152 per metric ton avoided (values expressed in 2020$). DOE derived values from 2051 to 2070 based on estimates published by EPA.[32] These estimates are based on methods, assumptions, and parameters identical to the 2020–2050 estimates published by the IWG. DOE derived values after 2070 based on the trend in 2060–2070 in each of the four cases in the IWG update.

DOE multiplied the CO_2 emissions reduction estimated for each year by the SC–CO_2 value for that year in each of the four cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SC–CO_2 values in each case.

b. Social Cost of Methane and Nitrous Oxide

The SC–CH_4 and SC–N_2O values used for this rule were generated using the values presented in the 2021 update from the IWG.[33] Table IV.13 shows the updated sets of SC–CH_4 and SC–N_2O estimates from the latest interagency update in 5-year increments from 2020 to 2050. To capture the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CH_4 and SC–N_2O values, as recommended by the IWG.

TABLE IV.13—ANNUAL SC–CH_4 AND SC–N_2O VALUES FROM 2021 INTERAGENCY UPDATE, 2020–2050

[2020$ per metric ton]

Year	SC–CH_4				SC–N_2O			
	Discount rate and statistic				Discount rate and statistic			
	5%	3%	2.5%	3%	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile	Average	Average	Average	95th percentile
2020	670	1500	2000	3900	5800	18000	27000	48000
2025	800	1700	2200	4500	6800	21000	30000	54000
2030	940	2000	2500	5200	7800	23000	33000	60000
2035	1100	2200	2800	6000	9000	25000	36000	67000
2040	1300	2500	3100	6700	10000	28000	39000	74000
2045	1500	2800	3500	7500	12000	30000	42000	81000
2050	1700	3100	3800	8200	13000	33000	45000	88000

DOE multiplied the CH_4 and N_2O emissions reduction estimated for each year by the SC–CH_4 and SC–N_2O estimates for that year in each of the cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the cases using the specific discount rate that had been used to obtain the SC–CH_4 and SC–N_2O estimates in each case.

2. Monetization of Other Air Pollutants

DOE estimated the monetized value of NO_X and SO_2 emissions reductions from electricity generation using benefit per ton estimates based on air quality modeling and concentration-response functions conducted for the Clean Power Plan final rule. 84 FR 32520. DOE used EPA's values for NO_X (as $PM_{2.5}$) and SO_2 for 2020, 2025, and 2030 calculated with discount rates of 3 percent and 7 percent, and EPA's values for ozone season NO_X, which do not involve discounting since the impacts are in the same year as emissions. DOE used linear interpolation to define values for the years between 2020 and 2025 and between 2025 and 2030; for years beyond 2030 the values are held constant.

DOE also estimated the monetized value of NO_X and SO_2 emissions reductions from site use of natural gas in buildings impacted by this rule using benefit-per-ton estimates from the EPA's

[32] See EPA, *Revised 2023 and Later Model Year Light-Duty Vehicle GHG Emissions Standards: Regulatory Impact Analysis,* Washington, DC, December 2021. Available at: *www.epa.gov/system/files/documents/2021-12/420r21028.pdf* (last accessed January 13, 2022).

[33] See Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021. Available at: *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf* (last accessed March 17, 2021).

Benefits Mapping and Analysis Program. Although none of the sectors covered by EPA refers specifically to residential and commercial buildings, the sector called ''area sources'' would be a reasonable proxy for residential and commercial buildings.[34] The EPA document provides high and low estimates for 2025 and 2030 at 3- and 7-percent discount rates.[35] DOE used the same linear interpolation and extrapolation as it did with the values for electricity generation. DOE primarily relied on the low estimates to be conservative.

DOE multiplied the emissions reduction (in tons) in each year by the associated $/ton values, and then discounted each series using discount rates of 3 percent and 7 percent as appropriate. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from relying on ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits in accordance with applicable Executive Orders, and applicable guidance.

C. Conclusion

This analysis results in a cumulative net present value (NPV) of total benefits of the rule of $1.66 billion (at a 7-percent discount rate) and $3.48 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating cost savings minus the estimated increased building costs for new Federal construction for 2022–2051 with a 30-year lifetime and includes monetized climate and health benefits (see Table IV.14). DOE estimates climate benefits from a reduction in greenhouse gases (GHG) using four different estimates of the social cost of CO_2 (''SC–CO_2''), the social cost of methane (''SC–CH_4''), and the social cost of nitrous oxide (''SC–N_2O''). Together these represent the social cost of GHG (SC–GHG). DOE used interim SC–GHG values developed by an Interagency Working Group on the Social Cost of Greenhouse Gases (IWG).[36] [37] DOE does not have a single central SC–GHG point estimate and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions.

The benefits and costs of the rulemaking can also be expressed in terms of annualized values. The annualized net benefit is (1) the annualized national economic value (expressed in 2020$) of the benefits from building to ASHRAE 90.1–2019, consisting primarily of operating cost savings from using less energy), minus increases in building costs, and (2) the annualized monetary value of the benefits of climate (GHG) and health (NO_X, and SO_2) emission reductions. Table IV.15 shows the annualized values for this rulemaking, expressed in 2020$. In the tables, total benefits for both the 3-percent and 7-percent cases are presented using the average GHG social costs with 3-percent discount rate, but the Department emphasizes the importance and value of considering the benefits calculated using all four SC–GHG cases.

TABLE IV.14—SUMMARY OF MONETIZED ECONOMIC BENEFITS AND COSTS

[Billion 2020$]

[2022–2051 plus 30-year lifetime]

	Billion $2020
3% discount rate	
Consumer Operating Cost Savings	1.86
Climate Benefits *	0.38
Health Benefits **	0.60
Total Benefits †	2.84
Consumer Incremental Product Costs ††	−0.64
Net Benefits	3.48
7% discount rate	
Consumer Operating Cost Savings	0.65

[34] ''Area sources'' represents all emission sources for which states do not have exact (point) locations in their emissions inventories. Because exact locations would tend to be associated with larger sources, ''area sources'' would be fairly representative of small dispersed sources like homes and businesses.

[35] ''Area sources'' are a category in the 2018 document from EPA, but are not used in the 2021 document cited above. See: *www.epa.gov/sites/default/files/2018-02/documents/sourceapportionmentbpttsd_2018.pdf.*

[36] See Interagency Working Group on Social Cost of Greenhouse Gases, Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990, Washington, DC, February 2021. *https://www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalvSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf.*

[37] On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

TABLE IV.14—SUMMARY OF MONETIZED ECONOMIC BENEFITS AND COSTS—Continued

[Billion 2020$]

[2022–2051 plus 30-year lifetime]

	Billion $2020
Climate Benefits *	0.38
Health Benefits **	0.22
Total Benefits †	1.25
Consumer Incremental Product Costs ††	−0.41
Net Benefits	1.66

Note: This table presents the costs and benefits associated with Federal new commercial and multi-family high-rise buildings built in 2022–2051. These results include benefits to consumers which accrue after 2051 from the buildings constructed in 2022–2051.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the social cost of greenhouse gases (SC–GHG). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown but the Department does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. See section IV.B of this document for more details.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.B of this document for more details.

† Total and net benefits include consumer operating cost savings and benefits related to public health and climate. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

†† Costs include incremental equipment costs as well as installation costs.

TABLE IV.15—ANNUALIZED MONETIZED BENEFITS, COSTS, AND NET BENEFITS

[Million 2020$]

[2022–2051 plus 30-year lifetime]

Category	Million 2020$/year	
	3% Discount rate	7% Discount rate
Consumer Operating Cost Savings	94.9	52.5
Climate Benefits *	19.1	19.1
Health Benefits **	30.7	18.1
Total Benefits †	144.8	89.7
Costs ††	−32.7	−32.7
Net Benefits	177.5	122.4

Note: This table presents the costs and benefits associated with Federal new commercial and multi-family high-rise buildings built in 2022–2051. These results include benefits to consumers which accrue after 2051 from the buildings constructed in 2022–2051.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the social cost of greenhouse gases (SC–GHG). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. See section IV.B of this document for more details.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.B of this document for more details.

† Total and net benefits include consumer operating cost savings and benefits related to public health and climate. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

†† Costs include incremental equipment costs as well as installation costs.

Accordingly, DOE has determined that the implementation of ASHRAE Standard 90.1–2019 versus Standard 90.1–2013 for Federal commercial and multi-family high-rise buildings is cost-effective. DOE is presenting monetized climate benefits in accordance with the applicable Executive Orders and DOE would reach the same conclusion

presented in this notice in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases.

V. Compliance Date

This final rule applies to new Federal commercial and multi-family high-rise residential buildings for which design for construction begins on or after one year from the publication date of this rulemaking in the **Federal Register**. (42 U.S.C. 6834(a)(1)) Such buildings must be designed to exceed the energy efficiency level of the appropriate updated voluntary standard by 30 percent if LCC effective. However, at a minimum, such buildings must achieve the energy efficiency equal to that of the appropriate updated voluntary standard. One year lead time before the design for construction begins is consistent with DOE's previous updates to the energy efficiency baselines and the original statutory mandate for Federal building standards. One year lead time before design for construction begins helps minimize compliance costs to agencies, which may have planned buildings in various stages of design and allows for design changes to more fully consider LCC-effective measures (as opposed to having to revise designs in development, which may make incorporation of energy efficiency measure more difficult or expensive).

VI. Reference Resources

DOE first prepared this list of resources to help Federal agencies achieve building energy efficiency levels for the original rulemaking establishing the baseline energy performance standards for new Federal commercial and multi-family high-rise residential buildings. DOE has reviewed these resources and believes that they continue to be useful for helping agencies maximize their energy efficiency levels. DOE has updated this resource list as necessary. These resources come in many forms and in a variety of media. Resources are provided for all buildings, and also specifically for commercial and multi-family high-rise residential buildings. FEMP offers an online search database of tools that can help agencies reduce energy use and meet Federal laws and requirements. Tools include software, calculators, data sets, and databases created by DOE and other Federal organizations. This resource can be found at *www.energy.gov/eere/femp/federal-energy-management-tools.*

A. Resources for Commercial and Multi-Family High-Rise Residential Buildings

The following references and sources are provided to aid interested parties in gathering additional information and specifics regarding various aspects of this rule.

(1) Energy Efficient Products—FEMP and U.S. Environmental Protection Agency (EPA) ENERGY STAR Program

www.energy.gov/eere/femp/search-energy-efficient-products
www.energy.gov/eere/femp/energy-efficient-products-and-energy-saving-technologies

Federal agencies are required by EPAct 2005 and 10 CFR part 436 to specify FEMP designated or ENERGY STAR equipment, including building mechanical and lighting equipment and builder-supplied appliances, for purchase and installation in all new construction unless the agency can show that the use of such equipment is not life-cycle cost-effective. This equipment is generally more efficient than the corresponding requirements of ASHRAE Standard 90.1–2019 and may be used to achieve part of the savings required of Federal building designs. (This rule does not require the use of EnergyStar or FEMP-designated equipment, but the FEMP websites, accessed through the previous links, are provided as useful resources for achieving part of the energy savings required by the rule.)

(2) LCC Analysis—FEMP

www.wbdg.org/FFC/NIST/hdbk_135.pdf
nvlpubs.nist.gov/nistpubs/ir/2018/NIST.IR.85-3273-33.pdf

As detailed previously, agencies are required to determine the percentage beyond compliance with ASHRAE Standard 90.1 that would be life-cycle cost effective and to design new Federal buildings to achieve that percentage. DOE has promulgated LCC analysis rules in 10 CFR part 436 subpart A *Life-Cycle Cost Methodology and Procedures* (55 FR 48220, Nov. 20, 1990, as amended at 61 FR 32650, June 25, 1996) that conform to requirements in the Federal Energy Management Improvement Act of 1988 (Pub. L. 100–615) and subsequent energy conservation legislation. LCC guidance and required discount rates and energy price projections are determined annually by FEMP and the Energy Information Administration (EIA) and are published in the Annual Supplement to The National Institute of Standards and Technology (NIST) Handbook 135: ''Energy Price Indices and Discount Factors for Life-Cycle Cost Analysis.''

(3) Building Energy Efficiency Support Resources—DOE Building Technologies Office

www.energy.gov/eere/buildings/building-technologies-office
www.energy.gov/eere/buildings/building-energy-modeling
www.energy.gov/eere/buildings/about-building-energy-modeling

The website for DOE's Building Technologies Office provides information, case studies, and tools to help evaluate energy efficiency, renewable energy, and sustainability in buildings. The Whole-Building Energy Modeling (BEM) is a versatile, multipurpose tool that is used in new building and retrofit design, code compliance, green certification, qualification for tax credits and utility incentives, and real-time building control. BEM can be used to assess the inherent performance of a building while controlling for specific use and operation.

(4) ASHRAE Standard 90.1–2019—ASHRAE

www.ashrae.org/technical-resources/standards-and-guidelines/read-only-versions-of-ashrae-standards

The baseline energy efficiency standard for commercial and multi-family high-rise buildings is ANSI/ASHRAE/IESNA Standard 90.1–2019. A read-only version of Standard 90.1–2019 can be found at the link ''Standard 90.1–2019, Energy Standard for Buildings Except Low-Rise Residential Buildings.''

(5) Whole Building Design Guide (WBDG)—National Institute of Building Sciences

www.wbdg.org
www.wbdg.org/design-objectives/sustainable/optimize-energy-use

The WBDG is a web-based portal providing government and industry practitioners with one-stop access to up-to-date information on a wide range of building-related guidance, criteria, and technology from a ''whole buildings'' perspective. Currently, WBDG is organized into three major categories—design guidance, project management, and operations & maintenance. Development of the WBDG is a collaborative effort among Federal agencies, private sector companies, non-profit organizations, and educational institutions.

(6) International Institute for Sustainable Laboratories (I2SL)

www.i2sl.org/resources/toolkit.html

Laboratory Benchmarking Tool

https://lbt.i2sl.org/

This website focuses on improving the energy efficiency and environmental performance of laboratory space. The website includes training, educational resources, and design and benchmarking tools focused on laboratories.

(7) Sustainable Facilities Tool—GSA Office of Federal High-Performance Buildings

https://sftool.gov/ www.gsa.gov/about-us/organization/office-of-governmentwide-policy/office-of-federal-highperformance-buildings

The GSA is tasked with putting our nation's public servants into efficient, healthy buildings and buying goods and services that provide maximum value to the taxpayer. The Sustainable Facilities Tool (SFTool) was created by the GSA Office of Federal High-Performance Green Buildings to connect Federal planners with new sustainability solutions and to assist the GSA in realizing healthier, more efficient workplaces. SFTool is an interactive website designed to show the user how to build, buy, and operate green property. Project managers can derive the most value from the SFTool by using it to understand Federal sustainability requirements; build effective project delivery teams and inform project planning; educate partners and stakeholders on the benefits of considering sustainable solutions; and discover high-performance, green building options and products.

(8) ASHRAE Advanced Energy Design Guide (AEDG) Series

www.ashrae.org/technical-resources/aedgs

To promote building energy efficiency, ASHRAE and its partners are making the AEDGs available for free download. The zero-energy guides offer designers and contractors the tools needed for achieving zero energy buildings. The 50 percent guides offer designers and contractors the tools needed for achieving a 50 percent energy savings compared to buildings that meet the minimum requirements of Standard 90.1–2004, and the 30 percent guides offer a 30 percent energy savings compared to buildings that meet the minimum energy requirements of Standard 90.1–1999. ASHRAE, in collaboration with the American Institute of Architects (AIA), IES, U.S. Green Building Council (USGBC), and DOE, continues to develop the AEDG series.

(9) ASHRAE Standard 90.1 Performance Based Compliance (Section 11 and Appendix G)

www.energycodes.gov/performance_based_compliance#tools

The website for DOE's Building Energy Codes Program (BECP) provides further information and tools to assist with the performance rating method, including the following:

- Spreadsheet-based compliance forms that meet the documentation requirements of ASHRAE Standard 90.1–2019 section 11 and Appendix G,
- The ASHRAE Standard 90.1 section 11 and Appendix G Submittal Review Manual (the Manual), a comprehensive reference for reviewing modeling-based submittals, and
- The 2010 and 2016 Performance Rating Method Reference Manuals, which include procedure and process descriptions to help provide consistency and accuracy to users of the Performance Rating Method.

VII. Regulatory Analysis

A. Review Under Executive Order 12866, ''Regulatory Planning and Review''

This final rule is an ''economically significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review.'' 58 FR 51735 (October 4, 1993). Accordingly, this action was subject to review by the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB). OMB has completed its review. DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011. 76 FR 3281 (January 21, 2011). E.O. 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866.

As discussed previously in this final rule, DOE is required to determine, based on cost-effectiveness, whether the standards for Federal buildings should be updated to reflect an amendment to the ASHRAE Standard. As stated previously, DOE complied with the statutory language by analyzing the cost-effectiveness of ASHRAE Standard 90.1–2019, which included, through DOE's involvement in the ASHRAE code development process, consideration of ASHRAE's cost-effectiveness criteria for Standard 90.1–2019.

Review under Executive Order 12866 requires an analysis of the economic effect of the rule. For this purpose, DOE estimated incremental first cost (in this case, the difference between the cost of a building designed to meet ASHRAE Standard 90.1–2019 and a building designed to meet ASHRAE Standard 90.1–2013) for the Federal commercial and high-rise multi-family residential buildings sector, as well as LCC net savings. First, DOE estimated that the annual full fuel cycle national energy savings would be 0.273 trillion Btu (associated with one year of Federal construction), that the cumulative (over the 30-year analysis period) full fuel cycle national energy savings would be 0.12 quadrillion Btu, and that the cumulative (including building lifetime savings) full fuel cycle national energy savings would be 0.23 quadrillion Btu (see Table VII.1, Table VII.2, and Table VII.3). Based on these energy savings and using the methodology described in section IV, DOE estimated the resulting incremental first cost, first year energy cost savings, and annual LCC net savings. DOE determined that the total incremental first cost estimate is a savings of $32.67 million per year, with an average first cost decrease of $1.67 per square foot. DOE determined that the total first year energy cost estimate is a savings of $3.4 million, with an average first year energy cost savings of $0.17 per square foot. DOE estimated $161.9 million in annual LCC net savings for the entire Federal commercial and multi-family high-rise buildings sector with an average LCC net savings of $8.29 per square foot. (See Table VII.4).

Table VII.5 shows the monetized economic benefits and costs expected to result from this rulemaking. Using a 7-percent discount rate for consumer benefits and costs and health benefits, and a 3-percent discount rate case for GHG social (climate) costs, the estimated cost of this rulemaking is −$0.41 billion in increased equipment costs, while the estimated benefits are $0.65 billion in reduced equipment operating costs, $0.38 billion in climate benefits, and $0.22 billion in health benefits. In this case, the net monetized benefit amounts to $1.66 billion. Using a 3-percent discount rate for all monetized benefits and costs, the estimated cost of this rulemaking is −$0.64 billion in increased equipment costs, while the estimated benefits are $1.86 billion in reduced equipment operating costs, $0.38 billion in climate benefits, and $0.60 billion in health benefits. In this case, the net monetized benefit amounts to $3.48 billion.

Table VII.6 shows the annualized monetized economic benefits and costs expected to result from this rulemaking. Using a 7-percent discount rate for consumer benefits and costs and health benefits, and a 3-percent discount rate case for GHG social (climate) costs, the

estimated cost of this rulemaking is −$32.7 million per year in increased equipment costs, while the estimated annual benefits are $52.5 million in reduced equipment operating costs, $19.1 million in climate benefits, and $18.1 million in health benefits. In this case, the net monetized benefit amounts to $122.4 million per year. Using a 3-percent discount rate for all monetized benefits and costs, the estimated cost of this rulemaking is −$32.7 million per year in increased equipment costs, while the estimated annual benefits are $94.9 million in reduced equipment operating costs, $19.1 million in climate benefits, and $30.7 million in health benefits. In this case, the net monetized benefit amounts to $177.5 million per year.

TABLE VII.1—ANNUAL ENERGY SAVINGS FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2013

Category	Results—ASHRAE 90.1–2019 compared to ASHRAE 90.1–2013 baseline (TBtu)
Annual Site National Energy Savings (Trillion Btu)	0.106
Annual Source National Energy Savings (Trillion Btu)	0.261
Annual Full Fuel Cycle National Energy Savings (Trillion Btu)	0.273

TABLE VII.2—CUMULATIVE ENERGY SAVINGS FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2013

[30-year analysis period]

Category	Results—ASHRAE 90.1–2019 compared to ASHRAE 90.1–2013 baseline (quads)
Cumulative Site National Energy Savings (quads)	0.049
Cumulative Source National Energy Savings (quads)	0.115
Cumulative Full Fuel Cycle National Energy Savings (quads)	0.120

TABLE VII.3—CUMULATIVE LIFETIME ENERGY SAVINGS FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2013

[2022–2051 plus 30-year lifetime]

Category	Results—ASHRAE 90.1–2019 compared to ASHRAE 90.1–2013 baseline (quads)
Cumulative Lifetime Site National Energy Savings (quads)	0.095
Cumulative Lifetime Source National Energy Savings (quads)	0.223
Cumulative Lifetime Full Fuel Cycle National Energy Savings (quads)	0.232

TABLE VII.4—COST-EFFECTIVENESS RESULTS FOR ASHRAE STANDARD 90.1–2019 VS. ASHRAE STANDARD 90.1–2013

[2020$]

Category	Results—ASHRAE 90.1–2019 compared to ASHRAE 90.1–2013 baseline
Average LCC Net Savings (2020$)	$8.29/ft^2.
Annual LCC Net Savings (2020$)	$161.9 million.
First Year Energy Cost Savings (2020$)	$0.17/ft^2.
Total First Year Energy Cost Savings (2020$)	$3.4 million.
Incremental First Cost (2020$)	−$1.67/ft^2.
Total Incremental First Cost (2020$)	−$32.7 million.

TABLE VII.5—SUMMARY OF MONETIZED ECONOMIC BENEFITS AND COSTS

[Billion 2020$]

[2022–2051 plus 30-year lifetime]

	Billion $2020
3% discount rate	
Consumer Operating Cost Savings	1.86

TABLE VII.5—SUMMARY OF MONETIZED ECONOMIC BENEFITS AND COSTS—Continued

[Billion 2020$]

[2022–2051 plus 30-year lifetime]

	Billion $2020
Climate Benefits *	0.38
Health Benefits **	0.60
Total Benefits †	2.84
Consumer Incremental Product Costs ††	−0.64
Net Benefits	3.48
7% discount rate	
Consumer Operating Cost Savings.	
Consumer Operating Cost Savings	0.65
Climate Benefits *	0.38
Health Benefits **	0.22
Total Benefits †	1.25
Consumer Incremental Product Costs ††	−0.41
Net Benefits	1.66

Note: This table presents the costs and benefits associated with Federal new commercial and multi-family high-rise buildings built in 2022–2051. These results include benefits to consumers which accrue after 2051 from the buildings constructed in 2022–2051.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the social cost of greenhouse gases (SC–GHG). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. See section IV.B of this document for more details.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.B of this document for more details.

† Total and net benefits include consumer operating cost savings and benefits related to public health and climate. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

†† Costs include incremental equipment costs as well as installation costs.

TABLE VII.6—ANNUALIZED MONETIZED BENEFITS, COSTS, AND NET BENEFITS

[Million 2020$]

[2022–2051 plus 30-year lifetime]

Category	Million 2020$/year	
	3% Discount rate	7% Discount rate
Consumer Operating Cost Savings	94.9	52.5
Climate Benefits *	19.1	19.1
Health Benefits **	30.7	18.1
Total Benefits †	144.8	89.7
Costs ††	−32.7	−32.7
Net Benefits	177.5	122.4

Note: This table presents the costs and benefits associated with Federal new commercial and multi-family high-rise buildings built in 2022–2051. These results include benefits to consumers which accrue after 2051 from the buildings constructed in 2022–2051.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC–CO_2), methane (SC–CH_4), and nitrous oxide (SC–N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the social cost of greenhouse gases (SC–GHG). For presentational purposes of this table, the climate benefits associated with the average SC–GHG at a 3 percent discount rate are shown but the Department does not have a single central SC–GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. See section IV.B of this document for more details.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.B of this document for more details.

† Total and net benefits include consumer operating cost savings and benefits related to public health and climate. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

†† Costs include incremental equipment costs as well as installation costs.

B. Review Under the Administrative Procedure Act

This rule, which updates energy efficiency performance standards for the design and construction of new Federal buildings, is a rule relating to public property, and therefore is not subject to the rulemaking requirements of the Administrative Procedure Act, including the requirement to publish a notice of proposed rulemaking. (See 5 U.S.C. 553(a)(2)) Additionally, DOE notes that the determinations regarding the increase in energy efficiency for commercial buildings using ASHRAE Standard 90.1–2016 and 90.1–2019 in the context of State building codes were subject to notice and comment. *See* 82 FR 34513 (July 25, 2017) for the preliminary determination and 83 FR 8463 (February 27, 2018) for the final determination on Standard 90.1–2016. *See* 86 FR 20674 (April 21, 2021) for the preliminary determination and 86 FR 40543 (July 28, 2021) for the final determination on Standard 90.1–2019. The determinations made in the context of the State codes are equally applicable in the context of Federal buildings. DOE finds that providing notice and comment again in the context of Federal buildings would therefore be unnecessary. (*See* 5 U.S.C. 553(b)(B)) The fact that the voluntary consensus codes apply to Federal buildings as opposed to the general building stock does not require a different evaluation of energy efficiency and cost-effectiveness.

C. Review Under the Regulatory Flexibility Act

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

As noted previously, DOE has determined that a notice of proposed rulemaking is not required by 5 U.S.C. 553 or any other law for issuance of this rule. As such, the analytical requirements of the Regulatory Flexibility Act do not apply. 5 U.S.C. 605(b).

D. Review Under the Paperwork Reduction Act of 1995

This rulemaking will impose no new information or record keeping requirements. Accordingly, OMB clearance is not required under the Paperwork Reduction Act. (44 U.S.C. 3501 *et seq.*)

E. Review Under the National Environmental Policy Act of 1969

DOE prepared an EA (DOE/EA–20165) entitled, ''Environmental Assessment for Final Rule, 10 CFR part 433, 'Baseline Energy Efficiency Standards Update for New Federal Commercial and Multi-Family High-Rise Residential Buildings' '',[38] pursuant to the Council on Environmental Quality's (CEQ's) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (40 CFR parts 1500–1508), the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and DOE's NEPA Implementing Procedures (10 CFR part 1021).

The EA addresses the possible incremental environmental effects attributable to the application of the final rule. The only anticipated impact would be a decrease in outdoor air pollutants resulting from decreased fossil fuel burning for energy use in Federal buildings. Therefore, DOE has issued a Finding of No Significant Impact (FONSI), pursuant to NEPA, the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and DOE's regulations for compliance with NEPA (10 CFR part 1021).

To identify the potential environmental impacts that may result from implementing the final rule on new Federal commercial buildings, DOE compared the requirements of the final rule updating energy efficiency performance standard for Federal new commercial and multi-family high rise residential buildings to ASHRAE Standard 90.1–2019 with the ''no-action alternative'' of using the current Federal standards (ASHRAE Standard 90.1–2013). This comparison is identical to that undertaken by DOE in its determinations of energy savings of those standards and codes.

Accordingly, DOE concludes in the EA that new Federal buildings designed and constructed to Standard 90.1–2019 will use less energy than new Federal buildings designed and constructed to Standard 90.1–2013 because Standard 90.1–2019 is more efficient than Standard 90.1–2013. This decrease in energy usage translates to reduced emissions of carbon dioxide (CO_2), nitrogen oxides (NO_X), mercury (Hg), and methane (CH_4) over the 30-year period examined in the EA. As reported in the EA, cumulative emission reductions for 30 years of construction and operation for Federal buildings built during the analysis period (2022 through 2051) were estimated at up to 4.5 million metric tons of CO_2, up to 6.9 thousand tons of NO_X, up to 0.01 tons of Hg, up to 33.5 thousand tons of CH_4, up to 1.6 thousand tons of SO_2, and up to 0.04 thousand tons of N_2O. In conducting the net benefits analysis, DOE also calculated the energy savings and associated emissions corresponding to the analysis period plus the lifetime of the building to capture the full benefits stream associated with Federal buildings constructed from 2022 through 2051. For 30 years of construction and operation including building lifetime, cumulative emission reductions were estimated at up to 8.4 million metric tons of CO_2, up to 13.1 thousand tons of NO_X, up to 0.02 tons of Hg, up to 64.5 thousand tons of CH_4, up to 3.0 thousand tons of SO_2, and up to 0.08 thousand tons of N_2O.

[38] The EA and FONSI may be found in the docket for this rulemaking and at *www.energy.gov/nepa/doeea-2165-energy-efficiency-standards-new-federal-commercial-and-multi-family-high-rise.*

F. Review Under Executive Order 13132, ''Federalism''

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. (*See* 65 FR 13735) DOE examined this rule and determined that it does not preempt State law and 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. No further action is required by Executive Order 13132.

G. Review Under Executive Order 12988, ''Civil Justice Reform''

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct, rather than a general standard and promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this rule meets the relevant standards of Executive Order 12988.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and tribal governments and the private sector. For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a) and (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and tribal governments on a proposed ''significant intergovernmental mandate'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *https://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf*. This final rule contains neither an intergovernmental mandate nor a mandate that may result in the expenditure of $100 million or more in any year by State, local, and tribal governments, in the aggregate, or by the private sector, so these requirements under the Unfunded Mandates Reform Act do not apply.

I. Review Under the Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act of 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 12630, ''Governmental Actions and Interference With Constitutionally Protected Property Rights''

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), that this rule would not result in any takings which might require compensation under the Fifth Amendment to the United States Constitution.

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

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf*. DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use''

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (OIRA) a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or

(3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. DOE's EIA estimates that new construction in the commercial sector will range from 1.91 billion square feet per year in 2022 to 2.52 billion square feet per year in 2050.[39] This rule is expected to incrementally reduce the energy usage of approximately 19.54 million square feet of Federal commercial and high-rise multi-family residential construction annually.[40] Thus, the rule represents approximately 1.17 percent of the expected annual U.S. commercial construction in 2022, falling to approximately 0.89 percent in the year 2050. This final rule would not have a significant adverse effect on the supply, distribution, or use of energy and, therefore, is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

M. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91), DOE must comply with section 32 of the Federal Energy Administration Act of 1974 (Pub. L. 93–275), as amended by the Federal Energy Administration Authorization Act of 1977 (Pub. L. 95–70). (15 U.S.C. 788) Section 32 provides that where a proposed rule authorizes or requires use of commercial standards, the final rule must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

Although section 32 specifically refers to the proposed rule stage, DOE is meeting these requirements at the final rule stage because there was no proposed rule for this action. This final rule incorporates testing methods contained in the following commercial standard: ANSI/ASHRAE/IES Standard 90.1–2019, Energy Standard for Buildings Except Low-Rise Residential Buildings, 2019, American Society of Heating Refrigerating and Air-Conditioning Engineers, Inc., ISSN 1041–2336.

DOE has evaluated these standards and notes that ASHRAE Standard 90.1 Standard is developed under ANSI-approved consensus procedures and is under continuous maintenance by a Standing Standard Project Committee. ASHRAE has established a program for regular publication of addenda, or revisions, including procedures for timely, documented, consensus action on requested changes to ASHRAE Standard 90.1. ANSI approved the final addendum for inclusion in the 2016 edition in August 2016 and in the 2019 edition in October 2019. Standard 90.1–2016 was published in October 2016 and Standard 90.1–2019 was published in October 2019. However, DOE is unable to conclude whether ASHRAE Standard 90.1 fully complies with the requirements of section 32(b) of the Federal Energy Administration Act (FEAA) (*i.e.,* whether they were developed in a manner that fully provides for public participation, comment, and review). DOE has consulted with both the Attorney General and the Chairman of the FTC about the impact on competition of using the methods contained in these standards and has received no comments objecting to their use.

N. Description of Materials Incorporated by Reference

In this final rule, DOE incorporates by reference ANSI/ASHRAE/IES Standard 90.1–2019, Energy Standard for Buildings Except Low-Rise Residential Buildings, (I–P Edition), 2019. This standard provides minimum requirements for energy efficient designs for buildings except for low-rise residential buildings. Copies of this standard are available from ASHRAE, Inc., 180 Technology Parkway NW, Peachtree Corners, GA 30092, (404) 636–8400, *www.ashrae.org.* ASHRAE provides a free, online, read-only version of Standard 90.1–2019 available at *www.ashrae.org/technical-resources/standards-and-guidelines.* Users must scroll down to locate and click on Standard 90.1–2019 (IP).

The Director of the Federal Register previously approved ANSI/ASHRAE/IES 90.1–2004, 2007, 2010, and 2013, Energy Standard for Buildings Except Low-Rise Residential Buildings for incorporation by reference in 10 CFR part 433.

VIII. Congressional Notification

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

IX. Approval of the Office of the Secretary

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

List of Subjects in 10 CFR Part 433

Buildings and facilities, Energy conservation, Engineers, Federal buildings and facilities, Housing, Incorporation by reference.

Signing Authority

This document of the DOE was signed on March 28, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, 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 DOE. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 29, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons set forth in the preamble, DOE amends chapter II Subchapter D of title 10 of the Code of Federal Regulations as set forth below:

PART 433—ENERGY EFFICIENCY STANDARDS FOR DESIGN AND CONSTRUCTION OF NEW FEDERAL COMMERCIAL AND MULTI FAMILY HIGH RISE RESIDENTIAL BUILDINGS

■ 1. The authority citation for part 433 continues to read as follows:

Authority: 42 U.S.C. 6831–6832; 6834–6835; 42 U.S.C. 7101 *et seq.*

■ 2. Amend § 433.2 by:

■ a. In the definition of ''*ASHRAE Baseline Building 2004*'', removing the text ''ANSI/ASHRAE/IES Standard 90.1–2004, Energy Standard for Buildings Except Low-Rise Residential Buildings, January 2004'' and adding, in

[39] *See* Table A5 of the 2021 Annual Energy Outlook at *www.eia.gov/outlooks/aeo/excel/aeotab_5.xlsx.*

[40] *See* Regulatory Analysis Section A. Review Under Executive Order 12866, ''Regulatory Planning and Review'' above for origin of the 25.85 million square foot estimate.

its place, the text, ''ASHRAE 90.1–2004'';

■ b. In the definition of ''*ASHRAE Baseline Building 2007*'', removing the text ''ANSI/ASHRAE/IES Standard 90.1–2007, Energy Standard for Buildings Except Low-Rise Residential Buildings, December 2007'' and adding, in its place, the text, ''ASHRAE 90.1–2007'';

■ c. In the definition of ''*ASHRAE Baseline Building 2010*'', removing the text ''ANSI/ASHRAE/IES Standard 90.1–2010, Energy Standard for Buildings Except Low-Rise Residential Buildings, 2010'' and adding, in its place, the text, ''ASHRAE 90.1–2010'';

■ d. In the definition of ''*ASHRAE Baseline Building 2013*'', removing the text ''ANSI/ASHRAE/IES Standard 90.1–2013, Energy Standard for Buildings Except Low-Rise Residential Buildings, 2013'' and adding, in its place, the text, ''ASHRAE 90.1–2013'';

■ e. Adding in alphabetical order the definition of ''ASHRAE Baseline Building 2019''; and

■ f. Revising the definition of ''New Federal building''.

The addition and revision read as follows:

§ 433.2 Definitions.

* * * * *

ASHRAE Baseline Building 2019 means a building that is otherwise identical to the proposed building but is designed to meet, but not exceed, the energy efficiency specifications in ASHRAE 90.1–2019 (incorporated by reference, see § 433.3).

* * * * *

New Federal building means any new building (including a complete replacement of an existing building from the foundation up) to be constructed by, or for the use of, any Federal agency. Such term shall include new buildings (including a complete replacement of an existing building from the foundation up) built for the purpose of being leased by a Federal agency, and privatized military housing.

* * * * *

■ 3. Amend § 433.3 by:

■ a. Revising paragraph (a) and the introductory text of paragraph (b); and

■ b. Adding paragraph (b)(5).

The revision and addition read as follows:

§ 433.3 Materials incorporated by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, DOE must publish a document in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at DOE, and at the National Archives and Records Administration (NARA). Contact DOE at: The U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, Sixth Floor, 950 L'Enfant Plaza SW, Washington, DC 20024, (202) 586–9127, *Buildings@ee.doe.gov*, *https://www.energy.gov/eere/buildings/building-technologies-office*. 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 sources in the following paragraphs of this section.

(b) *ASHRAE.* American Society of Heating Refrigerating and Air-Conditioning Engineers, Inc., 180 Technology Parkway NW, Peachtree Corners, GA 30092; (404) 636–8400; *www.ashrae.org*.

* * * * *

(5) ANSI/ASHRAE/IES 90.1–2019, (''ASHRAE 90.1–2019''), Energy Standard for Buildings Except Low-Rise Residential Buildings, I–P Edition, copyright 2019, IBR approved for §§ 433.2, 433.100 and 433.101.

■ 4. Amend § 433.100 by:

■ a. Revising paragraph (a)(4) and adding paragraph (a)(5);

■ b. Removing paragraph (b);

■ c. Redesignating paragraph (c) as (b); and

■ d. Revising newly redesignated paragraph (b).

The revisions and addition read as follows:

§ 433.100 Energy efficiency performance standard.

(a) * * *

(4) All Federal agencies shall design new Federal buildings that are commercial and multi-family high-rise residential buildings, for which design for construction began on or after November 6, 2016, but before April 7, 2023, to:

(i) Meet ASHRAE 90.1–2013, (incorporated by reference, see § 433.3); and

(ii) If LCC effective, achieve energy consumption levels, calculated consistent with paragraph (b) of this section, that are at least 30 percent below the levels of the ASHRAE Baseline Building 2013.

(5) All Federal agencies shall design new Federal buildings that are commercial and multi-family high-rise residential buildings, for which design for construction began on or after April 7, 2023, to:

(i) Meet ASHRAE 90.1–2019, (incorporated by reference, see § 433.3); and

(ii) If LCC effective, achieve energy consumption levels, calculated consistent with paragraph (b) of this section, that are at least 30 percent below the levels of the ASHRAE Baseline Building 2019.

(b) If a 30 percent reduction is not LCC effective, the design of the proposed building shall be modified so as to achieve an energy consumption level at or better than the maximum level of energy efficiency that is LCC effective, but at a minimum complies with paragraph (a) of this section.

■ 5. Amend § 433.101 by:

■ a. Revising paragraph (a)(4) and adding paragraph (a)(5); and

■ b. Revising paragraph (b).

The revisions and addition read as follows:

§ 433.101 Performance level determination.

(a) * * *

(4) For Federal buildings for which design for construction began on or after November 6, 2016, but before April 7, 2023, each Federal agency shall determine energy consumption levels for both the ASHRAE Baseline Building 2013 and proposed building by using the Performance Rating Method found in Appendix G of ASHRAE 90.1–2013 (incorporated by reference, see § 433.3), except the formula for calculating the Performance Rating in Section G1.2 shall read as follows:

(i) Percentage improvement = 100 × ((Baseline building consumption – Receptacle and process loads) – (Proposed building consumption – Receptacle and process loads))/(Baseline building consumption – Receptacle and process loads) (which simplifies as follows):

(ii) Percentage improvement = 100 × (Baseline building consumption – Proposed building consumption)/(Baseline building consumption – Receptacle and process loads).

(5) For Federal buildings for which design for construction began on or after April 7, 2023, each Federal agency shall determine energy consumption levels for both the ASHRAE Baseline Building 2019 and proposed building by using the Performance Rating Method found in Appendix G of ASHRAE 90.1–2019 (incorporated by reference, see § 433.3). The formula for determining the percentage improvement shall be as follows:

Percentage Improvement = 100 × (1 − PCI/PCIt)

Where

PCI = Performance Cost Index calculated in accordance with Section G1.2 of ASHRAE Standard 90.1–2019

PCIt = Performance Cost Index Target calculated by formula in Section 4.2.1.1 of ASHRAE Standard 90.1–2019

(b) Energy consumption for the purposes of calculating the 30 percent savings requirements shall include the building envelope and energy consuming systems normally specified as part of the building design by ASHRAE Standard 90.1 such as space heating, space cooling, ventilation, service water heating, and lighting, and all process and receptacle loads, except for energy-intensive process loads that are driven by mission and operational requirements, not necessarily buildings, and not influenced by conventional building energy conservation measures.

[FR Doc. 2022–06949 Filed 4–6–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0596; Airspace Docket No. 20–AGL–15]

RIN 2120–AA66

Amendment of V–6, V–10, V–30, V–100, and V–233 in the Vicinity of Litchfield, MI

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Final rule; withdrawal.

SUMMARY: This action withdraws the final rule published in the **Federal Register** on March 21, 2022, amending VHF Omnidirectional Range (VOR) Federal airways V–6, V–10, V–30, V–100, and V–233 in the vicinity of Litchfield, MI, due to the planned decommissioning of the VOR portion of the Litchfield, MI, VOR/Distance Measuring Equipment (VOR/DME) navigational aid. Unanticipated issues affecting the completion of related VOR Minimum Operational Network (MON) Program instrument procedure amendments and the associated flight inspection activities required to adopt those amendments have made this withdrawal action necessary.

DATES: As of April 7, 2022, the final rule published on March 21, 2022 (87 FR 15879) is withdrawn.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** for Docket No. FAA–2021–0596 (87 FR 15879; March 21, 2022) amending VOR Federal airways V–6, V–10, V–30, V–100, and V–233 due to the planned decommissioning of the VOR portion of the Litchfield, MI, VOR/DME. The effective date of that rule is May 19, 2022. Subsequent to the final rule, unanticipated requirements and issues affecting the completion of related instrument procedure amendments and the associated flight inspection activities required to adopt those amendments by the published effective date have been identified. As a result, the planned Litchfield, MI, VOR decommissioning has been slipped to April 20, 2023.

FAA's Conclusions

The FAA has reviewed the Litchfield, MI, VOR decommissioning project and determined additional time is required to complete the related instrument procedure amendments and associated flight inspection activities to ensure an efficient implementation and integration with other ongoing VOR MON program actions. Therefore, the final rule is being withdrawn.

The existing VOR Federal airways (V–6, V–10, V–30, V–100, and V–233) addressed in the final rule remain unchanged.

The FAA will publish a new notice of proposed rulemaking action at a later date, using a new airspace docket number, to coincide with the slipped Litchfield, MI, VOR decommissioning now planned for April 20, 2023.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Withdrawal

■ Accordingly, pursuant to the authority delegated to me, the final rule published in the **Federal Register** on March 21, 2022 (87 FR 15879), FR Doc. 2022–05546, is hereby withdrawn.

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.

Issued in Washington, DC, on March 31, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–07206 Filed 4–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 220331–0082]

RIN 0694–AI67

Additions of Entities to the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In response to the Russian Federation's (Russia's) further invasion of Ukraine on February 24, 2022, the Department of Commerce is amending the Export Administration Regulations (EAR) by adding 120 entities under 120 entries to the Entity List. These 120 entities have been determined by the U.S. Government to be acting contrary to the national security interests or foreign policy of the United States and will be listed on the Entity List under the destinations of Belarus and Russia.

DATES: This rule is effective April 1, 2022.

FOR FURTHER INFORMATION CONTACT: Chair, End-User Review Committee, Office of the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: *ERC@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Entity List (supplement no. 4 to part 744 of the Export Administration Regulations (EAR)) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States. The EAR (15 CFR parts 730–774) imposes additional license requirements on, and limit the availability of most license exceptions for exports, reexports, and transfers (in-country) to listed entities. The license review policy for each listed entity is identified in the ''License Review Policy'' column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document that added the entity to the Entity List. The Bureau of Industry and Security (BIS) places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR. Paragraphs (b)(1)

through (5) of § 744.11 include an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States. As discussed further later in this preamble, 95 entities are being added in this rule on the basis of §§ 744.11(b) and 744.21 and will receive a footnote 3 designation because the End-User Review Committee (ERC) has determined they are 'military end users' in accordance with § 744.21. A footnote 3 designation subjects these entities to the Russia/Belarus foreign ''direct product'' (FDP) rule, detailed in § 734.9(g). The other 25 entities are being added solely on the basis of § 744.11(b).

The ERC, composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and makes all decisions to remove or modify an entry by unanimous vote.

The ERC determined to add the following entities to the Entity List on the basis of §§ 744.11(b) and 744.21 under the destination of Belarus: 140 Repair Plant JSC; 558 Aircraft Repair Plant JSC; 2566 Radioelectronic Armament Repair Plant JSC; AGAT—Control Systems—Managing Company of Geoinformation Control Systems Holding JSC; Agat-Electromechanical Plant OJSC; AGAT–SYSTEM; ATE-Engineering LLC; BelOMO Holding; Belspetsvneshtechnika SFTUE; BSVT-New Technologies; CJSC Beltechexport; Department of Internal Affairs of the Gomel Region Executive Committee; Internal Troops of The Ministry of Internal Affairs of the Republic of Belarus; JSC Transaviaexport Airlines; KGB Alpha; Kidma Tech OJSC; Minotor-Service; Minsk Wheeled Tractor Plant; Oboronnye Initsiativy LLC; OJS KB Radar Managing Company; Peleng JSC; State Authority for Military Industry of the Republic of Belarus; State Security Committee of the Republic of Belarus; and Volatavto OJSC to the Entity List. All of these entities will be designated with a footnote 3. These entities are being added to the Entity List consistent with BIS's response to Belarus's substantial enabling and support of Russia's invasion of Ukraine and of Russia's military forces. Specifically, these entities are being added to the Entity List for acquiring and attempting to acquire items subject to the EAR in support of Belarus' military. Their addition to the Entity List and a footnote 3 designation means these entities are subject to a license requirement for the export, reexport, export from abroad (as described under Russia/Belarus foreign ''direct product'' (FDP) rule, § 746.8(a)(3)), or transfers (in-country) of all items subject to the EAR that are destined to these entities. BIS will review license applications under a policy of denial. No license exceptions are available for exports, reexports, exports from abroad (as described under Russia/Belarus foreign ''direct product'' (FDP) rule, § 746.8(a)(3)), or transfers (in-country) to the entities being added.

In addition, the ERC determined to add the following entities to the Entity List on the basis of §§ 744.11(b) and 744.21 under the destination of Russia: 5th Shipyard; Alagir Resistor Factory; All-Russian Scientific-Research Institute Etalon JSC; Almaz JSC; Dolgoprudniy Design Bureau of Automatics; Electronic Computing Technology Scientific-Research Center; Electrosignal JSC; Inteltech PJSC; Joint Stock Company NPO Elektromechaniki; Kulon Scientific-Research Institute JSC; Lutch Design Office JSC; Meteor Plant JSC; Moscow Communications Research Institute JSC; Moscow Order of the Red Banner of Labor Research Radio Engineering Institute JSC; Omsk Production Union Irtysh JSC; Omsk Scientific-Research Institute of Instrument Engineering JSC; Optron JSC; Polyot Chelyabinsk Radio Plant JSC; Pskov Distance Communications Equipment Plant; Radiozavod JSC; Razryad JSC; Research Production Association Mars; Ryazan Radio-Plant; Scientific-Production Association and Scientific-Research Institute of Radio-Components; Scientific-Production Enterprise Almaz JSC; Scientific-Production Enterprise ''Kant''; Scientific Production Enterprise ''Radiosviaz''; Scientific-Production Enterprise ''Svyaz''; Scientific-Production Enterprise Volna; Scientific-Production Enterprise Vostok JSC; Scientific-Research Institute ''Argon''; Scientific-Research Institute of Automated Systems and Communications Complexes Neptune JSC; Scientific Research Institute of Communication Management Systems; Scientific Research Institute Ferrite-Domen; Special Design and Technical Bureau for Relay Technology; Tactical Missile Corporation, 711 Aircraft Repair Plant (711 ARZ); Tactical Missile Corporation, AO GNPP ''Region''; Tactical Missile Corporation, AO TMKB ''Soyuz''; Tactical Missile Corporation, Azov Optical and Mechanical Plant; Tactical Missile Corporation, ''Central Design Bureau of Automation''; Tactical Missile Corporation, Concern ''MPO—Gidropribor''; Tactical Missile Corporation, Joint Stock Company Avangard; Tactical Missile Corporation, Joint Stock Company Concern Granit-Electron; Tactical Missile Corporation, Joint Stock Company Elektrotyaga; Tactical Missile Corporation, Joint Stock Company GosNIIMash; Tactical Missile Corporation JSC ''KRASNY GIDROPRESS''; Tactical Missile Corporation, Joint Stock Company PA Strela; Tactical Missile Corporation, Joint Stock Company ''Plant Dagdiesel''; Tactical Missile Corporation, Joint Stock Company Plant Kulakov; Tactical Missile Corporation, Joint Stock Company Ravenstvo; Tactical Missile Corporation, Joint Stock Company Ravenstvo-service; Tactical Missile Corporation, Joint-Stock Company ''Research Center for Automated Design''; Tactical Missile Corporation, Joint Stock Company ''Salute''; Tactical Missile Corporation, Joint Stock Company Saratov Radio Instrument Plant; Tactical Missile Corporation Joint Stock Company ''Scientific Research Institute of Marine Heat Engineering''; Tactical Missile Corporation, Joint Stock Company Severny Press; Tactical Missile Corporation, Joint Stock Company ''State Machine Building Design Bureau ''Vympel'' By Name I.I. Toropov''; Tactical Missile Corporation, Joint Stock Company ''URALELEMENT''; Tactical Missile Corporation, KB Mashinostroeniya; Tactical Missile Corporation, NPO Electromechanics; Tactical Missile Corporation, NPO Lightning; Tactical Missile Corporation, Petrovsky Electromechanical Plant ''Molot''; Tactical Missile Corporation, PJSC ANPP Temp Avia; Tactical Missile Corporation, PJSC ''MBDB ISKRA''; Tactical Missile Corporation, Raduga Design Bureau; Tactical Missile Corporation, RKB Globus; Tactical Missile Corporation, Smolensk Aviation Plant; Tactical Missile Corporation, TRV Engineering; Tactical Missile Corporation, Ural Design Bureau ''Detal''; Tactical Missile Corporation, Zvezda-Strela Limited Liability Company; and United Shipbuilding Corporation ''Production Association Northern Machine Building Enterprise''. All the entities will be designated with footnote 3. These entities are being added to the Entity List consistent with BIS's response to Russia's invasion of Ukraine, which include restricting Russia's access to items subject to the EAR that allow it to project power and fulfill its strategic ambitions. Specifically, these entities are being added to the Entity List for acquiring and attempting to acquire items subject

to the EAR in support of Russia's military. Their addition to the Entity List and footnote 3 designation means these entities are subject to a license requirement for exports, reexports, exports from abroad (as described under Russia/Belarus foreign ''direct product'' (FDP) rule, § 746.8(a)(3)), or transfers (in-country) of all items subject to the EAR that are destined to these entities. BIS will review license applications under a policy of denial. No license exceptions are available for exports, reexports, exports from abroad (as described under Russia/Belarus foreign ''direct product'' (FDP) rule § 746.8(a)(3)), or transfers (in-country) to the entities being added.

Moreover, the ERC determined to add the following entities to the Entity List on the basis of § 744.11(b) under the destination of Russia: 46th TSNII Central Scientific Research Institute; All Russia Scientific Research Institute of Optical Physical Measurements; Arzam Scientific Production Enterprise Temp Avia; Automated Procurement System for State Defense Orders, LLC; Engineering Center Moselectronproekt; Etalon Scientific and Production Association; Evgeny Krayushin; Far-East Factory Zvezda; Federal Center for Dual-Use Technology (FTsDT) Soyuz; Foreign Trade Association Mashpriborintorg; Ineko LLC; Informakustika JSC; Institute of High Energy Physics; Institute of Theoretical and Experimental Physics; ISE SO RAN Institute of High-Current Electronics; JSC Energiya, Kaluga Scientific-Research Institute of Telemechanical Devices JSC; OJSC Pella Shipyard; Scientific Production Center Vigstar JSC; Scientific-Production Enterprise Salyut JSC; Scientific-Research Institute and Factory Platan; Special Design Bureau Salute JSC; Tambov Plant (TZ) ''October''; Turayev Machine Building Design Bureau Soyuz; and Zhukovskiy Central Aerohydrodynamics Institute (TsAGI). These entities are being added to the Entity List consistent with BIS's response to Russia's invasion of Ukraine, which include restricting Russia's access to items subject to the EAR that allow it to project power and fulfill its strategic ambitions. Specifically, BIS is adding these entities to the Entity List for acquiring and attempting to acquire items subject to the EAR in support of Russia's military modernization efforts. These entities will be added to the Entity List with a license requirement for all items subject to the EAR. BIS will review license applications under a policy of denial. No license exceptions are available for exports, reexports, or transfers (in-country) to the entities being added.

For the reasons described above, this final rule adds the following 120 entities under 120 entries to the Entity List and includes, where appropriate, aliases:

Belarus

- 140 Repair Plant JSC,
- 558 Aircraft Repair Plant JSC,
- 2566 Radioelectronic Armament Repair Plant JSC,
- AGAT—Control Systems—Managing Company of Geoinformation Control Systems Holding JSC,
- Agat-Electromechanical Plant OJSC,
- AGAT–SYSTEM,
- ATE-Engineering LLC,
- BelOMO Holding,
- Belspetsvneshtechnika SFTUE,
- BSVT-New Technologies,
- CJSC Beltechexport,
- Department of Internal Affairs of the Gomel Region Executive Committee,
- Internal Troops of The Ministry of Internal Affairs of the Republic of Belarus,
- JSC Transaviaexport Airlines,
- KGB Alpha,
- Kidma Tech OJSC,
- Minotor-Service,
- Minsk Wheeled Tractor Plant,
- Oboronnye Initsiativy LLC,
- OJS KB Radar Managing Company,
- Peleng JSC,
- State Authority for Military Industry of the Republic of Belarus,
- State Security Committee of the Republic of Belarus, and
- Volatavto OJSC.

Russia

- 5th Shipyard,
- 46th TSNII Central Scientific Research Institute,
- Alagir Resistor Factory,
- All Russia Scientific Research Institute of Optical Physical Measurements,
- All-Russian Scientific-Research Institute Etalon JSC,
- Almaz JSC,
- Arzam Scientific Production Enterprise Temp Avia,
- Automated Procurement System for State Defense Orders, LLC,
- Dolgoprudniy Design Bureau of Automatics,
- Electronic Computing Technology Scientific-Research Center,
- Electrosignal JSC,
- Engineering Center Moselectronproekt,
- Etalon Scientific and Production Association,
- Evgeny Krayushin,
- Far-East Factory Zvezda,
- Federal Center for Dual-Use Technology (FTsDT) Soyuz,
- Foreign Trade Association Mashpriborintorg, Ineko LLC,
- Ineko LLC
- Informakustika JSC,
- Institute of High Energy Physics,
- Institute of Theoretical and Experimental Physics,
- Inteltech PJSC,
- ISE SO RAN Institute of High-Current Electronics,
- Joint Stock Company NPO Elektromechaniki,
- JSC Energiya,
- Kaluga Scientific-Research Institute of Telemechanical Devices JSC,
- Kulon Scientific-Research Institute JSC,
- Lutch Design Office JSC,
- Meteor Plant JSC,
- Moscow Communications Research Institute JSC,
- Moscow Order of the Red Banner of Labor Research Radio Engineering Institute JSC,
- OJSC Pella Shipyard,
- Omsk Production Union Irtysh JSC,
- Omsk Scientific-Research Institute of Instrument Engineering JSC,
- Optron JSC,
- Polyot Chelyabinsk Radio Plant JSC,
- Pskov Distance Communications Equipment Plant,
- Radiozavod JSC,
- Razryad JSC,
- Research Production Association Mars,
- Ryazan Radio-Plant,
- Scientific-Production Association and Scientific-Research Institute of Radio-Components,
- Scientific Production Center Vigstar JSC,
- Scientific-Production Enterprise Almaz JSC,
- Scientific-Production Enterprise ''Kant'',
- Scientific Production Enterprise ''Radiosviaz'',
- Scientific-Production Enterprise Salyut JSC,
- Scientific-Production Enterprise ''Svyaz'',
- Scientific-Production Enterprise Volna,
- Scientific-Production Enterprise Vostok JSC,
- Scientific-Research Institute and Factory Platan,
- Scientific-Research Institute ''Argon'',
- Scientific Research Institute Ferrite-Domen,
- Scientific-Research Institute of Automated Systems and Communications Complexes Neptune JSC,
- Scientific Research Institute of Communication Management Systems,
- Special Design and Technical Bureau for Relay Technology,

- Special Design Bureau Salute JSC,
- Tactical Missile Corporation, 711 Aircraft Repair Plant (711 ARZ),
- Tactical Missile Corporation, AO GNPP ''Region'',
- Tactical Missile Corporation, AO TMKB ''Soyuz'',
- Tactical Missile Corporation, Azov Optical and Mechanical Plant,
- Tactical Missile Corporation, ''Central Design Bureau of Automation'',
- Tactical Missile Corporation, Concern ''MPO—Gidropribor'',
- Tactical Missile Corporation, Joint Stock Company Avangard,
- Tactical Missile Corporation, Joint Stock Company Concern Granit-Electron,
- Tactical Missile Corporation, Joint Stock Company Elektrotyaga,
- Tactical Missile Corporation, Joint Stock Company GosNIIMash,
- Tactical Missile Corporation, Joint Stock Company PA Strela,
- Tactical Missile Corporation, Joint Stock Company ''Plant Dagdiesel'',
- Tactical Missile Corporation, Joint Stock Company Plant Kulakov,
- Tactical Missile Corporation, Joint Stock Company Ravenstvo,
- Tactical Missile Corporation, Joint Stock Company Ravenstvo-service,
- Tactical Missile Corporation, Joint-Stock Company ''Research Center for Automated Design'',
- Tactical Missile Corporation, Joint Stock Company ''Salute'',
- Tactical Missile Corporation, Joint Stock Company Saratov Radio Instrument Plant,
- Tactical Missile Corporation Joint Stock Company ''Scientific Research Institute of Marine Heat Engineering'',
- Tactical Missile Corporation, Joint Stock Company Severny Press,
- Tactical Missile Corporation, Joint Stock Company ''State Machine Building Design Bureau ''Vympel'' By Name I.I. Toropov'',
- Tactical Missile Corporation, Joint Stock Company ''URALELEMENT'',
- Tactical Missile Corporation JSC ''KRASNY GIDROPRESS'',
- Tactical Missile Corporation, KB Mashinostroeniya,
- Tactical Missile Corporation, NPO Electromechanics,
- Tactical Missile Corporation, NPO Lightning,
- Tactical Missile Corporation, Petrovsky Electromechanical Plant ''Molot'',
- Tactical Missile Corporation, PJSC ANPP Temp Avia,
- Tactical Missile Corporation, PJSC ''MBDB ISKRA'',
- Tactical Missile Corporation, Raduga Design Bureau,
- Tactical Missile Corporation, RKB Globus,
- Tactical Missile Corporation, Smolensk Aviation Plant,
- Tactical Missile Corporation, TRV Engineering,
- Tactical Missile Corporation, Ural Design Bureau ''Detal'',
- Tactical Missile Corporation, Zvezda-Strela Limited Liability Company,
- Tambov Plant (TZ) ''October'',
- Turayev Machine Building Design Bureau Soyuz,
- United Shipbuilding Corporation ''Production Association Northern Machine Building Enterprise'', and
- Zhukovskiy Central Aerohydrodynamics Institute (TsAGI).

In summary, for the 120 entities added to the Entity List by this final rule, BIS imposes a license requirement that applies to all items subject to the EAR. For the 95 entities added under both §§ 744.11 and 744.21, BIS is also listing those entities with a footnote 3 designation. No license exceptions are available for exports, reexports, exports from abroad (as described under Russia/Belarus foreign ''direct product'' (FDP) rule, § 746.8(a)(3)), or transfers (in-country) to these entities; BIS will review all license applications for these entities under a policy of denial.

For the 25 entities added solely on the basis of § 744.11, BIS is not listing those entities with a footnote 3 designation. No license exceptions are available for exports, reexports, or transfers (in-country) to these entities. BIS will review all license applications for these entities under a policy of denial.

Savings Clause

For the changes being made in this final rule, shipments of items removed from eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export, reexport, or transfer (in-country), on April 1, 2022, pursuant to actual orders for export, reexport, or transfer (in-country) to or within a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export, reexport, or transfer (in-country) without a license (NLR).

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and commodity classifications, and carries a burden estimate of 29.6 minutes for a manual or electronic submission for a total burden estimate of 33,133 hours. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule.

3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to section 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p.

608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 15, 2021, 86 FR 52069 (September 17, 2021); Notice of November 10, 2021, 86 FR 62891 (November 12, 2021).

■ 2. Supplement No. 4 to part 744 is amended:

■ a. Under BELARUS by adding, in alphabetical order, entries for ''140 Repair Plant JSC,'' ''558 Aircraft Repair Plant JSC,'' ''2566 Radioelectronic Armament Repair Plant JSC,'' ''AGAT—Control Systems—Managing Company of Geoinformation Control Systems Holding JSC,'' ''Agat-Electromechanical Plant OJSC,'' ''AGAT–SYSTEM,'' ''ATE-Engineering LLC,'' ''BelOMO Holding,'' ''Belspetsvneshtechnika SFTUE,'' ''BSVT-New Technologies,'' ''CJSC Beltechexport,'' ''Department of Internal Affairs of the Gomel Region Executive Committee,'' ''Internal Troops of The Ministry of Internal Affairs of the Republic of Belarus,'' ''JSC Transaviaexport Airlines,'' ''KGB Alpha,'' ''Kidma Tech OJSC,'' ''Minotor-Service,'' ''Minsk Wheeled Tractor Plant,'' ''Oboronnye Initsiativy LLC,'' ''OJS KB Radar Managing Company,'' ''Peleng JSC,'' ''State Authority for Military Industry of the Republic of Belarus,'' ''State Security Committee of the Republic of Belarus,'' and ''Volatavto OJSC''.

■ b. Under RUSSIA by adding, in alphabetical order, entries for ''5th Shipyard,'' ''46th TSNII Central Scientific Research Institute,'' ''Alagir Resistor Factory,'' ''All Russia Scientific Research Institute of Optical Physical Measurements,'' ''All-Russian Scientific-Research Institute Etalon JSC,'' ''Almaz JSC,'' ''Arzam Scientific Production Enterprise Temp Avia,'' ''Automated Procurement System for State Defense Orders, LLC,'' ''Dolgoprudniy Design Bureau of Automatics,'' ''Electronic Computing Technology Scientific-Research Center,'' ''Electrosignal JSC,'' ''Engineering Center Moselectronproekt,'' ''Etalon Scientific and Production Association,'' ''Evgeny Krayushin,'' ''Far-East Factory Zvezda,'' ''Federal Center for Dual-Use Technology (FTsDT) Soyuz,'' ''Foreign Trade Association Mashpriborintorg,'' ''Ineko LLC,'' ''Informakustika JSC,'' ''Institute of High Energy Physics,'' ''Institute of Theoretical and Experimental Physics,'' ''Inteltech PJSC,'' ''ISE SO RAN Institute of High-Current Electronics,'' ''Joint Stock Company NPO Elektromechaniki,'' ''JSC Energiya,'' ''Kaluga Scientific-Research Institute of Telemechanical Devices JSC,'' ''Kulon Scientific-Research Institute JSC,'' ''Lutch Design Office JSC,'' ''Meteor Plant JSC,'' ''Moscow Communications Research Institute JSC,'' ''Moscow Order of the Red Banner of Labor Research Radio Engineering Institute JSC,'' ''OJSC Pella Shipyard,'' ''Omsk Production Union Irtysh JSC,'' ''Omsk Scientific-Research Institute of Instrument Engineering JSC,'' ''Optron JSC,'' ''Polyot Chelyabinsk Radio Plant JSC,'' ''Pskov Distance Communications Equipment Plant,'' ''Radiozavod JSC,'' ''Razryad JSC,'' ''Research Production Association Mars,'' ''Ryazan Radio-Plant,'' ''Scientific-Production Association and Scientific-Research Institute of Radio-Components,'' ''Scientific Production Center Vigstar JSC,'' ''Scientific-Production Enterprise Almaz JSC,'' ''Scientific-Production Enterprise ''Kant'','' ''Scientific Production Enterprise ''Radiosviaz'','' ''Scientific-Production Enterprise Salyut JSC,'' ''Scientific-Production Enterprise ''Svyaz'','' ''Scientific-Production Enterprise Volna,'' ''Scientific-Production Enterprise Vostok JSC,'' ''Scientific-Research Institute and Factory Platan,'' ''Scientific-Research Institute ''Argon'','' ''Scientific Research Institute Ferrite-Domen,'' ''Scientific-Research Institute of Automated Systems and Communications Complexes Neptune JSC,'' ''Scientific Research Institute of Communication Management Systems,'' ''Special Design and Technical Bureau for Relay Technology,'' ''Special Design Bureau Salute JSC,'' ''Tactical Missile Corporation, 711 Aircraft Repair Plant (711 ARZ),'' ''Tactical Missile Corporation, AO GNPP ''Region'','' ''Tactical Missile Corporation, AO TMKB ''Soyuz'','' ''Tactical Missile Corporation, Azov Optical and Mechanical Plant,'' ''Tactical Missile Corporation, ''Central Design Bureau of Automation'','' ''Tactical Missile Corporation, Concern ''MPO—Gidropribor'','' ''Tactical Missile Corporation, Joint Stock Company Avangard,'' ''Tactical Missile Corporation, Joint Stock Company Concern Granit-Electron,'' ''Tactical Missile Corporation, Joint Stock Company Elektrotyaga,'' ''Tactical Missile Corporation, Joint Stock Company GosNIIMash,'' ''Tactical Missile Corporation, Joint Stock Company PA Strela,'' ''Tactical Missile Corporation, Joint Stock Company ''Plant Dagdiesel'','' ''Tactical Missile Corporation, Joint Stock Company Plant Kulakov,'' ''Tactical Missile Corporation, Joint Stock Company Ravenstvo,'' ''Tactical Missile Corporation, Joint Stock Company Ravenstvo-service,'' ''Tactical Missile Corporation, Joint-Stock Company ''Research Center for Automated Design'','' ''Tactical Missile Corporation, Joint Stock Company ''Salute'','' ''Tactical Missile Corporation, Joint Stock Company Saratov Radio Instrument Plant,'' ''Tactical Missile Corporation Joint Stock Company ''Scientific Research Institute of Marine Heat Engineering'','' ''Tactical Missile Corporation, Joint Stock Company Severny Press,'' ''Tactical Missile Corporation, Joint Stock Company ''State Machine Building Design Bureau ''Vympel'' By Name I.I. Toropov'','' ''Tactical Missile Corporation, Joint Stock Company ''URALELEMENT'','' ''Tactical Missile Corporation JSC ''KRASNY GIDROPRESS'','' ''Tactical Missile Corporation, KB Mashinostroeniya,'' ''Tactical Missile Corporation, NPO Electromechanics,'' ''Tactical Missile Corporation, NPO Lightning,'' ''Tactical Missile Corporation, Petrovsky Electromechanical Plant ''Molot'','' ''Tactical Missile Corporation, PJSC ANPP Temp Avia,'' ''Tactical Missile Corporation, PJSC ''MBDB ISKRA'','' ''Tactical Missile Corporation, Raduga Design Bureau,'' ''Tactical Missile Corporation, RKB Globus,'' ''Tactical Missile Corporation, Smolensk Aviation Plant,'' ''Tactical Missile Corporation, TRV Engineering,'' ''Tactical Missile Corporation, Ural Design Bureau ''Detal'','' ''Tactical Missile Corporation, Zvezda-Strela Limited Liability Company,'' ''Tambov Plant (TZ) ''October'','' ''Turayev Machine Building Design Bureau Soyuz,'' ''United Shipbuilding Corporation ''Production Association Northern Machine Building Enterprise'','' and ''Zhukovskiy Central Aerohydrodynamics Institute (TsAGI)''.

The additions read as follows:

Supplement No. 4 to Part 744—Entity List

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Country	Entity	License requirement	License review policy	Federal Register citation
*	* *	*	* *	*
BELARUS	140 Repair Plant JSC, a.k.a., the following two aliases: —Open Joint Stock Company 140 Repair Plant; *and* —JSC 140 Repair Plant. 19 Luysi Chalovskoy St., Borisov, 222512, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	558 Aircraft Repair Plant JSC, a.k.a., the following one alias: —JSC 558 ARP. 7 50 Years VLKSM St., Baranovichi, Brest region, 225320, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	2566 Radioelectronic Armament Repair Plant JSC, a.k.a., the following one alias: —JSC 2566 ZRREV. 54 Gagarina St., Borisov, 222511, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	AGAT—Control Systems—Managing Company of Geoinformation Control Systems Holding JSC, a.k.a., the following one alias: —AGAT—Control Systems. 117/1 Nezavisimosti Ave., Minsk, 220114, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Agat-Electromechanical Plant OJSC, a.k.a., the following two aliases: —JSC Agat Electromechanical Plant; *and* —Agat-Elektromekhanicheski Zavod. 6 Volgogradskaya St., Minsk, 220012, Belarus; *and* 117, Bld. 3, Nezavisimosti Ave., Minsk 220114, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	AGAT–SYSTEM, 51B Francyska Skaryna St., Minsk, 220141, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	ATE-Engineering LLC, 15A Smolenskaya St., Minsk, 220088, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	BelOMO Holding, a.k.a., the following one alias: —The Belarusian Optical and Mechanical Association. 23 Makaenka St., Minsk, 220114, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Belspetsyneshtechnika SFTUE, a.k.a., the following two aliases: —State-Owned Foreign Trade Unitary Enterprise Belspetsvneshtechnika; *and* —BSVT. 8 Kalinovsky St., Minks, 220103, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Beltechexport, CJSC, 86–B Nezavisimosti Ave., Minks, 220012, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	BSVT-New Technologies, 187 Soltysa Street, Minsk, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].

Country	Entity	License requirement	License review policy	Federal Register citation
	Department of Internal Affairs of the Gomel Region Executive Committee, a.k.a., the following one alias: —UVD of the Gomel Region Executive Committee. 3 Kommunarov Street, Gomel, 246050, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Internal Troops of The Ministry of Internal Affairs of the Republic of Belarus, a.k.a., the following one alias: —MVD Internal Troops. 4 Gorodskoi Val, Minsk, 220030, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	KGB Alpha, a.k.a., the following three aliases: —the State Security Committee Alpha; —Alpha Group; *and* —Group A. Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Kidma Tech OJSC, a.k.a., the following two aliases: —BSVT-New Technologies; *and* —BSVT–NT. 187 Soltysa Street, Minsk, 220070, Belarus; *and* 5/1 Ustenskiy Selsovyet, Orshanskiy Region, Vitebskaya Oblast, Ag. Ustye, 211003, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Minotor-Service, a.k.a., the following one alias: —Industrial-Commercial Private Unitary Enterprise Minotor-Service. 40 Radialnaya St., Minsk, 220070, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Minsk Wheeled Tractor Plant, a.k.a., the following two aliases: —MZKT; *and* —Production Republican Unitary Enterprise Minsk Wheeled Tractor Plant. 150 Partizansky Avenue, Minsk, 220021, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Oboronnye Initsiativy LLC, a.k.a., the following one alias: —LLC Defense Initiatives. 18 1st Lane F. Skaryna, Minsk, 220070, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	OJS KB Radar Managing Company, a.k.a., the following two aliases: —JSC KB Radar; *and* — KB Radar. 64A Partizanskyi Prospect, Minsk, 220026, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Peleng JSC, 25 Makaenka St., Minsk, 220114, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	State Authority for Military Industry of the Republic of Belarus, 115 Nezavisimosti Avenue, Minsk, 220114, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	State Security Committee of the Republic of Belarus, 17 Nezavisimosti Avenue, Minsk, 220030, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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Country	Entity	License requirement	License review policy	**Federal Register** citation
	Transaviaexport Airlines JSC, 44 Zakhariva Street, Minsk, 220034, Republic of Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Volatavto OJSC, a.k.a., the following one alias: —NPP VOLATauto. 2/1 Kulman St., Office 1–143, Minsk, 220013, Belarus; *and* 133 Socialist Street, Slutsk, Minsk Region, 223610, Belarus.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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RUSSIA	5th Shipyard, a.k.a., the following three aliases: —5-y Sudoremontnyy Zavod; —5 SRZ; *and* —JSC GF 5 SRZ JSC TsS Zvezdochka. 67 Lenina Street, Port, Temryuk, Krasnodarskiy Kray, 353500, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	46th TSNII Central Scientific Research Institute, a.k.a., the following two aliases: —46 TsNII; *and* —46 TsNII MO RF. 10 Chukotskiy Proyezd, Moscow, 129327, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Alagir Resistor Factory, a.k.a., the following one alias: —Alagirsky Resistor Factory. 202 L. Tolstogo Street, Alagir, Alagirsky District, Severnaya Ossetia-Alania Republic, Russia, 363240.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	All Russia Scientific Research Institute of Optical Physical Measurements, a.k.a., the following two aliases: —All-Russian Research Institute for Optical and Physical Measurements Federal State Unitary Enterprise; *and* —FSUE VNIIOFI. 46 Ozernaya St., Moscow, 119361, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	All-Russian Scientific-Research Institute Etalon JSC, a.k.a., the following one alias: —VNII Etalon JSC. 19/1 1st Yamskogo Polya St., Moscow, 125124, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Almaz JSC, a.k.a., the following one alias: —Almaz. 16 Tupoleva Street, Rostov-na-Donu, Rostovskaya Oblast, 344093, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Arzam Scientific Production Enterprise Temp Avia, a.k.a., the following three aliases: —OKB Temp; —Temp-Avia Arzamas Research and Production Association JSC; *and* —ANPP Temp-Avia. 26 Kirova St., Arzamas, 607220, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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Country	Entity	License requirement	License review policy	Federal Register citation
	Automated Procurement System for State Defense Orders, LLC, a.k.a., the following one alias: —AST GOZ LLC. 78/1 Profsoyuznaya St., Moscow, 117393, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Dolgoprudniy Design Bureau of Automatics, a.k.a., the following three aliases: —DKBA JSC; —Dolgoprudny; *and* —Dolgoprudno Design Bureau of Automation. Lyotnaya Street, Dolgoprudniy, Moskovskaya Oblast, 141700, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Electronic Computing Technology Scientific-Research Center, a.k.a., the following one alias: —NICEVEY. 125 Varshavskoye Highway, Moscow, 117587, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Electrosignal JSC, Electrosignalnaya Street, Voronezh, Voronezhskaya Oblast, 394026, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Engineering Center Moselectronproekt, a.k.a., the following two aliases: —Moselectronproekt (JSC); *and* —MosEP JSC. 12 Kosmonavta Volkova St., Room 22, Moscow, 127299, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Etalon Scientific and Production Association, a.k.a., the following one alias: —NPO Etalon. 3 Tsentralny Proezd, Dobryanka, Perm Territory, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Evgeny Krayushin, Building 41, 3 Zheleznodorozhniy Lane, Dmitrov, Moscow, Russia; *and* 9 Melitopolskaya ul., Str. 3, Moscow, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Far-East Factory Zvezda, a.k.a., the following one alias: —AO FEP Zvezda. 1 Stepan Lebedev St., Bolshoy Kamen, Primorsky krai, 692801, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Federal Center for Dual-Use Technology (FTsDT) Soyuz, a.k.a., the following one alias: —FSUE FCDT Soyuz. 42 Academician Zhukov St., Dzerzhinsky, 140090, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Foreign Trade Association Mashpriborintorg, a.k.a., the following one alias: —FTA Mashpriborintorg JSC. 3 Sherbakovskaya St., Moscow, 105318, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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Country	Entity	License requirement	License review policy	**Federal Register** citation
	Ineko LLC, a.k.a., the following one alias: —OOO Ineko. Building 41, 3 Zheleznodorozhniy Lane, Dmitrov, Moscow, Russia; *and* 9 Melitopolskaya ul., Str. 3, Moscow, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Informakustika JSC, 22A Polytechnic St., St. Petersburg, 194021, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Institute of High Energy Physics, a.k.a., the following two aliases: —IHEP; *and* —Kurchatovskiy Institute ITEF. 1/1 Pobeda St., Science Square, Protvino Moskovskaya Oblast, 142281, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Institute of Theoretical and Experimental Physics, a.k.a., the following three aliases: —ITEP; —ITEF; *and* —Kurchatovskiy Institute ITEF. 25 Bolshaya Cheremushkinskaya St., 117218; *and* 24 Sevastopolskiy Avenue, Moscow, 117186, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Inteltech PJSC, a.k.a., the following three aliases: —Information Telecommunications Technology PJSC; —Inteltech; *and* —Inteltekh. Electrosignalnaya Street, Voronezh, Voronezhskaya Oblast, 394026, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	ISE SO RAN Institute of High-Current Electronics, a.k.a., the following three aliases: —Institute of High Current Electronics Siberian Branch Russian Academy of Science —IHCE; *and* —IHCE SB RAS. 2/3 Prospekt Akeademicheskiy, Tomsk, 634055, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Joint Stock Company NPO Elektromechaniki, a.k.a., the following one alias: —JSC Scientific and Production Association of Electro Mechanic. 31 Mendeleeva street, Miass, Chelyabinsk Region, 456320, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	* *	*	* *	*
	JSC Energiya, 1 Elektrik St., Yelets, Lipetskaya Oblast, 399775, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Kaluga Scientific-Research Institute of Telemechanical Devices JSC, a.k.a., the following one alias: —KNIITMU JSC. 4 Karla Marksa St., Kaluga, 248000, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Kulon Scientific-Research Institute JSC, a.k.a., the following one alias: —NII Kulon JSC. 14 Murmankiv proezd, Moscow, 129075, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].

Country	Entity	License requirement	License review policy	Federal Register citation
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	Lutch Design Office JSC, a.k.a., the following three aliases: —Lutch Design Bureau JCS; —Lutch JSC; *and* —KB-Lutch. 25 Pobeda Blvd. Rybinsk, Yaroslavskaya Oblast, 152920, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Meteor Plant JSC, 1 Gorky St., Volzhkiy, Volgograd Oblast, 404130, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Moscow Communications Research Institute JSC, a.k.a., the following one alias: —MNIIS JSC. 34 Kutuzovsky prospect, Moscow, Russia, 121170; *and* 3/2 Kirovogradsky proezd, Moscow, 109044, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Moscow Order of the Red Banner of Labor Research Radio Engineering Institute JSC, a.k.a., the following one alias: —MNIRTI JSC. 2/1 Boshoy Trehsvyatitelskiy per., Moscow, 109028, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	OJSC Pella Shipyard, a.k.a., the following one alias: —OJSC Leningrad Shipyard Pella. 4 Tsentralnaya St., Kirovski raion, Otradnoe, Leningradskaya Obl., 187330, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Omsk Production Union Irtysh JSC, a.k.a., the following one alias: —OmPO Irtysh. 18 Gurt'yeva St., Omsk, 644060, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Omsk Scientific-Research Institute of Instrument Engineering JSC, a.k.a., the following one alias: —JSC ONIP. 231 Maslennikova St., Omsk, 644009, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Optron JSC, 53 Sherbakovskaya St., Office 37, Moscow, 105187, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Polyot Chelyabinsk Radio Plant JSC, a.k.a., the following one alias: —ChRZ Polyot (flight) JSC. 6 Ternopol'skaya St., Chelyabinsk, 454126, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Pskov Distance Communications Equipment Plant, a.k.a., the following two aliases: —Pskov Plant ADS JSC; *and* —Pskov Distance Communications Equipment (ADS) Plant JSC. 4 Yuri Gagarin Street, Pskov, Pskovskaya Oblast, 180004, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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Country	Entity	License requirement	License review policy	Federal Register citation
	Radiozavod JSC, 1 Baydukova Street, Penza, Penzenskaya Oblast, 440015, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Razryad JSC, 233 Kosta Avenue, Vladikavkaz, Severnaya Ossetia-Alania Republic, 362035, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Research Production Association Mars, a.k.a., the following two aliases: —RPA Mars; *and* —NPO Mars. 20 Solnechnaya Street, Ulyanovsk, 432022, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Ryazan Radio-Plant, 11 Lermontova Street, Ryazan, Ryazanskaya Oblast, 390023, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Scientific-Production Association and Scientific-Research Institute of Radio-Components, a.k.a., the following one alias: —NIIRK. 3 Krymsky Val Street, Building 1, Office 1, Moscow, 119049, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific Production Center Vigstar JSC, a.k.a., the following two aliases: —AO Nauchno-proizvodstvennyy tsentr Vigstar; *and* —JSC SRC Vigstar. 8 1st Dorozhnyy proyezd, Moscow, 117545, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific-Production Enterprise Almaz JSC, a.k.a., the following one alias: —JSC NPP Almaz. 1 I.V. Panfilov St., Saratov, 410033, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific-Production Enterprise ''Kant'', a.k.a., the following two aliases: —Kant; *and* —NPP Kant. 12 Talalikhina Street Floor 7, Moscow, 109316, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific Production Enterprise ''Radiosviaz'', a.k.a., the following one alias: —Radiosviaz. 19 Dekabristov Street, Krasnoyarsk, 660021, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific-Production Enterprise Salyut JSC, a.k.a., the following one alias: —JSC NPP Salyut. 7 Larina St., Nizhny Novgorod, 603950, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific-Production Enterprise ''Svyaz'', a.k.a., the following two aliases: —Svyaz; *and* —NPP Svyaz. 19 Shkolnaya Street, Yasnaya Polyana Village, Shekinsky District, Tulskaya Oblast, 301214, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].

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	Scientific-Production Enterprise Volna, a.k.a., the following one alias: —NPP Volna. 26 Varshavskoe Highway, Moscow, 117105, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific-Production Enterprise Vostok JSC, a.k.a., the following one alias: —JSC NPP Vostok. 276, D. Kovalchuk St., Novosibirsk, 630075, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific-Research Institute and Factory Platan, a.k.a., the following one alias: —NII Platan. 2 Zavodskoy Dr., Fryazino, Moscow oblast, 141190, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific-Research Institute ''Argon'', a.k.a., the following two aliases: —Argon Scientific-Research Institute JSC; *and* —NII Argon JSC. 4 Karla Marksa Street, Kaluga, 248000, Russia; *and* 125 Varshavskoe Shosse, Building 1, Moscow, 117587, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific Research Institute Ferrite-Domen, a.k.a., the following two aliases: —NII Domen; *and* —Ferrite-Domen Co. 25/3B Zvetochnaya St., Room 417, St. Petersburg, 196006, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Scientific-Research Institute of Automated Systems and Communications Complexes Neptune JSC, a.k.a., the following one alias: —NII Neptune JSC. 80–1/A, 7th Line of Vasilyavskiy Island, St. Petersburg, 199178, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Scientific Research Institute of Communication Management Systems, a.k.a., the following two aliases: —NIISU; *and* —NIISU JSC. 25/3B Zvetochnaya St., Room 417, St. Petersburg, 196006, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Special Design and Technical Bureau for Relay Technology, a.k.a., the following two aliases: —Relay Technology Bureau JSC; *and* —JSCT SKTB RT. 55 Nehinskaya St., Velikiy Novgorod, 173021, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Special Design Bureau Salute JSC, a.k.a., the following two aliases: —OKB Salute JSC; *and* —OKB Salyut JSC. 153 Krasniy Pr., Novosibirsk, Russia, 630049.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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	Tactical Missile Corporation, 711 Aircraft Repair Plant (711 ARZ), 18 Chkalova Pereulok, Borisoglebsk, Voronezhskaya Oblast, 397171, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].

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	Tactical Missile Corporation, AO GNPP "Region", a.k.a., the following three aliases: —GNPP Region, PAO; —Aktsionernoe Obshchestvo "Gosudarstvennoe Nauchno-Proizvodstvennoe Predpriyatie "Region,"; *and* —"Region" Scientific & Production Enterprise JSC. 10 Turaevo I.Z., Lytkarino City, Moscow Region, 140080, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, AO TMKB "Soyuz", a.k.a., the following four aliases: —Turaevskoe MKB "Soyuz"; —Aktsionernoe Obshchestvo Turaevskoe Mashinostroitelnoe Konstruktorskoe Byuro "Soyuz"; —Soyuz PAO; *and* —JSC "Turaevskoe Machine-Building Design Bureau "Soyuz. 10 Turaevo I.Z., Lytkarino City, Moscow Region, 140080, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Azov Optical and Mechanical Plant, a.k.a., the following three aliases: —PPO Azovski Optiko-Mekhanicheski Zavod; —Pervichnaya Profsoyuznaya Organizatsiya "Azovski Optiko-Mekhanicheski Zavod" Rossiskogo Profsoyuza Rabotnikov Promyshlennosti; *and* —JSC AOMZ). 5 Promyshlennaya Street, Azov, Rostovskaya Oblast, 346780, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, "Central Design Bureau of Automation", a.k.a., the following three aliases: — JSC "TsKBA"; — AO "TsKBA"; *and* — Aktsionernoe Obshchestvo "Tsentralnoe Konstruktorskoe Byuro Avtomatiki". 24A Kosmicheski Prospekt, Omsk, Omskaya Oblast, 44027, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Concern "MPO—Gidropribor", a.k.a., the following two aliases: —Joint Stock Company Concern Sea Underwater Weapons Gidropribor; *and* —Research Institute "Gidpropridor"; Central Research Institute "Gidropribor". 24, Sampsonievskiy pr., Saint Petersburg, 194044, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company Avangard, 78 Oktyabrskaya Street, Safonovo, Smolensk Region, 215500, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company Concern Granit-Electron, 3 Gospitalnaya St., St. Petersburg, 191014, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].

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	Tactical Missile Corporation, Joint Stock Company Elektrotyaga, a.k.a., the following two aliases: —Electric Traction; *and* —ZAO Elekrotjaga. 50–A Kalinina Str., St. Petersburg, 198095, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company GosNIIMash, a.k.a., the following five aliases: —PPO Rosprofprom V "GOSNIIMASH"; —State Research Institute of Mechanical Engineering; —Pervichnaya Profsoyuznaya Organizatsiya Rossiskogo Profsoyuza Rabotnikov Promyshlennosti V "GOSNIIMASH"; —Joint Stock Company "State Research Institute of Mechanical Engineering" named after V.V. Bakhirev"; *and* —SKB DNIKhTI. 11 Sverdlova Prospekt, Dzerzhinsk, Nizhegorodskaya Oblast, 606002, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company PA Strela, a.k.a. the following one alias: —Production Association Strela. 26 Shevchenko Str., Orenburg, 460005, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company "Plant Dagdiesel", 1 Lenina Street, Kaspiysk, Republic of Dagestan, 368300, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company Plant Kulakov, a.k.a., the following one alias: —JSC Plant Named After A.A. Kulakov. 12 Yablochkova Street, St. Petersburg, 197198, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company Ravenstvo, a.k.a., the following one alias: —Joint-Stock Company Ravenstvo; Equality. 19 Promyshlennaya Street, St. Petersburg, 198099, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company Ravenstvo-service, 19 Promyshlennaya Street, St. Petersburg, 198099, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint-Stock Company "Research Center for Automated Design", a.k.a., following two aliases: —NIC ASK; *and* —ASK JSC. 37 Leningradsky Prospekt, Room 12, Moscow, 125167, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company "Salute", a.k.a., the following two aliases: —Salyut, PAO; *and* —Kuibyshev Mechanical Plant. 20 Moskovskoe Shosse, Samara, 443028, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].

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	Tactical Missile Corporation, Joint Stock Company Saratov Radio Instrument Plant, 108 50 Years of October, Saratov, 410040, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation Joint Stock Company ''Scientific Research Institute of Marine Heat Engineering'', a.k.a., the following one alias: —Research Institute of Morteplotehniki. 44 Chernikova Street, Lomonosov, St. Petersburg, 198412, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company Severny Press, a.k.a., the following one alias: —Northern Press. 7 Tallinskaya Street, St. Petersburg, 195196, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company ''State Machine Building Design Bureau ''Vympel'' By Name I.I. Toropov'', a.k.a., the following two aliases: —AO Gos MKB ''Vympel'' named for II Toropov; *and* —Vympel NPO. 90 Voloklamskoe Shosse, Moscow, 125424, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Joint Stock Company ''URALELEMENT'', a.k.a., the following one alias: —Verkhneufalei Plant ''Uralelement''. 24 Dmitrieva St., Verkhny Ufaley, Chelyabinsk Region, 456800, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation JSC ''KRASNY GIDROPRESS'', a.k.a., the following five aliases: —Aktsionernoe Obshchestvo ''Krasny Gidropress,''; —Krasny Gidropress, PAO; —Red Hydraulic Press; —Krasny Gidropress JSC; *and* —Taganrog Krasnyy Gidropress Plan. 3 Severnaya Place, Taganrog, Rostovskaya Oblast, 347928, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, KB Mashinostroeniya, a.k.a., the following two aliases: —JSC Research and Production Corporation Design Bureau of Mechanical Engineering; *and* —JSC NPK KBM. 42 Oksky Prospect, Kolomna, Moscow Region, 140402, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, NPO Electromechanics, 31 Mendeleev Street, Chelyabinsk Region, 456320, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, NPO Lightning, a.k.a., the following one alias: —Research and Production Association Lightning JSC NPO Molniya. 5K1 Lodochnaya Street, Moscow, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Petrovsky Electromechanical Plant ''Molot'', 40 Gogol Street, Petrovsk, Saratov Region, 412541, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].

Country	Entity	License requirement	License review policy	Federal Register citation
	Tactical Missile Corporation, PJSC ANPP Temp Avia, a.k.a., the following six aliases: —ANPP "TEMP AVIA"; —Public Joint Stock Company "Arzamas Research and Production Enterprise"; —TEMP–AVIA; —ANPP TEMP AIR; —Joint Stock Company "Arzamas Research And Production Enterprise "TEMP–AVIA"; *and* —Publichnoe Aktsionernoe Obshchestvo "Arzamasskoe Nauchno-Proizvodstvennoe Predpriyatie "TEMP–AVIA". 26 G. Arzamas G.Arzamas. Street, Kirov, Nizhny Novgorod, 607220 Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, PJSC "MBDB ISKRA", a.k.a., the following two aliases: —Aktsionernoe Obshchestvo "Mashinostroitelnoe Konstruktorskoe Byuro "Iskra" Imeni Ivana Ivanovicha Kartukova"; *and* —AO MKB "ISKRA". 35 Leningradsky Prospekt, Moscow, 125284, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Raduga Design Bureau, a.k.a., the following four aliases: —AO "GosMKB "Raduga" IM. A.Ya.Bereznyaka,"; —Joint Stock Company "State Machine-Building Design Bureau "Raduga,"; —MKB Raduga; *and* —GosMKB "Rainbow" them. AND I. Bereznyak. 2A Zhukovskogo, Dubna, Moscowvskaya Oblast, 141983, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, RKB Globus, a.k.a., the following two aliases: —JSC Ryazan Design Bureau Globus; *and* —Federal State Unitary Enterprise RKB Globus. 6 Vysokovoltnaya Street, Ryazan, 390013, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Smolensk Aviation Plant, a.k.a., the following one alias: —JSC "SmAZ". 74 Frunze Street, Smolensk, 214006, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, TRV Engineering, a.k.a., the following one alias: —Zvezda-Strela Trading House LLC. 2A Ordzhonikidze Street, Korolev, Moscow Region, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].

Country	Entity	License requirement	License review policy	**Federal Register** citation
	Tactical Missile Corporation, Ural Design Bureau "Detal", a.k.a., the following four aliases: —Joint-Stock Company "Ural Design Bureau "Detal"; —Aktsionernoe Obshchestvo "Uralskoe Proektno-Konstruktorskoe Byuro "Detal"; —AO UPKB "Detal"; *and* —Uralskoe Proektno-Konstruktorskoe Byuro Detal, Pao. 8 Pionerskaya Street, Kamensk-Uralski, Sverdlovskaya Oblast, 623409, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
	Tactical Missile Corporation, Zvezda-Strela Limited Liability Company, a.k.a., the following two aliases: —Star Arrow; *and* —Zvezda-Arrow Corporation. 3 Taganrog Severnaya Square, Rostov Region, 347928, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
*	*	*	*	*
	Tambov Plant (TZ) "October", a.k.a., the following two aliases: —Tambov Plant (TZ) October JSC; *and* —JSC Octayabr. 1 Bastionaya Street, Tambov, Tambovskaya Oblast, 392029, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
*	*	*	*	*
	Turayev Machine Building Design Bureau Soyuz, a.k.a., the following one alias: —TMBDB SoyuZ PJSC. 10 Turaevo I.Z., Lytkarino, Moscow Region, 140080, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
*	*	*	*	*
	United Shipbuilding Corporation "Production Association Northern Machine Building Enterprise", a.k.a., the following one alias: —JSC PO Sevmash. 58 Archangelskoye Shosse, Severodvinsk, Archangelsk Region, 164500, Russia.	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
*	*	*	*	*
	Zhukovskiy Central Aerohydrodynamics Institute (TsAGI), a.k.a., the following two aliases: —TsAGI; *and* —The Central Aerohydrodynamic Institute named after N.E. Zhukovsky. 1 Zhukovsky Street, Zhukovsky, Moscow Region, 140180, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Policy of Denial	87 FR [INSERT FR PAGE NUMBER AND 4/7/2022].
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[3] For this entity, "items subject to the EAR" includes foreign-produced items that are subject to the EAR under § 734.9(g) of the EAR. See §§ 746.8 and 744.21 of the EAR for related license requirements, license review policy, and restrictions on license exceptions.

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2022–07284 Filed 4–1–22; 2:30 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–949]

Schedules of Controlled Substances: Placement of Daridorexant in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: On January 7, 2022, the United States Food and Drug Administration approved a new drug application for QUIVIVIQ (daridorexant) tablets for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place daridorexant and its salts in schedule IV of the Controlled Substances Act (CSA). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing daridorexant in schedule IV, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of such isomers is possible within the specific chemical designation, thereby facilitating the commercial distribution of QUIVIVIQ as a lawful controlled substance.

DATES: The effective date of this rule is April 7, 2022. Comments must be submitted electronically or postmarked on or before May 9, 2022. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before May 9, 2022.

ADDRESSES: Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). To ensure proper handling of comments, please reference ''Docket No. DEA–949'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov and follow the online instructions at that site for submitting comments.* Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, VA 22152.
- *Hearing requests:* All requests for hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available, unless reasonable cause is given, for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want DEA to make it publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want DEA to make it publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

DEA will generally make available in publicly redacted form comments containing personal identifying information and confidential business information identified, as directed above. If a comment has so much confidential business information or personal identifying information that DEA cannot effectively redact it, DEA may not make available publicly all or part of that comment. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as confidential as directed above.

An electronic copy of this document and supplemental information to this interim final rule (IFR) are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing''. Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and such requests must include a statement of the person's interests in the proceeding and the

objections or issues, if any, concerning which the person desires to be heard. 21 CFR 1316.47(a). Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for hearings and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above.

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114–89), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the Food and Drug Administration (FDA). As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of the Department of Health and Human Services (HHS) has advised DEA that an NDA has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an IFR controlling the drug within 90 days.

Subsection (j)(2) states that the 90-day timeframe starts the later of (1) the date DEA receives HHS' scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Subsection (j)(3) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause therefore. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.[1]

Subsection (j)(3) further provides that the IFR shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b).

Daridorexant, chemically known as [(S)-2-(5-chloro-4-methyl-1*H*-benzo[*d*]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2-(2*H*-1,2,3-triazol-2-yl)phenyl)methanone, is a new molecular entity (NME) with CNS activity. Daridorexant is a dual orexin receptor antagonist that inhibits the orexin neuropeptide-induced activation of the orexin receptor type 1 (OX1R) and orexin receptor type 2 (OX2R) subtypes. Daridorexant shares chemical structure and pharmacological mechanism of action with certain schedule IV CNS depressants such as suvorexant and lemborexant.

On January 8, 2021, Idorsia Pharmaceuticals, Ltd (Sponsor) submitted an NDA to FDA for QUIVIVIQ (daridorexant) tablets for use as a treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. On January 7, 2022, DEA received notification that FDA, on the same date, approved this NDA. The recommended dosage is 25–50 mg once per night, taken orally within 30 minutes before going to bed, with at least seven hours remaining prior to planned awakening.

Determination To Schedule Daridorexant

On December 22, 2021, DEA received from HHS a scientific and medical evaluation entitled ''Basis for the Recommendation to Control Daridorexant and its Salts in schedule IV of the Controlled Substances Act'' and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of daridorexant, along with HHS's recommendation to control daridorexant and its salts under schedule IV of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that daridorexant meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA.

Pursuant to subsection 811(j), and based on HHS' scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA's determination, DEA is issuing this IFR to schedule daridorexant as a schedule IV controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both DEA and HHS analyses are available in their entirety under ''Supporting Documents'' in the public docket for this interim final rule at *http://www.regulations.gov,* under Docket Number ''DEA–949.'' Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. Its Actual or Relative Potential for Abuse

Daridorexant is an NME that has not been marketed in the United States or any country; evidence regarding its diversion, illicit manufacturing, or deliberate ingestion is lacking. There are no reports of law enforcement encounters of daridorexant in the National Forensic Laboratory Information System (NFLIS) database.[2] However, daridorexant is related in action to schedule IV depressants such as suvorexant and lemborexant. It is thus reasonable to assume that daridorexant may be diverted from legitimate channels, used contrary to or without medical advice, and otherwise abused so as to create hazards to the users and to the safety of the community to an extent similar to that of schedule IV CNS depressants. In clinical studies, daridorexant produced abuse-related effects in humans similar to suvorexant and zolpidem (schedule IV sedatives) and shares pharmacological mechanism of action similar to suvorexant and lemborexant; thus, it is likely to be abused for its sedative effects contrary to medical advice.

2. Scientific Evidence of Its Pharmacological Effects, if Known

Daridorexant shares pharmacological profiles with other dual orexin receptor antagonists such as suvorexant and lemborexant, schedule IV CNS depressants. Data from the orexin binding studies demonstrated that daridorexant behaved as an insurmountable antagonist at the dual orexin receptors (OXIR and OX2R).

[1] Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

[2] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. It systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories. NFLIS data were queried on January 18, 2022.

Daridorexant is similar to suvorexant in its potency and duration of action at OX1R; however, it is more potent and has double the occupancy time as suvorexant at OX2R.

In animal studies, oral doses of daridorexant (100, 300, and 1000 mg/kg) produced transient decrease in rectally measured body temperature and increased incidence of whole-body tremors. Dose-dependent decline in activity was observed in unstimulated rats. In a study conducted to measure locomotor activity following daridorexant administration, rats given single oral dose of 300 mg/kg showed decline in locomotor activity when compared to the vehicle control group. Daridorexant's reinforcing properties were assessed by determining whether self-administration behavior was maintained when the drug was substituted for cocaine. Data from this study showed that rats self-administered cocaine (0.8 mg/kg/infusion), but doses of 0.1, 0.3, and 1 mg/kg/infusion of daridorexant produced a significantly lower mean number of active lever presses.

A randomized, double-blind, double-dummy, active-and placebo-controlled, 6-way cross-over study was conducted to determine the abuse potential of single oral doses of daridorexant. Suvorexant (150 mg) and Zolpidem (30 mg) served as the positive controls. Subjects received daridorexant at therapeutic (50 mg) and supratherapeutic (100 and 150 mg) doses. Bipolar visual analog scale (VAS) for Drug-Liking (0–100) served as the primary end. A score of 0 described a drug-disliking response; a score of 50 represented a neutral response, while a score of 100 described a strong drug liking. Drug liking scores following supratherapeutic doses (100 and 150 mg) of daridorexant showed statistically significant increases as compared to placebo on positive subjective measures (VAS measures for Drug Liking, Take Drug Again, Overall Drug Liking, High, and Good Drug Effects) and were statistically similar to those following suvorexant and zolpidem. Further, using a Drowsiness/Alertness VAS and an observer assessment of alertness/sedation, daridorexant's sedative properties were assessed. Both measures demonstrate that similar to suvorexant and zolpidem, daridorexant elicits drowsiness and sedation.

Data from Phase 1 clinical safety studies showed that daridorexant (5–200 mg) administered to 478 subjects produced somnolence in 52.7 percent (252), fatigue in 10.9 percent (52), and disturbances in attention in 3.8 percent (18) of subjects, respectively. Daridorexant at every dose produced somnolence at a rate that is 2- to 3-fold higher than that reported in the placebo-treated group. In two Phase 2 studies conducted to evaluate the efficacy and safety of daridorexant in subjects with insomnia disorder (one with adults (aged 18–64 years) at doses of 5–50 mg and the other with the elderly (≥65 years) at doses of 10–50 mg), daridorexant treatment led to reports of somnolence that exceeded reports of other effects that may be associated with abuse potential, including fatigue (5 (2.1 percent)) and dizziness (3 (1.3 percent). In three Phase 3 studies, which were conducted as confirmatory studies in adults and elderly subjects with insomnia disorder and were similarly designed to the two Phase 2 studies, the treatment-emergent adverse effects with the highest number of reports were somnolence (38 (2.14 percent)), fatigue (34 (1.91 percent)), and dizziness (26 (1.46 percent)). These types of reports were similar to those reported in the Phase 1 and 2 studies. The reported adverse events from the Phase 1, 2, and 3 studies demonstrate there were no significant abuse-related signals in these studies.

Daridorexant, similar to schedule IV drugs such as suvorexant and zolpidem, has sedative effects. In a human abuse potential (HAP) study, daridorexant produced abuse-related effects in humans similar to those of suvorexant and zolpidem. The abuse-related neuropharmacology profile of daridorexant is similar to that of schedule IV CNS depressants, such as suvorexant and lemborexant, and is consistent with its mechanism of action as a dual orexin receptors antagonist.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

Daridorexant, chemically known as [(S)-2-(5-chloro-4-methyl-1*H*-benzo[*d*]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2-(2*H*-1,2,3-triazol-2-yl)phenyl)methanone, is an NME. It is soluble in acidic water and slightly soluble in ethanol. It has one stereoisomer with one chiral center. The drug product is manufactured in tablet dose strengths that contain 25 mg and 50 mg of the active ingredient (*i.e.,* daridorexant) and a series of excipients to aid in taste and tablet disintegration. The excipients in the tablet have no known abuse liability. Daridorexant plasma exposure is dose proportional from 25 mg to 50 mg with an absolute bioavailability of 62 percent, and has consistent pharmacokinetic profile following multiple-dose and single-dose administration with no accumulation.

As discussed in the background section, daridorexant has an accepted medical use in the United States.

4. Its History and Current Pattern of Abuse

There is no information on the history and current pattern of abuse for daridorexant, since it has not been marketed, legally or illegally, in the United States or any country. There is no evidence of diversion of daridorexant that has been distributed for research, such as for clinical trials. Data from preclinical and clinical studies indicate that the abuse potential of daridorexant is similar to that of schedule IV CNS depressants such as suvorexant and lemborexant. Consistent with the fact that daridorexant is an NME; NFLIS database had no records of encounters by the law enforcement.

The pharmacological mechanism of action of daridorexant as a dual orexin receptor antagonist suggests that its pattern of abuse would be similar to schedule IV depressants with a similar mechanism of action, such as suvorexant and lemborexant.

5. The Scope, Duration, and Significance of Abuse

Data from preclinical and clinical studies showed that daridorexant has an abuse potential similar to that of the schedule IV depressants such as suvorexant and zolpidem. Thus, daridorexant, similar to these schedule IV substances, will have low potential for abuse relative to drugs and substances in schedule III. A search by DEA of the NFLIS database found no evidence of law enforcement encounters of daridorexant in the United States. Because daridorexant has a mechanism of action similar to schedule IV drugs suvorexant and lemborexant, it is likely that upon availability of daridorexant in the market, it will be abused similar to these schedule IV depressants.

6. What, if any, Risk There Is to the Public Health

The public health risk associated with daridorexant is largely due to its abuse potential. Data from preclinical and clinical studies showed that daridorexant has abuse potential similar to that of schedule IV depressants zolpidem and suvorexant. Therefore, upon availability for marketing, it is likely to pose a public health risk to a degree similar to these schedule IV depressants. Data from clinical trials showed that daridorexant has rewarding and depressant effects. The abuse of daridorexant may present risks to the

public health at a level similar to those associated with the abuse of schedule IV CNS depressants.

7. Its Psychic or Physiological Dependence Liability

Data obtained from a HAP study demonstrate that similar to suvorexant and zolpidem, daridorexant produced subjective responses to measures such as Drug Liking, Overall Drug Liking, Good Drug Effects, High, and Take Drug Again; indicative of psychological effects. HHS states that the data suggest daridorexant can produce psychic dependence similar to zolpidem and suvorexant, schedule IV depressants.

Results from a physiologic dependence study conducted in rats demonstrate that oral doses (0, 20, or 200 mg/kg/day) of daridorexant administered for 28-days followed by a 14-days discontinuation period did not produce alterations in physiological, neurobehavioral, or locomotor parameters during the discontinuation Phase of the study. Physical dependence signs were not observed in clinical studies after discontinuation of treatment in Phase 3 studies.

Data from animal studies and clinical trials demonstrate that chronic administration of daridorexant did not produce withdrawal signs or symptoms upon discontinuation. Daridorexant does not produce physical dependence.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

Daridorexant is not an immediate precursor of any controlled substance, as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation and scheduling recommendation provided by HHS, and its own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of potential for abuse of daridorexant. As such, DEA hereby schedules daridorexant as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA (Administrator), pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) Daridorexant has a low potential for abuse relative to the drugs or other substances in Schedule III.

Daridorexant, similar to schedule IV depressants such as suvorexant and lemborexant, is an orexin receptor antagonist. It produced sedation in general behavioral and locomotor studies. In a HAP study, oral administration of therapeutic (50 mg) and supratherapeutic doses (100 and 150 mg) of daridorexant produced increases in positive subjective measures such as Drug Liking, Overall Drug Liking, Good Drug Effects, High, and Take Drug Again that were statistically greater than those produced by placebo. These subjective responses following daridorexant were statistically similar to those produced by the positive control drugs that are schedule IV depressant such as zolpidem and suvorexant. These data show that daridorexant has an abuse potential that is similar to the schedule IV drugs zolpidem and suvorexant. Because daridorexant is similar to suvorexant and zolpidem in its abuse potential, daridorexant has a low potential for abuse relative to the drugs or other substances in schedule III.

(2) Daridorexant has a currently accepted medical use in treatment in the United States.

FDA recently approved the NDA for daridorexant as an oral treatment for adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Thus, daridorexant has a currently accepted medical use in treatment in the United States.

(3) Abuse of daridorexant may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Data from both preclinical and clinical studies demonstrate that discontinuation of daridorexant was not associated with withdrawal symptoms indicative of physical dependence. Because daridorexant produced positive subjective responses in a HAP study similar to those of zolpidem and suvorexant (both schedule IV drugs), it is likely that daridorexant can produce psychic dependence to an extent that is similar to these schedule IV substances. Thus, abuse of daridorexant may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule III.

Based on these findings, the Administrator concludes that daridorexant warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Daridorexant

Daridorexant is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule IV substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, daridorexant must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles or intends to handle daridorexant and is not registered with DEA must submit an application for registration and may not continue to handle daridorexant unless DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess daridorexant pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule IV registration must surrender all quantities of currently held daridorexant, or may transfer all quantities of currently held daridorexant to a person registered with DEA. Daridorexant is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, state, local, and tribal laws.

3. *Security.* Daridorexant is subject to schedule III–V security requirements for DEA registrants and it must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling daridorexant must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess daridorexant pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of daridorexant must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of

daridorexant must take an inventory of daridorexant on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA to handle daridorexant must take an initial inventory of all stocks of controlled substances (including daridorexant) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all stocks of controlled substances (including daridorexant) on hand every two years, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. These requirements, however, are not applicable to patients (end users) who possess daridorexant pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for daridorexant, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for daridorexant, or products containing daridorexant, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of daridorexant may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act (FDCA), as applicable, and the CSA.

9. *Importation and Exportation.* All importation and exportation of daridorexant must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving daridorexant not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

Section 553 of the APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. As stated in the legal authority section, the 90-day time frame is the later of: (1) The date DEA receives HHS's scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause.

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

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 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 rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does 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.

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.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this IFR.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* 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 annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this IFR to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b) unless otherwise noted.

■ 2. In § 1308.14:
■ a. Redesignate paragraphs (c)(16) through (58) as (c)(17) through (59); and
■ b. Add new paragraph (c)(16).
■ The addition reads as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(16) Daridorexant 2410

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2022–07322 Filed 4–6–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–491]

Schedules of Controlled Substances: Placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: By this rule, the Drug Enforcement Administration permanently places five synthetic cannabinoids, as identified in this final rule, in schedule I of the Controlled Substances Act. These five substances are currently listed in schedule I pursuant to a temporary scheduling order. As a result of this rule, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle these five specified controlled substances will continue to apply.

DATES: Effective April 7, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

In this final rule, the Drug Enforcement Administration (DEA) is permanently scheduling the following five controlled substances in schedule I of the Controlled Substances Act (CSA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- Ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA),
- Methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: 5F-MDMB-PICA; 5F-MDMB-2201),
- *N*-(Adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (other names: FUB-AKB48; FUB-APINACA; AKB48 *N*-(4-fluorobenzyl)),
- 1-(5-Fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA; SGT-25), and
- (1-(4-Fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (other name: FUB-144).

Legal Authority

The CSA provides that issuing, amending, or repealing of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). The then-Acting Administrator of DEA (as delegated by the Attorney General to the Administrator of DEA) initiated this action on his own motion, and is supported by, *inter alia,* a recommendation from the then-Acting Assistant Secretary for Health of HHS and an evaluation of all relevant data by DEA. The regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or proposes to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 will continue to apply as a result of this action.

[1] As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

Background

On April 16, 2019, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (trivial name: FUB-144) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 84 FR 15505. That temporary scheduling order took effect on the date of publication, and was based on findings by the then-Acting Administrator of DEA that the temporary scheduling of these five synthetic cannabinoids (SCs) was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

On March 30, 2021, DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** to permanently control the five SCs in schedule I of the CSA. 86 FR 16553. On March 31, 2021, DEA published an order to extend the temporary scheduling of the five SCs by one year, until April 16, 2022. 86 FR 16669.

DEA and HHS Eight Factor Analyses

On February 26, 2021, HHS provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration (FDA), entitled ''Basis for the Recommendation to Place Ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-EDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [5F-MDMB-PICA]; *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [FUB-AKB48;FUB-APINACA; AKB48 *N*-(4-fluorobenzyl)]; 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide [5F-CUMYL-PINACA; SGT-25]; and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone [FUB-144; FUB-UR-144] and Their Salts, Isomers, and Salts of Isomers in Schedule I of the Controlled Substances Act.''

After considering the eight factors in 21 U.S.C. 811(c), each substance's abuse potential, lack of legitimate medical use in the United States, and lack of accepted safety for use under medical supervision pursuant to 21 U.S.C. 812(b), the then-Acting Assistant Secretary for Health of HHS recommended that 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 be placed in schedule I of the CSA. In response, DEA conducted its own eightfactor analysis of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144.

Both DEA and HHS eight-factor analyses are available in their entirety in the public docket for this rule (Docket Number DEA–491) at *http://www.regulations.gov* under ''Supporting Documents.''

NPRM To Schedule 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144

On March 30, 2021, DEA published an NPRM entitled ''Schedules of Controlled Substances: Placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA and FUB-144 in Schedule I.'' 86 FR 16553. Specifically, the NPRM proposed to add the five SCs to the hallucinogenic substances list under 21 CFR 1308.11(d), and assign them paragraph numbers 87 through 91 under paragraph (d). In addition, the NPRM listed these five SCs by their chemical and trivial names as follows:

- (87) Ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA);
- (88) methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA);
- (89) *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 *N*-(4-fluorobenzyl));
- (90) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and
- (91) (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (trivial name: FUB-144).

The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations, as well as to submit comments on the proposed rule, on or before April 29, 2021. DEA did not receive any requests for such a hearing or any public comments on the proposed rule.

Scheduling Conclusion

After considering the scientific and medical evaluations and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of abuse potential for 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144. DEA is therefore permanently scheduling 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the then-Acting Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 have a high potential for abuse that is comparable to other schedule I substances such as delta-9-tetrahydrocannabinol (Δ^9-THC) and JWH-018;

(2) 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 currently have no accepted medical use in treatment in the United States; [2] and

(3) There is a lack of accepted safety for use of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 under medical supervision.

Based on these findings, the Administrator concludes that ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: 5F-MDMB-PICA; 5F-MDMB-2201); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (other names: FUB-AKB48; FUB-APINACA; AKB48 *N*-(4-fluorobenzyl)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (other name: FUB-144), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Summary of Minor Changes in the Final Rule

As discussed in the above NPRM section, DEA proposed to place 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 in 21 CFR 1308.11(d) as paragraphs 87 through 91, respectively. The NPRM listed chemical, as well as trivial, names for the five substances. Regarding the substance methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate, the NPRM listed only one trivial name (5F-MDMB-PICA). Since the publication of the NPRM, DEA has found another trivial name (5F-MDMB-2201) for this substance. In addition, DEA has issued several final rules which updated the numbering of listed hallucinogenic substances in paragraph (d). As a result, this final rule assigns paragraphs 89 through 93 to 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144, respectively. This final rule now refers to ''trivial'' names as ''other'' names, and lists both 5F-MDMB-PICA and 5F-MDMB-2201 as other names for methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate.

Requirements for Handling 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144

5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 will continue [3] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture,

[2] Although there is no evidence suggesting that 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 have currently accepted medical uses in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[3] 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 have been subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h), by virtue of the April 16, 2019 temporary scheduling order (84 FR 15505) and the subsequent one year extension of that order (March 31, 2021, 86 FR 16669).

distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles, or desires to handle, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, or FUB-144 must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling these five substances must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, or FUB-144 in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Every DEA registrant who possesses any quantity of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 was required to keep an inventory of all stocks of these substances on hand as of April 16, 2019, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

6. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and/or FUB-144, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and/or FUB-144 to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, or FUB-144 must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 must continue to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, or FUB-144 not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

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

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 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 rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

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.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On April 16, 2019, DEA published an order to temporarily place these five substances in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h).

DEA estimates that all entities handling or planning to handle these substances have already established and implemented the systems and processes required to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 as schedule I controlled substances. There are currently 28 registrations authorized to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and/or FUB-144 specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. DEA estimates these 28 registrations encompass 22 entities. Some of these entities are likely to be large entities. However, DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities. Therefore, DEA conservatively estimates as many as 22 small entities are affected by this rule.

A review of the 28 registrations indicates that all entities that currently handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, or FUB-144 also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, or FUB-144. Therefore, DEA anticipates that this rule will impose minimal or no economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies 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 annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to the Government Accountability Office, the House, and the Senate under the CRA.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Determination To Make Rule Effective Immediately

As indicated above, this rule finalizes the schedule I control status of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 that has already been in effect for over two years by virtue of the April 16, 2019, temporary scheduling order (84 FR 15505) and the subsequent one-year extension of that order (March 31, 2021, 86 FR 16669). The April 2019 order was effective on the date of publication, and was based on findings by the then-Acting Administrator that the temporary scheduling of these substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

Because this rule finalizes the control status of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 that has already been in effect for over two years, it does not alter the legal obligations of any person who handles these substances. Rather, it merely makes permanent the current scheduling status and corresponding legal obligations. Therefore, DEA is making the rule effective on the date of publication in the **Federal Register**, as any delay in the effective date is unnecessary and would be contrary to the public interest. *See* 5 U.S.C. 553(d).

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:
■ a. Add paragraphs (d)(89) through (d)(93); and
■ b. Remove and reserve paragraphs (h)(37) through (41);

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(89) ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA)	7036
(90) methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: 5F-MDMB-PICA; 5F-MDMB-2201)	7041
(91) *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL))	7047
(92) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA; SGT-25)	7083
(93) (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (other name: FUB-144)	7014

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2022–07320 Filed 4–6–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 38

Notification of Interpretation of Section 188 of the Workforce Innovation and Opportunity Act

AGENCY: Office of the Secretary, Labor.

ACTION: Notification of interpretation.

SUMMARY: This Notification is to inform the public that, consistent with the Supreme Court's 2020 decision in *Bostock* v. *Clayton County* and Title IX of the Education Amendments of 1972, the U.S. Department of Labor (DOL), beginning April 7, 2022, will interpret the prohibition on discrimination on the basis of sex that is codified in Section 188 of the Workforce Innovation and Opportunity Act to include discrimination on the basis of sexual orientation. DOL will continue to interpret and enforce Section 188's prohibition on discrimination on the basis of sex to include discrimination on the basis of gender identity and transgender status. This interpretation will guide DOL's Civil Rights Center in processing complaints and conducting investigations and compliance reviews, but does not determine the outcome in any particular case or set of facts.

DATES: This notification is effective April 7, 2022.

FOR FURTHER INFORMATION CONTACT: Naomi Barry-Perez, Director, Civil Rights Center, U.S. Department of Labor, 200 Constitution Ave. NW, Room N–4123, Washington, DC 20210.

SUPPLEMENTARY INFORMATION: DOL is informing the public that, consistent with the Supreme Court's decision in *Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020), and Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.,* DOL, beginning April 7, 2022, will interpret the prohibition on discrimination on the basis of sex in Section 188 of the Workforce Innovation and Opportunity Act (WIOA), 29 U.S.C. 3248, to include discrimination on the basis of sexual orientation.[1] DOL will continue to interpret and enforce Section 188's prohibition on discrimination on the basis of sex to include discrimination on the basis of gender identity and transgender status, as set forth in the regulations issued under Section 188.29 CFR 38.7.

The Civil Rights Center (CRC) at DOL is responsible for enforcing Section 188 of WIOA and regulations issued under Section 188, which prohibit exclusion of an individual from participation in, denial of the benefits of, discrimination in, or denial of employment in the administration of or in connection with, any programs and activities funded or otherwise financially assisted in whole or in part under Title I of WIOA on various bases, including sex. 29 U.S.C. 3248(a).

On June 15, 2020, the U.S. Supreme Court held that the prohibition on employment discrimination based on sex in Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.,* encompasses discrimination based on sexual orientation, gender identity, and transgender status. The Court concluded that the plain meaning of ''because of

[1] The regulations implementing WIOA Section 188 (29 CFR part 38) use the phrases ''on the basis of . . . sex'' and ''based on sex.'' The relevant statutory language (at 29 U.S.C. 3248(a)(2)) uses the phrase ''because of . . . sex.'' These phrases are used interchangeably in this notification.

sex'' in Title VII necessarily includes discrimination because of sexual orientation, gender identity, and transgender status. *Bostock* v. *Clayton County,* 140 S. Ct. 1731, 1753–54 (2020).

Since *Bostock,* at least one Federal circuit court of appeal has concluded that the plain language of Title IX's prohibition on sex discrimination must be read similarly, and the Supreme Court has denied review of that decision. *Grimm* v. *Gloucester Cnty. Sch. Bd.,* 972 F.3d 586, 616 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *petition for cert. denied,* No. 20–1163 (June 28, 2021).

On March 26, 2021, the Civil Rights Division of the U.S. Department of Justice, the agency charged with coordination of the implementation and enforcement of Title IX by executive agencies, issued a memorandum concluding that ''the best reading of Title IX's prohibition on discrimination 'on the basis of sex' is that it includes discrimination on the basis of gender identity and sexual orientation.'' [2] The Civil Rights Division reached this conclusion after considering the text of Title IX, *Bostock* and other Supreme Court case law, including dissenting opinions, and developing jurisprudence in this area, including the circuit court opinion cited above. The Civil Rights Division subsequently updated its Title IX Legal Manual to state that the Department of Justice interprets Title IX to prohibit discrimination based on gender identity and sexual orientation.[3]

In addition, on June 22, 2021, the Office for Civil Rights of the U.S. Department of Education, the agency responsible for that Department's enforcement of Title IX, published a notice in the **Federal Register** clarifying that it will enforce Title IX's prohibition on discrimination based on sex to include discrimination based on both sexual orientation and gender identity.[4] The Office for Civil Rights concluded that the Supreme Court's interpretation of sex discrimination in *Bostock* properly applies to Title IX based on the textual similarity between Title VII and Title IX; subsequent case law including the *Grimm* decision cited above, as well as cases recognizing the harm that students may endure as a result of differential treatment based on gender identity or sexual orientation; [5] and the Civil Rights Division's memorandum discussed above.

Section 188 of WIOA expressly incorporates Title IX's prohibition on sex discrimination. 29 U.S.C. 3248(a)(2) (specifying that ''[n]o individual shall be excluded from participation in, denied the benefits of, subjected to discrimination under, or denied employment in the administration of or in connection with, any such program or activity [funded or otherwise financially assisted in whole or in part under Title I of WIOA] because of . . . sex (except as otherwise permitted under title IX of the Education Amendments of 1972 . . .)''); *see also id.* 3248(a)(1) (providing that ''programs and activities funded or otherwise financially assisted in whole or in part under [WIOA] are considered to be programs and activities receiving Federal financial assistance'' for the purpose of applying the prohibition against discrimination on the basis of sex under Title IX).

Consistent with the Supreme Court's interpretation of Title VII in *Bostock* and with the case law and interpretations discussed above applying the same conclusion to Title IX, beginning April 7, 2022, CRC interprets Section 188's prohibition on discrimination on the basis of sex to include discrimination on the basis of sexual orientation, as well as gender identity and transgender status. This interpretation will guide CRC in processing complaints and conducting investigations and compliance reviews, but it does not determine the outcome in any particular case, which will depend on the specific facts and circumstances. Any action taken by CRC in a specific case will take account of all relevant facts and legal requirements, including, where applicable, Title IX's religious exemption and other exemptions, which are incorporated into Section 188, *see* 29 U.S.C. 3248(a)(2), and the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.*

If you think that you have, or any specific class of individuals has, been subjected to discrimination under a WIOA Title I-financially assisted program or activity, you may file a complaint within 180 days from the date of the alleged violation with either: (1) The recipient's Equal Opportunity Officer (or the person whom the recipient has designated for this purpose) or (2) CRC, via postal mail addressed to The Director, Civil Rights Center (CRC), U.S. Department of Labor, 200 Constitution Avenue NW, Room N–4123, Washington, DC 20210, or electronically as directed on the CRC website at *https://www.dol.gov/agencies/oasam/centers-offices/civil-rights-center/external/how-to-file-complaint.* The complaint will be processed in accordance with the procedures at 29 CFR 38.69–.85. After investigating the complaint, if the Director of CRC finds reasonable cause to believe that the recipient has violated WIOA Section 188 or its implementing regulations, the Director is required to issue an Initial Determination that includes the opportunity for the recipient to engage in voluntary compliance negotiations. 29 CFR 38.87(e).

Martin J. Walsh,

Secretary, Department of Labor.

[FR Doc. 2022–07290 Filed 4–6–22; 8:45 am]

BILLING CODE 4510–04–P

[2] Memorandum from Principal Deputy Assistant Attorney General Pamela S. Karlan, Civil Rights Division, U.S. Department of Justice, to Federal Agency Civil Rights Directors and General Counsels, Application of *Bostock* v. *Clayton County* to Title IX of the Education Amendments of 1972 (Mar. 26, 2021), available at *https://www.justice.gov/crt/page/file/1383026/download.*

[3] Civil Rights Division, U.S. Department of Justice, Title IX Legal Manual, Title IX Cover Addendum post-Bostock, available at *https://www.justice.gov/file/1423496/download.*

[4] U.S. Department of Education, Enforcement of Title IX of the Education Amendments of 1972 with Respect to Discrimination Based on Sexual Orientation and Gender Identity in Light of *Bostock* v. *Clayton County,* Notice of Interpretation, 86 FR 32637 (June 22, 2021).

[5] *See, e.g., Grimm,* 972 F.3d at 617–18 (describing injuries to a transgender boy's physical and emotional health as a result of denial of equal treatment); *Dodds* v. *U.S. Dep't of Educ.,* 845 F.3d 217, 221–22 (6th Cir. 2016) (describing ''substantial and immediate adverse effects on the daily life and well-being of an eleven-year-old'' transgender girl from denial of equal treatment); *Doe* v. *Univ. of Scranton,* No. 3:19–CV–01486, 2020 WL 5993766, at *1–3 (M.D. Pa. Oct. 9, 2020) (describing harassment and physical targeting of a gay college student that interfered with the student's educational opportunity); *Harrington* v. *City of Attleboro,* No. 15–CV–12769–DJC, 2018 WL 475000, at *6–7 (D. Mass. Jan. 17, 2018) (describing '''wide-spread peer harassment' and physical assault [of a lesbian high school student] because of stereotyping animus focused on [the student's] sex, appearance, and perceived or actual sexual orientation'').

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0212]

RIN 1625–AA00

Safety Zone; Anacostia River, Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Anacostia River. The safety zone is needed to protect personnel, vessels, and the marine environment on these navigable waters near Washington, DC on April 16, 2022

(rain date April 17, 2022) from potential hazards during a fireworks display occurring as a part of the National Cherry Blossom Festival. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Maryland-National Capital Region or a designated representative.

DATES: This rule is effective from 7:30 p.m. on April 16, 2022, through 9:30 p.m. on April 17, 2022. This rule will be enforced from 7:30 p.m. through 9:30 p.m. on April 16, 2022, or those same hours on April 17, 2022, in the case of inclement weather on April 16, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0212 in the ''SEARCH'' box and click ''SEARCH.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email MST3 Melissa Kelly, Sector Maryland-National Capital Region Waterways Management Division, U.S. Coast Guard; telephone 410–576–2596, email *Melissa.C.Kelly@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
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 and contrary to the public interest to do so. We must establish this safety zone by April 16, 2022, to protect the public from hazards associated with the fireworks event. Hazards include explosive materials, dangerous projectiles, and falling debris. The fireworks fall out zone extends across the navigable channel.

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 impracticable and contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the fireworks display.

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, Maryland-National Capital Region (COTP) has determined that potential hazards associated with the fireworks to be used in the April 16, 2022 display will be a safety concern for anyone near the fireworks barge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 7:30 p.m. on April 16, 2022, through 9:30 p.m. on April 17, 2022. The rule will be enforced from 7:30 p.m. through 9:30 p.m. on April 16, 2022, or in the event of inclement weather on April 16, those same hours on April 17, 2022. The safety zone covers all navigable waters of the Anacostia River within 500 feet of the fireworks barge in approximate position latitude 38°52′15.39″ N, longitude 77°00′09.39″ W, located near Nationals Park in Washington, DC. The size of the zone and duration of the rule are intended to protect personnel, vessels, and the marine environment in these navigable waters before, during, and after the scheduled fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

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 time-of-day of the safety zone, which will impact a small designated area of the Anacostia River for no more than 4 enforcement-hours during evening hours when vessel traffic is normally low. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone.

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 safety 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 call or email 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.

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, 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 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 safety zone that will be enforced for 3 hours that will prohibit entry within a portion of the Anacostia River. It is categorically excluded from further review under paragraph L60(a) of 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 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.T05–0212 to read as follows:

§ 165.T05–0212 Safety Zone; Anacostia River, Washington, DC.

(a) *Location.* The following area is a safety zone: All navigable waters of the Anacostia River within 500 feet of the fireworks barge in approximate position latitude 38°52′15.39″ N, longitude 77°00′09.39″ W located near Nationals Park, in Washington, DC. These coordinates are based on datum NAD 83.

(b) *Definitions.* As used in this section—

Captain of the Port (COTP) means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region.

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Maryland-National Capital Region to assist in enforcing the safety zone described in paragraph (a) of this section.

(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 telephone at 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio VHF–FM channel 16 (156.8 MHz). 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 officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement period.* This section will be enforced from 7:30 p.m. to 9:30 p.m. on April 16, 2022, or in the event of inclement weather, from 7:30 p.m. through 9:30 p.m. on April 17, 2022.

Dated: April 1, 2022.

David E. O'Connell,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2022–07403 Filed 4–6–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2021–0411; FRL–9547–02–R5]

Air Plan Approval; Minnesota; Bulk Silos PM_{10} FESOP Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a site-specific revision to the Minnesota State Implementation Plan (SIP) for particulate matter less than 10 microns (PM_{10}) for the portland cement distribution terminal owned and operated by Bulk Silos, LLC (Bulk Silos), formerly known as Lafarge North America Corporation on Childs Road Terminal (Lafarge-Childs Road Terminal), located in Saint Paul, Ramsey County, Minnesota. In its June 16, 2021, submittal, the Minnesota Pollution Control Agency (MPCA) requested that EPA approve certain conditions contained in Bulk Silos' federally enforceable state operating permit (FESOP) into the Minnesota PM SIP. The request is approvable because it satisfies the requirements of the Clean Air Act (CAA). MPCA's submission

included an updated modeling demonstration to show the construction changes incorporated in the title I SIP Conditions will not interfere with the ability to maintain the National Ambient Air Quality Standards (NAAQS), as Bulk Silos' allowable PM_{10} emissions limits will be decreased with this action.

DATES: This direct final rule will be effective June 6, 2022, unless EPA receives adverse comments by May 9, 2022. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2021–0411 at *https://www.regulations.gov,* or via email to *arra.sarah@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Olivia Davidson, Physical Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0266, *davidson.olivia@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. What is the background for this action?

Bulk Silos is a portland cement distribution terminal in the Ramsey County PM_{10} maintenance area, also known as the Red Rock Road maintenance area, in St. Paul (Ramsey County), Minnesota. The area was designated nonattainment for the 1987 PM_{10} standard on March 15, 1991 (56 FR 11101), and was redesignated to attainment on July 26, 2002 (67 FR 48787). On June 16, 2021, MPCA submitted a request to EPA to approve into the Minnesota SIP the conditions cited as ''Title I Condition: 40 CFR 50.6 (PM_{10} SIP).'' The submission contains measures for Bulk Silos to implement changes that increase efficiency through new and existing equipment, as well as clarifying amendments to the document's language. MPCA posted a background document and permit issuance notice for public comment in the Minnesota State Register on April 30, 2021, and the comment period ended on June 1, 2021. MPCA received no comments on the document or permit.

Bulk Silos currently operates six silos with pollution control equipment; the silos are used for storage and distribution of cementitious products. The material is currently received by rail, stored in silos, and distributed by truck. The facility is subject to a State Individual Permit containing title I PM_{10} SIP conditions (Permit No. 12300391–002, published September 11, 2007, 72 FR 51713), which will continue to apply until this SIP revision is approved by the EPA. These conditions are intended to ensure that the Red Rock Road area continues to maintain the PM_{10} NAAQS.

The previous SIP revision, approved September 11, 2007 (72 FR 51713), consisted of a FESOP issued to Lafarge-Childs Road Terminal which serves as a joint title I/FESOP document. In the September 11, 2007, action, EPA approved into the Minnesota PM_{10} SIP the portions of Minnesota Air Emission Permit No. 12300391–002 issued to Lafarge-Childs Road Terminal on November 17, 2006, cited as ''Title I condition: SIP for PM_{10} NAAQS.'' As part of that action, EPA approved Minnesota's request to revoke from the SIP several Administrative Orders for Lafarge-Childs Road Terminal that had been approved on February 15, 1994 (60 FR 7218), June 13, 1995 (60 FR 31088), and February 8, 1999 (64 FR 5936).

The 2007 title I SIP revisions approved the installation of a new rail siding for rail delivery of material to the silos, the installation of a related railcar-to-silo pneumatic conveyance, the redesign of the pneumatic conveyance system to allow dedicated use of Silos Nos. 1 and 2, and the installation of new pollution control devices (a low temperature fabric filter) on each of the two dedicated silos. The modeling results demonstrated that to comply with the FESOP, Lafarge-Childs Road Terminal was limited to a maximum daily throughput of 1,100 tons per day (tpd) using a 24-hour rolling average and an annual throughput of 100,000 tons per year (tpy), using a 12-month rolling average.

This SIP revision is being approved in conjunction with a major amendment to a State Individual Permit containing federally enforceable title I SIP conditions (Air Emission Permit No. 12300391–102), submitted to EPA on June 16, 2021. The submittal included the replacement of three existing fabric filters, the construction of three new silos, a new bucket elevator, twelve new fabric filters, paving of roads, and new barge unloading operations. The suggested facility changes in operation require increased throughput limits for overall facility operations, truck loading operations, and bucket elevator operations. To offset increases in throughput limits, Bulk Silos' new permit allows unloading of product from one silo at a time, and the emission limits of unloading will be decreased after approval of the updated title I SIP conditions. Further, MPCA included updated modeling with improved emission factors demonstrating decreased allowable PM_{10} emissions with the proposed facility changes and reduced emission limits. New equipment would not be operable by Bulk Silos until EPA approves the requirements into Minnesota's SIP.

II. What is EPA's analysis of the SIP revision?

MPCA's June 16, 2021, submission contains amended SIP conditions that, when combined, decrease total allowable emission rates of PM_{10} from Bulk Silos while increasing throughput limits, adding/improving fabric filters, and constructing three new silos. *See* Table 1 at the end of this review for a list of detailed changes to PM_{10} allowable emissions limits associated with this action. Additionally, *see* ''Process flow diagram'' included at the end of MPCA's Background document submission for a detailed diagram of the facility's operations. The amended SIP conditions in the provided background document include:

A. New Fabric Filters, New Construction

New construction in the SIP revision would include the installation of twelve new fabric filters: Replacement of three fabric filters (Treatment ''TREA'' 5, 6 and 9 replacing TREA 1–3) and installation of nine new fabric filters (TREA 7, 8, 10–16). Additionally, the revised SIP would authorize construction and operation of a new bucket elevator (Equipment ''EQUI'' 5) and three new silos (EQUI 8–10). Further, because Bulk Silos' roadways have been paved since the issuance of Permit No. 123000391–102, the SIP revision will remove the emission limit requirements for unpaved roads at the permit condition addressing fugitive emissions at ''FUGI'' 2. The facility will be subject to emission limit requirements for paved roads that were previously SIP-approved on July 27, 2020 (85 FR 45094), and contain permit content requirements in Minnesota Rule (Minn. R.) 7007.0800, subpart 2(A) and subpart 5, prevention of airborne particulate matter in Minn. R. 7011.0150, and standards for dry bulk agricultural commodity requirements in Minn. R. 7011.1005, subpart 1(A).

B. Throughput Limits

Throughput limits for facility operations, specifically silo unloading (COMG 2), truck loading operations (EQUI 4), and bucket elevator operations (EQUI 5), will be increased or established for new processes with this SIP revision. Previously, unloading operations were limited to rail and required throughput limits of 1,100 tpd/100,000 tpy, truck loading operations had no emission limits, and the facility did not include bucket elevator operations or barge unloading. The proposed revisions add barge unloading to the facility's operations, incorporate throughput limits of 2,500 tpd/740,000 tpy each for unloading and truck loading, and 1,100 tpd/100,000 tpy for the proposed bucket elevator operations. Facility-specific emission factors and other proposed facility changes demonstrate no increased emissions of PM_{10} from increased throughput limits based on improved modeling. Permit No. 12300391–102 includes language specifying ''This requirement expires upon startup of the Project'' for current operational throughput, or silo unloading (COMG 2, 5.3.1 and 5.3.2). Additionally, the permit states the increased limits would go into effect ''Upon startup of the Project'' (COMG 2, 5.3.3 and 5.3.4) for operational throughput, and similarly for the newly established truck loading throughput limits (EQUI 4, 5.7.3 and 5.7.4) and bucket elevator throughput limits (EQUI 5, 5.8.1 and 5.8.2). *See* Table 1 for equipment-specific emission limit changes from the effective permit (No. 12300391–002, 72 FR 51713) to the new permit (No. 12300391–102).

C. Changes to Modeling Requirements

To approve the new conditions listed in Permit No. 12300391–102, the MPCA conducted Significant Impact Level (SIL) modeling to determine compliance with the PM_{10} NAAQS using both existing and new PM_{10} emissions sources. The permit update replaces equivalent-or-better modeling demonstration requirements at the permit condition titled Total Facility ''TFAC'' 1, 5.1.1 and 6.1.1 to include specific modeling triggers when future changes are made in the parameters contained in Appendix A or emission sources. Specifically, TFAC 5.1.1 indicates no change can be made to the facility that would result in an increase in PM_{10} or $PM_{2.5}$ emissions until it can be demonstrated that it would not cause an exceedance of the NAAQS and 6.1.1 contains corrective actions for failed emission rate performance tests.

D. Facility-Specific Emissions Factors

The required modeling exercise to review and reissue Permit No. 12300391–102 to Bulk Silos included new, significantly lower process-specific factors not identified in prior modeling demonstrations for the facility, provided by Bulk Silos through performance testing [1] and reference from EPA's Compilation of Air Pollutant Emissions Factors (AP–42).[2] The SIL modeling demonstration allowed MPCA to increase throughput limits while decreasing the allowable PM_{10} emission rate (Table 1). Performance testing requirements at a minimum of once every 60 months will be used to demonstrate continued compliance and verify the updated emission factors (see 6.2.1 (permit condition titled Component Group ''COMG'' 2 unloading silos), 6.3.1 (COMG 3 existing unloading silos), 6.4.1 (COMG 4, bucket elevator and silo 3 operations), 6.5.1 (EQUI 4, truck loading operations)).

III. PM_{10} SIP and Emissions Impacts

The approval of MPCA's submittal would strengthen the Minnesota SIP by requiring more stringent emission limits, counteracting the revision of increased throughput limits. Table 1, below, shows the previous emission limit and new emission limit applicable to each unit at the facility. Considered together, allowable emissions will be decreased by 1.18 lb/hr and 0.45 lb/hr for the 24-hour limit and the annual limit, respectively. These changes become effective upon the effective date of EPA's approval of MPCA's June 16, 2021, request.

TABLE 1—SUMMARY OF CHANGES TO ALLOWABLE PM_{10} EMISSIONS IN REVISED TITLE I SIP CONDITIONS FOR BULK SILOS

Unit description	Previous unit ID	New unit ID	Previous PM_{10} emission limit	New emission PM_{10} limit
Pneumatic Conveyance to Silo 6.	EQUI 1	COMG 2 (EQUI 11 excluded)	0.25 lb/hr *	0.009 lb/hr.*
Pneumatic Conveyance to Silo 5.	EQUI 2		0.25 lb/hr. *	
Unloading Silos	EQUI 3 (EQUI 6, 7, 11, AND 12).		0.84 lb/hr. *	
New Silos	EQUI 8, 9, 10		NA.	
Silo 3 (storage silo)	EQUI 11	EQUI 11	0.84 lb/hr *	0.0008 lb/hr.*
Truck loading	EQUI 4	EQUI 4	.04 lb/hr, * 0.15 tpy **	.009 lb/hr.*
New Bucket Elevator	NA	EQUI 5 (bucket elevator	NA	.0031 lb/hr.*

[1] New emission factors were calculated based on methods contained in AP–42 (Compilation of Air Pollution Emission Factors) Section 11.12 and an emission factor created using the results of Bulk Silos' self-reported performance test (*https://www.epa.gov/sites/production/files/2020–09/documents/toc_kwrd.pdf*).

[2] *See* EPA's documentation of AP–42 at *https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors#5thed*.

TABLE 1—SUMMARY OF CHANGES TO ALLOWABLE PM_{10} EMISSIONS IN REVISED TITLE I SIP CONDITIONS FOR BULK SILOS—Continued

Unit description	Previous unit ID	New unit ID	Previous PM_{10} emission limit	New emission PM_{10} limit
Unpaved roads	FUGI 2	FUGI 2	0.3 tpy **	NA.

* Daily average.
** 24-Hour rolling average and 12 month rolling average.

The approval of the SIP revisions allows the unloading of product into EQUIs 1, 2, 6, 7, 8, 9, 10, or 12, contained in COMG 2. Product would no longer be loaded into Silo 3 (EQUI 11). Instead, Silo 3 would serve as a storage silo to transfer cementitious product between silos 7–9 (EQUI 8, 9 and 10). Units contained in COMG 2 are collectively subject to the Unloading Process Throughput limits and the ''New SIP PM_{10} Limit'' of 0.009 lb/hr. Previously, EQUI 3 contained EQUI 6, EQUI 7, EQUI 11, and EQUI 12. These four units are subject to the combined PM_{10} limit of 0.84 lb/hr at COMG 1 until startup of the Project. Then, the PM_{10} limit for EQUIs 6, 7, and 12 will be encompassed by the PM_{10} limit at COMG 2 and the PM_{10} limit for EQUI 11 will be at EQUI 11.

IV. Section 110(l) Obligations

In this action, EPA is approving MPCA's request to update title I SIP Conditions related to the Bulk Silos' portland cement distribution terminal. MPCA's submission includes a noninterference demonstration clarification letter included within the docket of this rulemaking intended to show that its SIP revision is approvable under Section 110(l) of the CAA; such a demonstration is sometimes called an anti-backsliding demonstration. Section 110(l) provides that EPA cannot approve a SIP revision if the revision would interfere with any applicable requirement concerning attainment or reasonable further progress (RFP), or any other applicable requirement of the CAA.

Additionally, Section 110(l) makes clear that each SIP revision is subject to the requirements of Section 110(l). A state may demonstrate the revision will not interfere with attainment of the NAAQS through an air quality modeling analysis. As previously mentioned, MPCA performed a SIL modeling demonstration to determine compliance with the PM_{10} NAAQS, concluding that the facility changes at Bulk Silos will not interfere with the facility's ability to maintain the PM_{10} NAAQS and total allowable PM_{10} emissions will be decreased. The modeling demonstration included updated facility-specific emission factors developed through performance testing. Further, MPCA has made updates to the modeling requirements in the Bulk Silos' permit, specifically, TFAC 5.1.1 states no change can be made to the facility that would result in an increase in PM_{10} or $PM_{2.5}$ emissions until it can be demonstrated that it would not cause an exceedance of the NAAQS. For these reasons, we conclude that the revisions will not interfere with attainment and maintenance of the NAAQS, RFP, or any other applicable requirement of the CAA. EPA has determined that MPCA's SIP submission meets the requirements of section 110(l) of the CAA.

V. What is a ''Title I condition?''

SIP control measures were contained in permits issued to culpable sources in Minnesota until 1990 when EPA determined that limits in state-issued permits are not federally enforceable because the permits expire. The state then issued permanent Administrative Orders to culpable sources in nonattainment areas from 1991 to February of 1996.

Minnesota's consolidated permitting regulations, approved into the State SIP on May 2, 1995 (60 FR 21447), include the term ''Title I condition'' which was written, in part, to satisfy EPA requirements that SIP control measures remain permanent. A ''Title I condition'' is defined as ''any condition based on source-specific determination of ambient impacts imposed for the purposes of achieving or maintaining attainment with the national ambient air quality standard and which was part of the state implementation plan approved by EPA or submitted to the EPA pending approval under section 110 of the act . . .'' The rule also states that ''Title I conditions and the permittee's obligation to comply with them, shall not expire, regardless of the expiration of the other conditions of the permit.'' Further, ''any title I condition shall remain in effect without regard to permit expiration or reissuance, and shall be restated in the reissued permit.''

Minnesota has also initiated using joint title I/title V–FESOP documents as the enforceable document for imposing emission limitations and compliance requirements in SIPs. The SIP requirements in joint title I/title V–FESOP documents submitted by MPCA are cited as ''Title I conditions,'' therefore ensuring that SIP requirements remain permanent and enforceable. EPA reviewed the State's procedure for using joint title I/title V–FESOP documents to implement site-specific SIP requirements and found it to be acceptable under both titles I and V of the Act (July 3, 1997 letter from David Kee, EPA, to Michael J. Sandusky, MPCA).

VI. What action is EPA taking?

EPA is approving a revision to Minnesota's PM_{10} SIP for Bulk Silos, as submitted by MPCA on June 16, 2021, and reflected in conditions labeled ''40 CFR pt. 51, Title I Condition: 40 CFR 50.6 (PM_{10} SIP), Title I Condition: 40 CFR pt. 52, subp. Y'' in the background document and permit (No. 12300391–102).

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the State plan if relevant adverse written comments are filed. This rule will be effective June 6, 2022 without further notice unless we receive relevant adverse written comments by May 9, 2022. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any

comments, this action will be effective June 6, 2022.

VII. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Minnesota Regulations described in this preamble and set forth in the amendments to 40 CFR part 52 below. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[3]

VIII. Statutory and Executive Order Reviews

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

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

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

This action is subject to the Congressional Review Act, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 6, 2022. 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. 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, Particulate matter, Reporting and recordkeeping requirements.

Dated: March 31, 2022.

Debra Shore,

Regional Administrator, Region 5.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 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.*

■ 2. In § 52.1220, the table in paragraph (d) is amended by:

■ a. Adding an entry for ''Bulk Silos'' immediately following the entry for ''BAE Technology Center''; and

■ b. Removing the entry for ''Lafarge North America Corporation, Childs Road Terminal''.

The addition reads as follows:

§ 52.1220 Identification of plan.

* * * * *

(d) * * *

[3] 62 FR 27968 (May 22, 1997).

EPA-APPROVED MINNESOTA SOURCE-SPECIFIC PERMITS

Name of source	Permit No.	State effective date	EPA approval date	Comments
*	*	*	*	*
Bulk Silos	12300391–102	6/3/2021	4/7/2022, [INSERT **Federal Register** CITATION].	Only conditions cited as ''Title I Condition: 40 CFR 50.6 (PM_{10} SIP).''
*	*	*	*	*

* * * * *

[FR Doc. 2022–07288 Filed 4–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2021–0932; FRL–9461–02–R7]

Air Plan Approval; Iowa; Determination of Attainment by the Attainment Date for the 2010 1-Hour Sulfur Dioxide Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to determine that the Muscatine sulfur dioxide (SO_2) nonattainment area attained the 2010 1-hour SO_2 primary national ambient air quality standard (NAAQS) by the applicable attainment date of October 4, 2018, based upon a weight-of-evidence analysis using available air quality information. Additional analysis of the attainment determination is provided in a Technical Support Document (TSD) included in the docket to this rulemaking. This action addresses the EPA's obligation under a consent decree which established a deadline of March 31, 2022 for the EPA to determine under Clean Air Act (CAA) section 179(c) whether the Muscatine SO_2 nonattainment area attained the NAAQS by the October 4, 2018, attainment date. The consent decree deadline was extended to June 30, 2022.

DATES: This final rule is effective on May 9, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2021–0932. 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, *i.e.,* 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 information.

FOR FURTHER INFORMATION CONTACT: Jason Heitman, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7664; email address: *heitman.jason@epa.gov.*

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

Table of Contents

I. What is being addressed in this document?
II. Determination
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V. Statutory and Executive Order Reviews

I. What is being addressed in this document?

The EPA is taking final action to determine that the Muscatine SO_2 nonattainment area attained the 2010 1-hour SO_2 primary NAAQS by the applicable attainment date of October 4, 2018, based upon a weight-of-evidence analysis using available air quality information. This action also fulfills the EPA's obligation under a consent decree in *Center for Biological Diversity, et al.* v. *Regan,* No. 3:20–cv–05436–EMC (N.D. Cal June 25, 2021), which established a deadline of March 31, 2022, for the EPA to determine under CAA section 179(c) whether the Muscatine SO_2 nonattainment area attained the NAAQS by the October 4, 2018, attainment date. The consent decree deadline was extended by stipulation to June 30, 2022.

II. Determination

CAA section 179(c)(1) requires the Agency to ''determine, based on the area's air quality as of the attainment date, whether the area attained the standard by that date.''

On January 26, 2022, the EPA published a notice of proposed rulemaking (NPRM) to determine that the Muscatine SO_2 nonattainment area attained the NAAQS by the October 4, 2018, attainment date. (87 FR 3958) During the comment period on EPA's NPRM, open from January 26, 2022, to February 25, 2022, EPA received no comments.

As discussed in the NPRM, the EPA first assessed what air quality information was available related to making a determination of attainment by the attainment date for the Muscatine area. The EPA chose to employ a weight-of-evidence approach for making this determination because the EPA does not have any analysis (including modeling) associated with the monitor siting to demonstrate that the monitors record maximum ambient SO_2 concentrations in the NAA, nor does EPA have modeling of actual emissions to support a determination based on modeled ambient concentrations whether the area attained the NAAQS by the attainment date. The available modeling of permitted allowable emissions in the area, as discussed in the NPRM, does not on its own provide a basis for determining whether the area attained by the attainment date. Thus, EPA relied upon SO_2 emissions data and trends, relevant air monitoring data and trends, SO_2 monitoring data incorporated with local meteorological data, as well as available modeling information in order to make its determination under CAA section 179(c)(1).

The EPA finds that the analysis of multiple types of air-quality related information supports our determination and is consistent with section 179(c)(1)'s direction to determine the area's air quality as of the attainment date. Further detail on EPA's weight-of-evidence analysis is contained in the NPRM and TSD included in the docket for this action.

As discussed in the NPRM and in the TSD, we find that the weight of the available evidence indicates that the Muscatine area attained the 2010 1-hour SO_2 NAAQS in the 2015–2017

timeframe by the October 4, 2018, attainment date. Specifically, the significant reductions in emissions during the relevant time period from sources within the nonattainment area and a nearby source outside the nonattainment area, coupled with corresponding decreased monitored SO_2 concentrations within the nonattainment area during that same time period lead us to our determination that the area attained by its attainment date.

III. Final Action

The EPA conducted a weight-of-evidence analysis, described in detail in the NPRM and the TSD, to determine if the Muscatine SO_2 nonattainment area attained the 2010 1-hour SO_2 NAAQS by the October 4, 2018, attainment date by evaluating all available technical information and data relevant to the SO_2 air quality (*e.g.,* emissions, monitoring, meteorological data, and modeling) in the Muscatine, Iowa, area. Based on the analysis and information presented in the NPRM and the TSD contained in the docket for this action, the EPA determines that the Muscatine SO_2 NAA attained the 2010 1-hour SO_2 standard by the applicable attainment date of October 4, 2018, consistent with CAA section 179(c)(1).

On January 26, 2022, the EPA published a NPRM to determine that the Muscatine SO_2 nonattainment area attained the NAAQS by the October 4, 2018, attainment date. (87 FR 3958) The EPA sought public comment on the proposed determination and received no comments. Therefore, the EPA is finalizing the determination as proposed.

In addition, this action addresses EPA's obligation under a consent decree in *Center for Biological Diversity, et al.* v. *Regan,* which established a deadline of March 31, 2022, for the EPA to determine under CAA section 179(c) whether the Muscatine County SO_2 nonattainment area attained the NAAQS by the October 4, 2018, attainment date. The consent decree deadline was extended by stipulation to June 30, 2022.

This action does not constitute a redesignation of the Muscatine SO_2 NAA to attainment for the 2010 1-hour SO_2 NAAQS under CAA section 107(d)(3) because we have not yet approved a maintenance plan for the area as meeting the requirements of section 175A of the CAA and have not determined that the area has met the other CAA section 107(d)(3)(E) requirements for redesignation. The classification and designation status in 40 CFR part 81 will remain nonattainment until the EPA has determined that Iowa has met the CAA requirements for redesignation to attainment for the Muscatine SO_2 nonattainment area.

IV. Environmental Justice Concerns

When the EPA establishes a new or revised NAAQS, the CAA requires the EPA to designate all areas of the U.S. as either nonattainment, attainment, or unclassifiable. Area designations address environmental justice concerns by ensuring that the public is properly informed about the air quality in an area.

The EPA utilized the EJSCREEN tool to evaluate environmental and demographic indicators within the area. The tool outputs report is contained in the docket for this action. While the EPA's EJSCREEN tool demonstrates that demographic indicators are consistent or lower than national averages, there are vulnerable populations in the area including low-income populations and persons over 64 years of age.

This action addresses EPA's determination, as required by the CAA, of whether the Muscatine County, Iowa, area attained the 2010 1-hour SO_2 NAAQS by the relevant attainment date. This action determines an area has attained the NAAQS by the relevant attainment date, but it does not change the geographic status of the area nor does it impose additional or modify existing requirements on sources. Based on the information presented in the NPRM and the TSD, the EPA determines that the air quality in the Muscatine County area is attaining the NAAQS. For these reasons, this action does not result in disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples.

V. Statutory and Executive Order Reviews

This action determines an area has attained the NAAQS by the relevant attainment date and does not impose additional or modify existing requirements. 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);
- Is not subject to requirements of the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; and
- This action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The basis for this determination is contained in section IV of this action, ''Environmental Justice Concerns.''
- This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).
- Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 6, 2022. 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, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: March 31, 2022.

Meghan A. McCollister,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as set forth below:

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 Q—Iowa

■ 2. Revise § 52.834 to read as follows:

§ 52.834 Control strategy: Sulfur dioxide.

(a) *Approval.* On April 21, 1997, the Iowa Department of Natural Resources (IDNR) submitted a maintenance plan and redesignation request for the Muscatine County nonattainment area for the 1971 SO_2 national ambient air quality standard (NAAQS). The maintenance plan and redesignation request satisfy all applicable requirements of the Clean Air Act.

(b) *Determination of attainment by the attainment date.* As of May 9, 2022, the EPA has determined that the Muscatine, Iowa SO_2 nonattainment area has attained the 2010 1-hour SO_2 primary NAAQS by the applicable attainment date of October 4, 2018.

[FR Doc. 2022–07291 Filed 4–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R05–OAR–2008–0138; EPA–R05–OAR–2011–0827; FRL–9397–02–R5]

Air Plan Approval; Indiana, Ohio; Definition of Chemical Process Plants Under State Prevention of Significant Deterioration Regulations and Operating Permit Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving revisions to the State Implementation Plan (SIP) for Indiana and revisions to the operating permit program for Ohio. The revisions incorporate changes to the definition of ''chemical process plants'' under Indiana's Prevention of Significant Deterioration (PSD) regulations and under Ohio's operating permit program. EPA also provided an opportunity for public comment on similar changes to the definition of ''major stationary source'' in Ohio's PSD regulations that were approved into the SIP on October 28, 2014. The changes to the State rules described below are approvable because they are consistent with EPA regulations governing state PSD and title V programs and will not interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171 of the Clean Air Act (CAA)), or any other applicable requirement of the CAA. EPA proposed to approve this action on January 19, 2022, and received no adverse comments.

DATES: This final rule is effective on May 9, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2008–0138 (Ohio) and EPA–R05–2011–0827 (Indiana). All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* 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 either through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19. We recommend that you telephone Michael Langman, Physical Scientist, at (312) 886–6867 or Mari González, Environmental Engineer, at (312) 886–6175 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: For information regarding Indiana's PSD permit program: Michael Langman, Physical Scientist, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6867, *langman.michael@epa.gov.* For information regarding Ohio's title V operating permit or PSD permit programs: Mari González, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6175, *gonzalez.mari@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. Background Information

On January 19, 2022 (87 FR 2731), EPA proposed to approve revisions excluding ethanol production facilities that produce ethanol by natural fermentation from the chemical process plant source category in Indiana's PSD rules at 326 Indiana Administrative Code (IAC) 2–2–1 and Ohio's title V operating permit rules at Ohio Administrative Code (OAC) 3745–77–01. An explanation of the CAA requirements, a detailed analysis of the revisions, and EPA's reasons for proposing approval were provided in the notice of proposed rulemaking (NPRM), and will not be restated here. The public comment period for this proposed rule ended on February 18, 2022. EPA received no comments on the proposal.

II. Final Action

EPA is approving revisions to the Indiana SIP in 40 CFR 52.770. EPA is also approving revisions to the Ohio title V operating permit program in 40 CFR part 70, appendix A. The revisions that EPA is approving change the definition of ''major stationary source'' under Indiana's PSD regulations at 326 IAC 2–2–1(ff)(1) and Ohio's operating permit program at 3745–77–01(W). EPA is not taking action on changes related to Indiana's nonattainment new source review regulations in this action. EPA is taking no further action with respect to the 2014 revisions to the Ohio PSD SIP in 40 CFR 52.1870 related to the 2007 Ethanol Rule because we received no comments on this issue in the NPRM. As explained in the NPRM, EPA has determined that these revisions are consistent with EPA's PSD and title V regulations and that approval of these revisions is consistent with the requirements of CAA section 110(l) and will not adversely impact air quality.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Indiana Regulations described in Section II of this preamble and set forth in the amendments to 40 CFR part 52 below. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov,* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER**

INFORMATION CONTACT section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission and a state title V program submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a); 42 U.S.C. 7661a(d); 40 CFR 70.1(c), 70.4(i). Thus, in reviewing SIP submissions and title V program revision submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

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

This action is subject to the Congressional Review Act, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 6, 2022. 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

40 CFR Part 52

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

40 CFR Part 70

Environmental protection, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: March 31, 2022.

Debra Shore,

Regional Administrator, Region 5.

For the reasons stated in the preamble, EPA amends 40 CFR parts 52 and 70 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.*

■ 2. In § 52.770, the table in paragraph (c) is amended by revising the entries for ''2–2–1'' to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED INDIANA REGULATIONS

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
*	*	*	*	*
2–2–1	Definitions	3/16/2011	9/28/2011, 76 FR 59899	(a) through (e), (f)(2) through (f)(3), (g) through (cc), (dd)(2) through (dd)(3), (ee)(1) through (ee)(2), (ff)(2) through (ff)(6), (gg)(1)(A) through (gg)(1)(B), (gg)(2) through (gg)(3), (hh) through (rr), (ss)(2) through (ss)(6), (tt) through (vv), (ww)(1)(A) through (ww)(1)(E), (ww)(1)(G) through (ww)(1)(W), (ww)(2), (xx) through (aaa).
2–2–1	Definitions	7/11/2012	10/29/2012, 77 FR 65478	(dd)(1), (ff)(7), (ss)(1), (ww)(1)(F) and (ww)(1)(G) only.
2–2–1	Definitions	7/11/2012	7/2/2014, 79 FR 37646	(f)(1), (ee)(3), and (gg)(1)(C) only.

[1] 62 FR 27968 (May 22, 1997).

EPA-APPROVED INDIANA REGULATIONS—Continued

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
2–2–1	Definitions	9/16/2011	4/7/2022, [INSERT **Federal Register** CITATION].	(ff)(1) only.
*	*	*	*	*

* * * * *

PART 70—STATE OPERATING PERMIT PROGRAMS

■ 3. The authority citation for part 70 continues to read as follows:

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

■ 4. In appendix A to part 70 the entry for ''Ohio'' is amended by adding paragraph (e) to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Ohio

* * * * *

(e) The Ohio Environmental Protection Agency submitted an operating permits program amendment on February 4, 2008. The program amendment contained in the February 4, 2008 submittal revises the definition of major source to exclude ethanol production facilities that produce ethanol by natural fermentation from the chemical process plant source category. The state is hereby granted approval effective on May 9, 2022.

* * * * *

[FR Doc. 2022–07285 Filed 4–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0154; FRL–9648–01–OCSPP]

Cyantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of cyantraniliprole in or on sugarcane, cane. Syngenta Crop Protection, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 7, 2022. Objections and requests for hearings must be received on or before June 6, 2022 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0154, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744.

Due to the public emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–2659; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

To access the OCSPP test guidelines referenced in this document electronically, please go to *https://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0154 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before June 6, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0154, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically

any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 22, 2021 (86 FR 21317) (FRL–10022–59), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F8868) by Syngenta Crop Protection, LLC, P.O. Box 18300 Greensboro, NC 27419. The petition requested that 40 CFR 180.672 be amended by establishing a tolerance for inadvertent residues of the insecticide, cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl] phenyl]-1H-pyrazole-5-carboxamide in or on sugarcane at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket (EPA–HQ–OPP–2021–0154), *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the commodity definition for sugarcane. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyantraniliprole including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with cyantraniliprole follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for cyantraniliprole in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to cyantraniliprole and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. For a discussion of the Toxicological Profile of cyantraniliprole, see Unit III.A of the cyantraniliprole tolerance rulemaking published in the **Federal Register** of November 13, 2018, 83 FR 56262 (FRL–9985–32).

Toxicological Points of Departure/Levels of Concern. For a discussion of the Toxicological Points of Departure/Levels of Concern used for the safety assessment of cyantraniliprole, see Unit III.B of the February 5, 2014, rulemaking (79 FR 5826) (FRL–9388–7).

Exposure Assessment. Much of the exposure assessment for cyantraniliprole remains unchanged from the discussion in Unit III.C of the November 13, 2018, rulemaking, except as described below.

EPA's current exposure assessment has been updated to include the additional exposure from this petitioned-for tolerance for residues of cyantraniliprole on sugarcane. The rotational crop use does not result in an increase in the estimated residue levels in drinking water or in exposure from residential sources relative to those used in the last assessment. EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure from drinking water and from residential sources. There are no changes to EPA's conclusions in the November 13, 2018, rulemaking concerning cumulative effects.

Safety Factor for Infants and Children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that decision are articulated in Unit III.D of the November 13, 2018, rulemaking.

Assessment of aggregate risks. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Acute dietary risks are below the Agency's level of concern. Since no effects of concern have been identified for cyantraniliprole resulting from 1-day or single exposures, a qualitative acute dietary exposure assessment is unnecessary. Chronic dietary risks are likewise below the Agency's level of concern: 64% of the cPAD for all infants (<1 year old), the group with the highest exposure. EPA has concluded the combined short-term food, water, and residential exposures result in aggregate margins of exposure above the level of concern of 100 for all scenarios assessed and are not of concern. All risk estimates for intermediate-term aggregate risk are not of concern. An aggregate cancer risk assessment was not conducted because cyantraniliprole is not considered to be a carcinogen. The chronic aggregate assessment did not result in risk estimates of concern.

Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyantraniliprole residues.

Further information about EPA's risk assessment and determination of safety supporting the new cyantraniliprole tolerance can be found at *https://www.regulations.gov* in the document titled ''Cyantraniliprole. Human Health Risk Assessment for an Inadvertent Tolerance on Sugarcane'' in docket ID EPA–HQ–OPP–2021–0154.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectroscopy (LC/MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are no Codex MRLs established for residues of cyantraniliprole on sugarcane.

C. Response to Comments

EPA received one comment in response to the April 22, 2021, notice of filing. The comment seems to express general concern about pesticides, and specifically requests that EPA not permit the use of ''cyanide''—a completely unrelated chemical—on ''sugar''. No specific concerns about EPA's current evaluation were raised. While the agency recognizes that some people oppose the use of pesticides in or on food commodities, the FFDCA allows EPA to establish tolerances for residues of pesticides in or on food as long as the Agency can determine those tolerances are safe. The Agency has evaluated the aggregate exposures of cyantraniliprole and has determined that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyantraniliprole residues. The commenter has provided no information to support a conclusion that the tolerance is not safe.

D. Revisions to Petitioned-For Tolerances

The Agency is establishing a tolerance for the commodity ''sugarcane, cane'' rather than ''sugarcane'', as requested, to be consistent with the food commodity nomenclature.

V. Conclusion

Therefore, a tolerance is established for inadvertent residues of cyantraniliprole in or on sugarcane, cane at 0.01 ppm.

VI. Statutory and Executive Order Reviews

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

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 31, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.672, the table in paragraph (d) is amended by:

■ a. Adding a table heading; and

■ b. Adding the commodity ''Sugarcane, cane'' to the table in alphabetical order.

The additions read as follows:

§ 180.672 Cyantraniliprole; tolerances for residues.

(d) * * *

TABLE 2 TO PARAGRAPH (d)

Commodity	Parts per million
* * * * *	
Sugarcane, cane	0.01

[FR Doc. 2022–07277 Filed 4–6–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2022–0024; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BG21

Endangered and Threatened Wildlife and Plants; Emergency Listing of the Dixie Valley Toad as Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Temporary rule; emergency action.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), exercise our authority pursuant to the Endangered Species Act of 1973, as amended (Act), to emergency list the Dixie Valley toad (*Anaxyrus williamsi*) as endangered. Due to the imminent development of a geothermal project in Dixie Meadows, Nevada, and the potential resulting effects to the geothermal springs relied upon by the Dixie Valley toad, there is a significant risk to the well-being of the species. We find that emergency listing is necessary in order to provide the protective measures afforded by the Act to the Dixie Valley toad. This emergency action (emergency rule) provides Federal protection pursuant to the Act for a period of 240 days. A proposed rule to list the Dixie Valley toad as endangered is published concurrently with this emergency rule in the Proposed Rules section of this issue of the **Federal Register**.

DATES: This temporary rule is effective April 7, 2022, through December 2, 2022.

ADDRESSES: This temporary rule, the species status assessment report and other materials related to this temporary rule, and the proposed rule are available on the internet at *https://www.regulations.gov* under Docket No. FWS–R8–ES–2022–0024.

FOR FURTHER INFORMATION CONTACT: Marc Jackson, Field Supervisor, U.S. Fish and Wildlife Service, Reno Fish and Wildlife Office, 1340 Financial Blvd., Suite 234, Reno, Nevada 89502; telephone 775–861–6300. 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.

SUPPLEMENTARY INFORMATION:

Previous Federal Actions

We received a petition from the Center for Biological Diversity (CBD) on September 18, 2017, requesting that the Dixie Valley toad be listed as a threatened or endangered species and that the petition be considered on an emergency basis (CBD 2017, entire). The Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*), does not provide a process to petition for emergency listing; therefore, we evaluated the petition to determine if it presented substantial scientific or commercial information indicating that the petitioned action may be warranted. We published a 90-day finding in the **Federal Register** on June 27, 2018 (83 FR 30091), stating that the petition presented substantial scientific or commercial information indicating that listing the Dixie Valley toad may be warranted.

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Dixie Valley toad. The SSA team was composed of Service biologists, in consultation with other scientific experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species and its habitat. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we will seek expert opinions of at least three appropriate specialists regarding the SSA concurrent with the open comment period identified in the proposed rule that is published concurrently with this emergency action (emergency rule) and found in the Proposed Rules section of this issue of the **Federal Register**. The SSA report and other materials related to this emergency rule, including the proposed rule, can be found at *https://www.regulations.gov* under Docket No. FWS–R8–ES–2022–0024. We note that, because we were already conducting a status review of the species, we had completed an SSA prior to publishing this emergency listing rule. Therefore, we have incorporated the information from the SSA here. However, given the purpose of emergency listing rules, they do not require this level of detail and analysis.

Background

A thorough review of the taxonomy, life history, and ecology of the Dixie Valley toad (*Anaxyrus williamsi*) is presented in the SSA report (Service 2022, entire).

The Dixie Valley toad was described as a distinct species in the western toads (*Anaxyrus boreas*) species complex in 2017 due to morphological differences, genetic information, and its isolated distribution (Gordon et al. 2017, entire). Forrest et al. (2017, entire) also published a paper describing Dixie Valley toad and came up with similar results but stopped short of concluding it is a unique species. We evaluated both papers and concluded that the Gordon et al. (2017, entire) paper provided a better sampling design to answer species-level genetic questions and included a more thorough morphological analysis. Additionally, the Dixie Valley toad has been accepted as a valid species by the two leading authoritative amphibian internet sites: (1) Amphibiaweb.org (AmphibiaWeb 2022, website) and (2) Amphibian Species of the World (Frost 2021, website). Because both the larger scientific community and our own analysis of the best available scientific information indicate that the findings of Gordon et al. (2017 entire) are well supported, we are accepting their conclusions that the Dixie Valley toad is a unique species (*Anaxyrus williamsi*). Therefore, we have determined that the Dixie Valley toad is a listable entity under the Act.

Fourteen different morphological characteristics of Dixie Valley toads were measured and compared to several other species within the western toads species complex (Gordon et al. 2017, pp. 125–131). While all 14 morphological characteristics measured for Dixie Valley toad were significantly different from the other species within the western toads species complex, the most striking differences were the average size of adults (the mean snout-to-vent length (SVL) is 54.6 millimeters (mm)

(2.2 inches (in)), which makes the Dixie Valley toad the smallest species within the *A. boreas* species complex), the close-set eyes and perceptively large tympanum (eardrum), and its unique coloration (Gordon et al. 2017, pp. 125–131).

Limited information is available specific to the life history of the Dixie Valley toad; therefore, closely associated species are used as surrogates where appropriate. Breeding (denoted by observing a male and female in amplexus, egg masses, or tadpoles) occurs annually between March and May (Forrest 2013, p. 76). Breeding appears protracted due to the thermal nature of the habitat and can last up to 3 months (March–May) with toads breeding early in the year in habitats closer to the thermal spring sources and then moving downstream into habitats as they warm throughout spring and early summer. Other toad species typically have a much more contracted breeding season of 3–4 weeks (*e.g.,* Sherman 1980, pp. 18–19, 72–73). Dixie Valley toad tadpoles hatch shortly after being deposited; time to hatching is not known but is likely dependent on water temperature (*e.g.,* black toad (*Anaxyrus exsul*) tadpoles hatch in 7 to 9 days; Sherman 1980, p. 97). Fully metamorphosed Dixie Valley toadlets were observed 70 days after egg laying (Forrest 2013, pp. 76–77).

The Dixie Valley toad is a narrow-ranging endemic (highly local and known to exist only in their place of origin) known from one population in the Dixie Meadows area of Churchill County, Nevada. The species occurs primarily on Department of Defense (DoD; Fallon Naval Air Station) lands (90 percent) and Bureau of Land Management (BLM) lands (10 percent). The wetlands located in Dixie Meadows cover 307.6 hectares (ha) (760 acres (ac)) and are fed by geothermal springs. The potential area of occupancy is estimated to be 146 ha (360 ac) based on the extent of wetland-associated vegetation. The species is heavily reliant on these wetlands, as it is rarely encountered more than 14 meters (m) (46 feet (ft)) from aquatic habitat (Halstead et al. 2021, p. 7).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because 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.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the species' expected response and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''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. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species (Service 2022, entire). The SSA report does not represent our decision on whether the species should be listed as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS–R8–ES–2022–0024 on *https://www.regulations.gov.*

To assess Dixie Valley toad viability, we used the three conservation biology principles of resiliency, redundancy,

and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We used this information to inform our regulatory decision.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. To assess the current and future condition of the species, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

Species Needs

Wetted Area

Dixie Meadows contains 122 known spring and seep sources and discharges approximately 1,109,396 cubic meters per year (m^3/yr) (900 acre-feet per year (afy)) (McGinley and Associates 2021, pp. 1–2), which distributes across the wetland complex water that then flows out to the playa or is collected in a large ephemeral pond in the northeast portion of the wetland complex. Some of the larger springs have springbrooks that form channels while in other areas the water spreads out over the ground or through wetland vegetation creating a thin layer of water or wet soil that helps maintain the wetland. Spring discharge is inherently linked to the amount of wetted area within the wetland complex. Spring discharge is important for the viability of the Dixie Valley toad because changes to discharge rates likely impact the ability of the toad to survive in a particular spring complex.

Dixie Valley toad is a highly aquatic species rarely found more than 14 m (46 ft) away from water (Halstead et al. 2021, pp. 28, 30). The species needs wetted area for shelter, feeding, reproduction, and dispersal. Any change in the amount of wetted area will directly influence the amount of habitat available to the Dixie Valley toad. Due to the already restricted range of the habitat, the species needs to maintain the entirety of the 1.46-square-kilometer (km^2) (360-ac) potential area of occupancy, based on the extent of the wetland-associated vegetation.

Adequate Water Temperature

In addition to the Dixie Valley toad being highly aquatic, the temperature of the water is also important to its life history. The species needs warm temperatures for shelter and reproduction. The Dixie Valley toad selects water or substrate that is warmer compared to nearby random paired locations, particularly in spring, fall, and winter months (Halstead et al. 2021, pp. 30, 33–34). During spring, they select areas with warmer water for breeding (oviposition sites), which allows for faster egg hatching and time to metamorphosis (Halstead et al. 2021, pp. 30, 33–34). During fall, they select warmer areas (closer to thermal springs with dense vegetation), which satisfies their thermal preferences as nighttime temperatures decrease (Halstead et al. 2021, pp. 30, 33–34). As winter approaches, toads find areas with consistent warm temperatures during brumation (hibernation for cold-blooded animals), so they do not freeze (Halstead et al. 2021, pp. 30, 33–34). This affinity for warm water temperature during brumation is unique to the Dixie Valley toad as compared to other species within the western toad species complex, which select burrows, rocks, logs, or other structures to survive through winter (Browne and Paszkowski 2010, pp. 53–56; Halstead et al. 2021, p. 34). Therefore, although the exact temperatures are unknown (range between 10–41 degrees Celsius (°C) (50–106 degrees Fahrenheit (°F)), Dixie Valley toad requires water temperatures warm enough to successfully breed and survive colder months during the year.

Wetland Vegetation

The most common wetland vegetation found within Dixie Meadows includes *Juncus balticus* (Baltic rush), *Schoenoplectus* spp. (bulrushes), *Phragmites australis* (common reed), *Eleocharis* spp. (spikerushes), *Typha* spp. (cattails), *Carex* spp. (sedges), and *Distichilis spicata* (saltgrass) (AMEC Environment and Infrastructure 2014, p. I–1; Tierra Data 2015, pp. 2–25—2–29; McGinley and Associates 2021, pp. 50–52, 93–99). Several species of invasive and nonnative plants also occur in Dixie Meadows including *Cicuta maculate* (water hemlock), *Cardaria draba* (hoary cress), *Lepidium latifolium* (perennial pepperweed), *Eleagnus angustifolius* (Russian olive), and *Tamarix ramosissima* (saltcedar) (AMEC Environment and Infrastructure 2014, p. 3–59). The Dixie Valley toad needs sufficient wetland vegetation to use as shelter. At a minimum, maintaining the current heterogeneity of the wetland vegetation found in Dixie Meadows is a necessary component for maintaining the resiliency of the Dixie Valley toad (Halstead et al. 2021, p. 34).

Adequate Water Quality

Amphibian species spend all or part of their life cycle in water; therefore, water quality characteristics directly affect amphibians. Dissolved oxygen, potential hydrogen (pH), salinity, water conductivity, and excessive nutrient concentrations (among other water quality metrics) all have direct and indirect impacts to the survival, growth,

maturation, and physical development of amphibian species when found to be outside of naturally occurring levels for any particular location (Sparling 2010, pp. 105–117).

Various water quality data have been collected from a few springs within Dixie Meadows and from wells drilled during geothermal exploration activities (McGinley and Associates 2021, pp. 57–64). The exact water quality parameters preferred by the Dixie Valley toad are unknown; however, this species has evolved only in Dixie Meadows and is presumed to thrive in the current existing, complex mix of water emanating from both the basin-fill aquifer and the deep geothermal reservoir. Within the unique habitat in Dixie Meadows, and given the life history and physiological strategies employed by the species, a good baseline of existing environmental water quality factors that are most important for all life stages should be studied (Rowe et al. 2003, p. 957). The Dixie Valley toad needs the natural variation of the current water quality parameters found in Dixie Meadows to maintain resiliency.

Threats Analysis

We reviewed the potential risk factors (*i.e.,* threats, stressors) that may be currently affecting the Dixie Valley toad. In this rule, we discuss only those factors in detail that could meaningfully affect the status of the species.

The primary threats affecting the status of the Dixie Valley toad are geothermal development and associated groundwater pumping (Factor A); establishment of *Batrachochytrium dendrobatidis* (*Bd;* hereafter referred to as amphibian chytrid fungus), which causes the disease chytridiomycosis (Factor C); predation by the invasive American bullfrog (*Lithobates catesbeianus*) (Factor C); groundwater pumping associated with human consumption, agriculture, and county planning (Factor A); and climate change (Factor A). Climate change may further influence the degree to which these threats, individually or collectively, may affect the Dixie Valley toad. The risk factors that are unlikely to have significant effects on the Dixie Valley toad, such as livestock grazing and historical spring modifications, are not discussed here but are evaluated in the current condition assessment of the SSA report.

Geothermal Development

Geothermal resources are reservoirs of hot water or steam found at different temperatures and depths below the ground. These geothermal reservoirs can be used to produce energy by drilling a well and bringing the heated water or steam to the surface. Geothermal energy plants use the steam or heat created by the hot water to drive turbines that produce electricity. Three main technologies are being used today to convert geothermal water into electricity: Dry steam, flash steam, and binary cycle. Binary technology is the focus for this analysis, because that type of geothermal power technology has been approved for development at Dixie Meadows.

Binary cycle power plants use the heat from the geothermal reservoir to heat a secondary fluid (*e.g.,* butane) that generally has a much lower boiling point than water. This process is accomplished through a heat exchanger, and the secondary fluid is flashed into vapor by the heat from the geothermal fluid; the vapor drives the turbines to generate electricity. The geothermal fluid is then reinjected back into the ground to maintain pressure and be reheated.

General impacts from geothermal production facilities are presented below. Because every geothermal field is unique, it is difficult to predict what effects from geothermal production may occur.

Prior to geothermal development, the flow path of water underneath the land surface is usually not known with sufficient detail to understand and prevent impacts to the surface wetlands dependent upon those flows (Sorey 2000, p. 705). Changes associated with surface expression of thermal waters from geothermal production are common and are expected. Typical changes seen in geothermal fields include, but are not limited to, changes in water temperature, flow, and water quality, which are all resource needs of the Dixie Valley toad that could be negatively affected by geothermal production (Sorey 2000, entire; Bonte et al. 2011, pp. 4–8; Kaya et al. 2011, pp. 55–64; Chen et al. 2020, pp. 2–6).

Steam discharge, land subsidence (*i.e.,* gradual settling or sudden sinking of the ground surface due to the withdrawal of large amounts of groundwater), and changes in water temperature and flow have all been documented from geothermal production areas throughout the western United States (Sorey 2000, entire). For example:

(1) Long Valley Caldera near Mammoth, California. Geothermal pumping in the period 1985–1998 resulted in several springs ceasing to flow and declines in pressure of the geothermal reservoir, which has caused reductions of 10–15 °C (50–59 °F) in the reservoir temperature and a localized decrease of approximately 80 °C (176 °F) near the reinjection zone (Sorey 2000, p. 706).

(2) Steamboat Springs near Reno, Nevada. Geothermal development resulted in the loss of surface discharge (geysers and springs) on the main terrace and a reduction of thermal water discharge to Steamboat Creek by 40 percent (Sorey 2000, p. 707).

(3) Northern Dixie Valley near Reno, Nevada. Other common changes that accompany the loss of surficial water sources, such as geysers and thermal springs, from geothermal production include an increase in steam discharge and land subsidence (Sorey 2000, p. 705). Both steam discharge and land subsidence were detected at an existing 56-megawatt (MW) geothermal plant in northern Dixie Valley, Nevada, which has been in production since 1985 (Sorey 2000, p. 708; Huntington et al. 2014, p. 5). The northern Dixie Valley geothermal plant began pumping water from the cold basin fill aquifer (local aquifer) and reinjecting it above the hot geothermal reservoir (regional aquifer) to try and alleviate land subsidence issues (Huntington et al. 2014, p. 5). This approach may have led to an increase in depth to groundwater from 1.8 m (6 ft) in 1985 to 4.3–4.6 m (14–15 ft) in 2009–2011 (Albano et al. 2021, p. 78).

(4) Jersey Valley near Reno, Nevada. In 2011, a 23.5–MW geothermal power plant started production in Jersey Valley, just north of Dixie Valley. Measured springflow of 0.08–0.17 cubic feet per second (cfs) (35–75 gallons per minute (gpm)) at a perennial thermal spring began to decline almost immediately after the power plant began operation (BLM 2022, p. 1; Nevada Department of Water Resources (NDWR) 2022, unpublished data). By 2014, the Jersey Valley Hot Spring ceased flowing (BLM 2022, p. 1; NDWR 2022, unpublished data). The loss of aquatic insects from the springbrook has diminished the foraging ability of eight different bat species that occur in the area (BLM 2022, p. 28). To mitigate for the spring going dry, the BLM proposed to pipe geothermal fluid 1.1 km (3,600 ft) to the spring source (BLM 2022, p. 8); however, mitigation has not yet occurred. If a similar outcome were to occur in Dixie Meadows, resulting in the complete drying of the springs, the Dixie Valley toad would likely be extirpated if mitigation to prevent the drying of the springs is not satisfactorily or timely achieved.

In an effort to minimize changes in water temperature, quantity, and quality, and to maintain pressure of the

geothermal reservoir, geothermal fluids are reinjected into the ground, though reinjected water is at a lower temperature than when it was pumped out of the ground. This practice entails much trial and error in an attempt to equilibrate subsurface reservoir pressure. It can take several years to understand how a new geothermal field will react to production and reinjection wells; however, reinjection does not always have the desired effect (Kaya et al. 2011, pp. 55–64).

Geothermal energy production has been cited as the greatest threat to the persistence of Dixie Valley toad (Forrest et al. 2017, pp. 172–173; Gordon et al. 2017, p. 136; Halstead et al. 2021, p. 35). Geothermal environments often harbor unique flora and fauna that have evolved in these rare habitats (Boothroyd 2009, entire; Service 2019, entire). Changes to these rare habitats often cause declines in these endemic organisms or even result in the destruction of their habitat (Yurchenko 2005, p. 496; Bayer et al. 2013, pp. 455–456; Service 2019, pp. 2–3). Because the Dixie Valley toad relies heavily on wetted area and warm water temperature to remain viable, reduction of these two resource needs could cause significant declines in the population and changes to its habitat that are detrimental to the species and result in it being in danger of extinction.

Disease

Over roughly the last four decades, pathogens have been associated with amphibian population declines, mass die-offs, and extinctions worldwide (Bradford 1991, pp. 174–176; Muths et al. 2003, pp. 359–364; Weldon et al. 2004, pp. 2,101–2,104; Rachowicz et al. 2005, pp. 1,442–1,446; Fisher et al. 2009, pp. 292–302; Knapp et al. 2011, pp. 8–19). One pathogen strongly associated with dramatic declines on all continents that harbor amphibians is chytridiomycosis caused by amphibian chytrid fungus (Rachowicz et al. 2005, pp. 1,442–1,446). Chytrid fungus has now been reported in amphibian species worldwide (Fellers et al. 2001, pp. 947–952; Rachowicz et al. 2005, pp. 1,442–1,446). Early doubt that this particular pathogen was responsible for worldwide die-offs has largely been overcome by the weight of evidence documenting the appearance, spread, and detrimental effects to affected populations (Vredenburg et al. 2010, pp. 9,690–9,692).

Clinical signs of chytridiomycosis and diagnosis include abnormal posture, lethargy, and loss of righting reflex (the ability to correct the orientation of the body when it is not in its normal upright position) (Daszak et al. 1999, p. 737). Chytridiomycosis also causes gross lesions, which are usually not apparent and consist of abnormal epidermal sloughing and ulceration, as well as hemorrhages in the skin, muscle, or eye (Daszak et al. 1999, p. 737). Chytridiomycosis can be identified in some species of amphibians by examining the oral discs (tooth rows) of tadpoles that may be abnormally formed or lacking pigment (Fellers et al. 2001, pp. 946–947).

Despite the acknowledged impacts of chytridiomycosis to amphibians, little is known about this disease outside of mass die-off events. There is high variability between species of amphibians in response to being infected including within the western toads species complex. Two long-term study sites have documented differences in apparent survival of western toads between two different sites in Montana and Wyoming (Russell et al. 2019, pp. 300–301). The chytrid-positive western toad population in Montana was reduced by 19 percent compared to chytrid-negative toads in that area—in comparison to the western toad population in Wyoming, which was reduced by 55 percent (Russell et al. 2019, p. 301). Various diseases are confirmed to be lethal to Yosemite toads (Green and Sherman 2001, p. 94), and research has elucidated the potential role of chytrid fungus infection as a threat to Yosemite toad populations (Dodge 2013, pp. 6–10, 15–20; Lindauer and Voyles 2019, pp. 189–193). These various diseases and infections, in concert with other factors, have likely contributed to the decline of the Yosemite toad (Sherman and Morton 1993, pp. 189–197) and may continue to pose a risk to the species (Dodge 2013, pp. 10–11; Lindauer and Voyles 2019, pp. 189–193). Amargosa toads are known to have high infection rates and high chytrid fungus loads; however, they do not appear to show adverse impacts from the disease (Forrest et al. 2015, pp. 920–922). Not all individual amphibians that test positive for chytrid fungus develop chytridiomycosis.

Dixie Valley toad was sampled for chytrid fungus in 2011–2012 (before it was recognized as a species) and 2019–2021 (Forrest 2013, p. 77; Kleeman et al. 2021, entire); chytrid fungus was not found during either survey. However, chytrid fungus has been documented in bullfrogs in Dixie Valley (Forrest 2013, p. 77), which is a known vector species for spreading chytrid fungus and diseases to other species of amphibians (Daszak et al. 2004, pp. 203–206; Urbina et al. 2018, pp. 271–274; Yap et al. 2018, pp. 4–8).

The best available information indicates that the thermal nature of the Dixie Valley toad habitat may keep chytrid fungus from becoming established; therefore, it is imperative that the water maintains its natural thermal characteristics (Forrest 2013, pp. 75–85; Halstead et al. 2021, pp. 33–35). Boreal toads exposed to chytrid fungus survive longer when exposed to warmer environments (mean 18 °C (64 °F)) as compared to boreal toads in cooler environments (mean 15 °C (59 °F)) (Murphy et al. 2011, pp. 35–38). Additionally, chytrid fungus zoosporangia grown at 27.5 °C (81.5 °F) remain metabolically active; however, no zoospores are produced, indicating no reproduction at this high temperature (Lindauer et al. 2020, pp. 2–5). Generally, chytrid fungus does not seem to become established in water warmer than 30 °C (86 °F) (Forrest and Schlaepfer 2011, pp. 3–7). Dixie Meadows springhead water temperatures range from 13 °C (55 °F) to 74 °C (165 °F), though the four largest spring complexes (springs that create the largest wetland areas and are inhabited by a majority of the Dixie Valley toad population) range from 16 °C (61 °F) to 74 °C (165 °F) with median temperatures of at least 25 °C (77 °F). Additionally, water temperatures measured in 2019 at toad survey sites throughout Dixie Meadows (*i.e.,* not at springheads) ranged from 10 to 41 °C (50 to 106 °F). Any reduction in water temperature, including reductions caused by geothermal development, would not only affect the ability of Dixie Valley toads to survive during cold months, but could also make the species vulnerable to chytrid fungus.

Predation

Predation has been reported in species similar to the Dixie Valley toad and likely occurs in Dixie Meadows; however, predation of Dixie Valley toads has not been documented. Likely predators on the egg and aquatic larval forms of Dixie Valley toad include predacious diving beetles (*Dytiscus* sp.) and dragonfly larvae (Odonata). Common ravens (*Corvus corax*) and other corvids are known to feed on juvenile and adult black toads and Yosemite toads (Sherman 1980, pp. 90–92; Sherman and Morton 1993, pp. 194–195). Raven populations are increasing across the western United States and are clearly associated with anthropogenic developments, such as roads and power lines (Coates and Delehanty 2010, pp. 244–245; Howe et al. 2014, pp. 44–46). Ravens are known to nest within Dixie Valley (Environmental Management and Planning Solutions 2016, pp. 3–4).

The American bullfrog, a ranid species native to much of central and eastern North America, now occurs within Dixie Meadows (Casper and Hendricks 2005, pp. 540–541; Gordon et al. 2017, p. 136). Bullfrogs are recognized as one of the 100 worst invasive species in the world (Global Invasive Species Database 2021, pp. 1–17). Bullfrogs are known to compete with and prey on other amphibian species (Moyle 1973, pp. 19–21; Kiesecker et al. 2001, pp. 1,966–1,969; Pearl et al. 2004, pp. 16–18; Casper and Hendricks 2005, pp. 543–544; Monello et al. 2006, p. 406; Falaschi et al. 2020, pp. 216–218).

Bullfrogs are a gape-limited predator, which means they eat anything they can swallow (Casper and Hendricks 2005, pp. 543–544). Dixie Valley toad is the smallest toad species in the western toads species complex and can easily be preyed upon by bullfrogs. Smaller bullfrogs eat mostly invertebrates (Casper and Hendricks 2005, p. 544), and thus may compete with Dixie Valley toad for food resources. Within Dixie Valley, bullfrogs are known to occur at Turley Pond and in one area of Dixie Meadows adjacent to occupied Dixie Valley toad habitat (Forrest 2013, pp. 74, 87; Rose et al. 2015, p. 529; Halstead et al. 2021, p. 24).

Climate Change

Both human settlements and natural ecosystems in the Southwestern United States are largely dependent on groundwater resources, and decreased groundwater recharge may occur as a result of climate change (U.S. Global Change Research Program 2009, p. 133). Furthermore, the human population in the Southwest is expected to increase 70 percent by mid-century (Garfin 2014, p. 470). Resulting increases in urban development, agriculture, and energy-production facilities will likely place additional demands on already limited water resources. Climate change will likely increase water demand while at the same time shrink water supply, since water loss may increase evapotranspiration rates and runoff during storm events (Archer and Predick 2008, p. 25).

In order to identify changing climatic conditions more specific to Dixie Meadows, we conducted a climate analysis using the Climate Mapper web tool (Hegewisch et al. 2020, online). The Climate Mapper is a web tool for visualizing past and projected climate and hydrology of the contiguous United States. This tool maps real-time conditions, current forecasts, and future projections of climate information across the United States to assist with decisions related to agriculture, climate, fire conditions, and water.

For our analysis, we analyzed mean annual temperature and percent precipitation using the historical period of 1971–2000 and the projected future time period 2040–2069. We examined emission scenarios that used representative concentration pathways (RCPs) 4.5 and 8.5 using ArcGIS Pro.

Our analysis predicts increased air temperatures in Dixie Meadows, along with a slight increase in precipitation. Annual mean air temperature is projected to increase between 2.5 and 3.4 °C (4.5 and 6.1 °F) and result in average temperatures 3.0 °C (5.3 °F) warmer throughout Dixie Meadows between 2040 and 2069 (Hegewisch et al. 2020, Geographic Information System (GIS) data). Under two emission scenarios, annual precipitation is projected to increase by 4.5 to 7.7 percent (Hegewisch et al. 2020, GIS data).

Climate change may impact the Dixie Valley toad and its habitat in two main ways: (1) Reductions in springflow as a result of changes in the amount, type, and timing of precipitation, increased evapotranspiration rates, and reduced aquifer recharge; and (2) reductions in springflow as a result of changes in human behavior in response to climate change (*e.g.,* increased groundwater pumping as surface water resources disappear). A reduction in springflow could be exacerbated by the greater severity of droughts being experienced in the Southwestern United States, including Nevada (Snyder et al. 2019, pp. 2–4; Williams et al. 2020, pp. 1–5). Higher temperatures and drier conditions could result in greater evapotranspiration, leading to increased drying of wetland habitat. Impacts vary geographically, and identifying the vulnerability of individual springs is challenging. For example, a study examining different springs over a 14-year period at Arches National Park in Utah found that each spring responded to local precipitation and recharge differently, despite similarities to Dixie Valley in topographic setting, aquifer type, and climate exposure (Weissinger 2016, p. 9).

Predicting individual spring response to climate change is further complicated by the minimal information available about the large hydrological connections for most sites and the high degree of uncertainty inherent in future precipitation models. Regardless, the best available data indicate that Dixie Valley toad may be vulnerable to climate change to an unknown degree, but we cannot say with any certainty where impacts may be manifested or the greatest.

Groundwater Pumping

The basin is fully appropriated for consumptive groundwater uses (18,758,663 cubic meters per year (m^3/yr) (15,218 acre-feet per year (afy)) of an estimated 18,489,943 m^3/yr (15,000 afy) perennial yield), and the proposed Dixie Valley groundwater export project by Churchill County is seeking an additional 12,326,628–18,489,943 m^3/yr (10,000–15,000 afy) (Huntington et al. 2014, p. 2). Total geothermal water rights appropriated in Dixie Valley as of 2020 are 15,659,749 m^3/yr (12,704 afy) (BLM 2021b, pp. 2–28).

Increased groundwater pumping in Nevada is primarily driven by human water demand for municipal purposes, irrigation, and development for oil, gas, geothermal resources, and minerals. Many factors associated with groundwater pumping can affect whether or not an activity will impact a spring. These factors include the amount of groundwater to be pumped, period of pumping, the proximity of pumping to a spring, depth of pumping, and characteristics of the aquifer being impacted. Depending on these factors, groundwater withdrawal may result in no measurable impact to springs or may reduce spring discharge, change the temperature of the water, reduce free-flowing water, dry springs, alter Dixie Valley toad habitat size and heterogeneity, or create habitat that is more suited to nonnative species than to native species (Sada and Deacon 1994, p. 6). Pumping rates that exceed perennial yield can lower the water table, which in turn will likely affect riparian vegetation (Patten 2008, p. 399).

Determining when groundwater withdrawal exceeds perennial yield is difficult to ascertain and reverse due to inherent delays in detection of pumping impacts and the subsequent lag time required for recovery of discharge at a spring (Bredehoeft 2011, p. 808). Groundwater pumping initially captures stored groundwater near the pumping area until water levels decline and a cone of depression expands, potentially impacting water sources to springs or streams (Dudley and Larson 1976, p. 38). Spring aquifer source and other aquifer characteristics influence the ability and rate at which a spring fills and may recover from groundwater pumping (Heath 1983, pp. 6, 14). Depending on aquifer characteristics and rates of pumping, recovery of the aquifer is variable and may take several years or even centuries (Heath 1983, p. 32; Halford and Jackson 2020, p. 70). Yet where reliable records exist, most

springs fed by even the most extensive aquifers are affected by exploitation, and springflow reductions relate directly to quantities of groundwater removed (Dudley and Larson 1976, p. 51).

The most extreme potential effects of groundwater withdrawal on Dixie Valley toad are likely desiccation and extirpation or extinction. If groundwater withdrawal occurs but does not cause a spring to dry, there can still be adverse effects to Dixie Valley toads or their habitat because reduction in springflow reduces both the amount of water and amount of occupied habitat. If the withdrawals also coincide with altered precipitation and temperature from climate change, even less water will be available. Cumulatively, these conditions could result in a delay in groundwater recharge at springs, which may then result in a greater effect to the Dixie Valley toad than the effects of the individual threats acting alone. Across the Dixie Meadows springs, discharge varies greatly, with some springs with low discharge at the current time likely due to a combination of influences, both natural and anthropogenic. Though there is much uncertainty around the magnitude and timing of groundwater withdrawal, and thus the possible effects on the Dixie Meadows spring system, we anticipate that the future effects of groundwater withdrawal could have significant effects on the Dixie Meadows spring system.

Current Condition

Redundancy, Representation, and Resiliency

Population estimates are not available for the Dixie Valley toad. Time-series data of toad abundance are available from various surveys conducted by the Service and the Nevada Department of Wildlife (NDOW) during the period 2009–2012 (before the Dixie Valley toad was recognized as a species); however, differences in sample methodology between years and low recapture rates indicate that consistent reproduction is occurring.

In 2018, Dixie Valley toads were detected in 38 of 60 randomized plots in the Dixie Meadows wetlands, with a 95 percent credible interval (Bayesian equivalent of a confidence interval) for probability of toad occurrence of 0.55–0.98 in plots of average water temperature (18.8 °C (65.8 °F)) (Halstead et al. 2019, p. 9). In other words, adult toads currently have high occupancy rates and are generally more likely than not to occur across the Dixie Meadows wetlands. The 95 percent credible interval for the probability of reproduction in an average plot (18.8 °C (65.8 °F) and 45 percent wetted area) was 0.01–0.26 and increased as a function of wetted surface area in plots with adults present (Halstead et al. 2019, p. 10). Although larvae have a lower probability of occurring within an average plot than adults, warmer water temperatures strongly influence the probability of reproduction (Halstead et al. 2019, pp. 10–11). This finding suggests that adult toads are seeking out a specific subset of habitat for reproduction based in part on water temperature. The percentage of the range currently occupied by adults remained similarly high throughout 2018–2021 and across seasons (Rose et al. 2022, entire).

The high occupancy rate observed from 2018 through 2021 and evidence of reproduction observed in the period 2009–2021 suggest that the Dixie Valley toad is currently maintaining resilience to the historical and current environmental stochasticity present at Dixie Meadows. However, the narrowly distributed, isolated nature of the single population of the species indicates that the Dixie Valley toad has little ability to withstand stochastic or catastrophic events through dispersal. Because the species evolved in a unique spring system with little historical variation, we conclude that it has low potential to adapt to a fast-changing environment. As a single-site endemic with no dispersal opportunities outside the current range, the species has inherently low redundancy and representation and depends entirely on the continued availability of habitat in Dixie Meadows.

The following section discusses the potential impacts the Dixie Meadows Geothermal Utilization Project could have on both the current and future status of the Dixie Valley toad. Based on an expert knowledge elicitation (discussed further below) conducted on the potential outcomes of this geothermal project, peak change to the spring system could occur as early as the current year of 2022 (year 1 of geothermal pumping), with a 90 percent chance that peak change will occur within 10 years of the start of geothermal pumping (Service 2022, pp. 42–43).

Dixie Meadows Geothermal Project

In addition to 50 active geothermal leases within Dixie Valley in Churchill County, two geothermal exploration projects were approved in Dixie Meadows in 2010 and 2011 (BLM 2010, entire; BLM 2011, entire). Most recently, on November 23, 2021, BLM approved and permitted the Dixie Meadows Geothermal Utilization Project (BLM 2021b, entire) after issuing two draft environmental assessments, receiving extensive comments from the Service and NDOW, and developing an Aquatic Resources Monitoring and Mitigation Plan (hereafter referred to as the Monitoring and Mitigation Plan). This project will consist of up to two 30–MW geothermal power plants on 6.5 ha (16 ac) each; up to 18 well pads (107×114 m (350×375 ft)), upon which up to three wells per pad may be drilled for exploration, production, or injection; pipelines to carry geothermal fluid between well fields and the power plant(s); and either a 120-kilovolt (kV) or a 230-kV transmission gen-tie and associated access roads and structures (BLM 2021b, p. 1–1). The project proponent (Ormat Nevada Inc. (Ormat)) began construction on the first geothermal plant the week of February 14, 2022, and plans to begin geothermal production by December 2022; therefore, we assume it is possible that both construction and production will occur in 2022. To see a more detailed overview of the approved and permitted project, refer to the BLM environmental assessment (BLM 2021b, entire).

As mentioned above, two geothermal exploration projects were approved by the BLM in 2010 and 2011 (BLM 2010, entire; BLM 2011, entire); however, required monitoring and baseline environmental surveys for those exploration projects did not occur (BLM 2021a, pp. 3–17–3–18). As a result, key environmental information (*e.g.,* water quality metrics data such as flow, water temperature, and water pressure) is lacking to determine the effects of the project on the surrounding environment. Most of the information collected during this timeframe were singular measurements taken quarterly or annually, which do not characterize the variability in environmental conditions observed in Dixie Meadows. The lack of robust baseline environmental information is part of why we, along with experts from the expert knowledge elicitation workshop panel (described below), conclude that the Monitoring and Mitigation Plan associated with the Dixie Meadows Geothermal Utilization Project, discussed further in the Conservation Efforts and Regulatory Mechanisms section, below, needs further refinement to adequately detect and respond to changes in the wetlands and toad populations. The ability of the Monitoring and Mitigation Plan to detect changes in baseline conditions, and mitigate those changes, is discussed further in the Expert Knowledge

Elicitation and Conservation Efforts and Regulatory Mechanisms sections, below.

Expert Knowledge Elicitation

An expert knowledge elicitation workshop was carried out during the period August 17–20, 2021, using the [then] proposed Dixie Meadows Geothermal Utilization Project, January 2021 draft environmental assessment (BLM 2021a, entire) and draft Monitoring and Mitigation Plan (BLM 2021a, Appendix H), and a summary of all existing data to determine the range of outcomes of the approved project. This analysis used a modified version of the Sheffield elicitation framework, which follows established best practices for eliciting expert knowledge (Gosling 2018, entire; O'Hagan 2019, pp. 73–81; Oakley and O'Hagan 2019, entire). The expert panel consisted of a multidisciplinary group with backgrounds in the geologic structure of basin and range systems, various components of deep and shallow groundwater flow, as well as geothermal exploration and development. All panelists have direct experience in the Great Basin, and most in Dixie Valley and Dixie Meadows, specifically. The panelists were asked questions regarding the time until peak changes to the spring system would occur, the ability of the Monitoring and Mitigation Plan to detect and mitigate change, the amount of time it would take to mitigate change if mitigation is possible, and what the peak changes to springflow and spring temperature could be. For a detailed overview of the expert knowledge elicitation process, refer to the SSA report (Service 2022, Appendix A).

The expert panelists concluded that the Dixie Meadows spring system will change quickly, and detrimentally, once geothermal energy production begins, with a median response time of roughly 4 years and a 90 percent chance that the largest magnitude changes will occur within 10 years (Service 2022, Appendix A). Uncertainty within individual judgments on response time was related to the efficacy of mitigation measures and interactions between short-term impacts from geothermal development and longer term impacts from climate change and consumptive water use.

Experts had low confidence in the ability of the Monitoring and Mitigation Plan to both detect and mitigate changes to the temperature and flow of surface springs in Dixie Meadows. Although the aggregated distribution for the ability to detect changes ranged from 0 to 100 percent, the median expectation was a roughly 38 percent chance of detecting changes (Service 2022, Appendix A). These judgments reflect an expectation that there is less than 50 percent confidence from the experts that the Monitoring and Mitigation Plan could detect changes in the spring system due to the complexity and natural variability of the system, limited baseline data, and perceived inadequacies of the Monitoring and Mitigation Plan. The Monitoring and Mitigation Plan was perceived as inadequate due in part to limited monitoring locations, low frequency of monitoring and reporting, and lack of a statistical approach for addressing variability and uncertainty. The degree of confidence in the ability to mitigate environmental impacts of the project was even lower (median of roughly 29 percent; Service 2022, Appendix A) based on previously stated concerns about the plan, lack of information on how water quality would be addressed, interacting effects of climate change and extractive water use, and questions about the motivation to mitigate if measures ran counter to other operating goals of the plant.

The expert panel was asked what timeframe would be required to fully mitigate changes in spring temperature and springflow once detected—assuming that changes have been detected, it is technically feasible to mitigate the problem, and there is a willingness to participate from all parties. Based on those assumptions, the experts judged that it could take multiple years to mitigate perturbations once detected, with a median expectation of 4 years (Service 2022, Appendix A).

At the time the expert knowledge elicitation occurred, the Dixie Meadows Geothermal Utilization Project was not approved. However, in the discussion about expected peak change in spring temperature and springflow, the experts considered how the spring system would change if the geothermal project was not approved or the Monitoring and Mitigation Plan was improved. Expert judgments on expected peak change in spring temperature and springflow that considered the geothermal project not getting approved and an improvement in the Monitoring and Mitigation Plan were not considered in our analysis because the geothermal project was approved (BLM 2021b, entire) in November 2021. Additionally, although the Monitoring and Mitigation Plan was changed, changes were minimal and did not affect the ability of the plan to detect or mitigate changes. Therefore, the results of the expert knowledge elicitation completed on the January 2021 draft environmental assessment and the then-existing Monitoring and Mitigation Plan (BLM 2021a, entire) would not have changed meaningfully in response to the final approved environmental assessment and Monitoring and Mitigation Plan (BLM 2021b, entire).

Although there is large uncertainty in the magnitude of expected changes from the approved project, there is a high degree of certainty that geothermal energy development will have severe and negative effects on the geothermal springs relied upon by the Dixie Valley toad, including reductions in spring temperature and springflow, which directly affect the resource needs of the species. The plausible range of changes to spring temperatures ranged from a lower limit of a 55- °C (99- °F) decrease to an upper limit of a 10- °C (18- °F) decrease (Service 2022, Appendix A). This uncertainty is due to the wide spatial variation in spring temperatures across the spring system and reflects the expectation that the spring temperatures could plausibly drop to ambient levels (*i.e.,* a complete loss of geothermal contributions). Similarly, the lower limit of the aggregated expert judgments considered it plausible that springs in Dixie Meadows could dry up (no surface discharge) as the geothermal contribution was reduced, with an upper limit of a 31-percent decrease in surface discharge. These judgments reflect the high anticipated pumping rates of the proposed plants, perceived inadequacies with the Monitoring and Mitigation Plan, and the fact that drying of surface springs has been documented at other nearby geothermal development projects (BLM 2019, p. 1).

Scenario Considerations for Current and Future Conditions

In the SSA report, we analyzed four scenarios based on the expert knowledge elicitation. As mentioned earlier, these scenarios could plausibly affect both the current and future condition of the species. Three of the scenarios (scenarios 1–3) assume the Dixie Meadows Geothermal Utilization Project will begin construction as approved, while scenario 4 assumes there will be no geothermal development or the Monitoring and Mitigation Plan will be significantly improved before project implementation. Scenario 4 was not considered in this decision given the approval of the geothermal project, the beginning of construction on the project, and the lack of substantive improvements to the Monitoring and Mitigation Plan. As discussed above in the Expert Knowledge Elicitation section, we have low confidence in the ability of the Monitoring and Mitigation

Plan to detect or mitigate changes to the spring system. Therefore, only scenarios 1–3 were considered for this decision.

The scenarios incorporated the following considerations from the expert knowledge elicitation: The efficacy of the Monitoring and Mitigation Plan; how the surficial spring system will respond to geothermal production; and changes in temperature, evapotranspiration, and extreme precipitation events related to climate change. For all scenarios, we project that the basin will remain over-allocated. The lower bound of scenarios (scenario 1) projects that the Monitoring and Mitigation Plan is ineffective, the springs dry completely, and there are increases in air temperature, evapotranspiration, and extreme precipitation events seen under RCP 8.5. This scenario represents the low confidence the experts have in the Monitoring and Mitigation Plan and reflects the results in a similar situation that occurred in Jersey Valley where geothermal production caused the spring system to go dry within 3 years of the start of operation (BLM 2022, p. 1; NDWR 2022, unpublished data). The upper bound of scenarios (scenario 3) projects that the Monitoring and Mitigation Plan is moderately effective, geothermal production has moderate effects on the surficial spring system, and increases in temperature, evapotranspiration, and moderate changes in precipitation seen under RCP 4.5 occur. Because the experts expressed less than 50 percent confidence in the ability of the Monitoring and Mitigation Plan to both detect and mitigate change, it was logical for this scenario to represent the upper bound of plausibility.

These scenarios include the range of peak changes to spring temperature and springflow as discussed earlier (a 55- °C (99- °F)) decrease to a 10- °C (18- °F) decrease in spring temperature and a 100-percent decrease to a 31-percent decrease in springflow). These projected changes in spring temperature and flow were used as inputs into a multistate, dynamic occupancy model, which is described further in the SSA report (Service 2022, pp. 61–64). Scenario 1 results in complete reproductive failure because of the drying of springs, and scenarios 2 and 3 project a risk of reproductive failure after 1 year of geothermal production (lower credible interval of 0 percent of the range occupied by larvae). Under scenario 2, the mean percentage of the range occupied by larvae drops to 0 percent by 2024 with an upper credible interval of 2 percent of the range occupied by larvae. Scenario 3 projects a mean of 1 percent of the range occupied by larvae with an upper credible interval of 5 percent of the range occupied by 2026. All scenarios result in a high level of risk of reproductive failure for the Dixie Valley toad in the near future.

Although the occupancy model described above represents the best available projection framework for the Dixie Valley toad, not all demographic and risk factors relevant to understanding species viability are included. One major threat not accounted for is the synergistic effect of changes in temperature with the risk posed by exposure to the fungal pathogen chytrid fungus that causes the disease chytridiomycosis (see Disease, above). Chytrid fungus growth and survival are sensitive to both cold and hot temperatures, with optimal growth conditions in culture occurring between 15 and 25 °C (59 and 77 °F). There is equivocal evidence on whether colder temperatures limit the effects of chytrid fungus (Voyles et al. 2017, pp. 367–369); however, hot geothermal waters above 25 °C (77 °F) appear to provide protection against chytrid fungus by allowing individuals to raise body temperatures through behavioral fever (Forrest and Schlaepfer 2011, entire; Murphy et al. 2011, p. 39). This information indicates that future decreases in water temperature associated with scenarios 2 and 3 are likely to increase the risk that chytrid fungus could become established within the Dixie Valley toad population. If chytrid fungus becomes established within the Dixie Valley toad population, there would be negative, and plausibly catastrophic, effects to the species.

The seasonal timing of changes in water temperature is also particularly important. Dixie Valley toads strongly rely on aquatic environments throughout their life cycle (Halstead et al. 2021, entire). Unlike Western toads that may be found hundreds to thousands of meters from aquatic breeding sites, in surveys Dixie Valley toads are almost always found in water (Halstead et al. 2021, pp. 30–31). When not detected in water, Dixie Valley toads are found 4.2 m (13.8 ft) from water on average and are found both in and above water during brumation (Halstead et al. 2021, p. 30). Autumn brumation sites are found to be warmer than random locations available, and toads are 1.3 times more likely to select sites for each 1- °C increase in water temperature (Halstead et al. 2021, p. 30). Because toads are found closer to spring heads in autumn compared to sites selected during other times of year, it is likely that they are selecting areas where water temperatures will remain stable throughout the winter (Halstead et al. 2021, p. 34). The selection of areas with stable, warm water temperatures indicates that reductions in geothermal contributions during winter could lead to thermal stress, reductions in available habitat as waters cool, or even mortality if geothermal contributions are removed completely or reduced to a level that toads are unable to adapt their brumation strategies.

Conservation Efforts and Regulatory Mechanisms

The Dixie Valley toad occurs only on Federal lands (the DoD's Fallon Naval Air Station and BLM). Various laws, regulations, policies, and management plans may provide conservation or protections for Dixie Valley toads. As such, the following management plans are the existing conservation tools driving the management of Dixie Valley toads and their habitat:

- As required by the Sikes Act (16 U.S.C. 670 *et seq.,* as amended), the DoD has an integrated natural resources management plan in place for supporting both the installation mission as well as protecting and enhancing installation resources for multiple use, sustainable yield, and biological integrity. This plan also includes a strategic plan for amphibian (and reptile) conservation and management, to include management for Dixie Meadows and the Dixie Valley toad.
- As required by the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*), BLM has a resource management plan for all actions and authorizations involving BLM-administered lands and resources, including actions specific to Dixie Valley toads and their habitat.

In compliance with the National Environmental Policy Act of 1970 (as amended; 42 U.S.C. 4321 *et seq.*), which is a procedural statute, for projects that Federal agencies fund, authorize, or carry out, BLM, with input from Ormat, developed a Monitoring and Mitigation Plan (McGinley and Associates 2021, entire) for the Dixie Meadows Geothermal Utilization Project; it is an appendix in BLM's environmental assessment (BLM 2021b, Appendix H). The goal of the Monitoring and Mitigation Plan is to identify hydrologic and biologic resources, spring-dependent ecosystems, aquatic habitat, and species that could be affected by geothermal exploration, production, and injection in the Dixie Meadows area (McGinley and Associates 2021, p. 1). The Monitoring and Mitigation Plan will describe the plan Ormat would implement to monitor and mitigate potential effects to those resources,

ecosystems, habitat, and species (McGinley and Associates 2021, p. 1).

The Monitoring and Mitigation Plan includes adaptive management and mitigation measures that Ormat would implement if changes are detected in baseline conditions and threshold values are exceeded. Management actions may include geothermal reservoir pumping and injection adjustments (*e.g.,* redistribution of injection between shallow and deep aquifers). Other more aggressive actions include augmenting affected springs with geothermal fluids or fresh water to restore preproduction temperature, flow, stage, and water chemistry. The Monitoring and Mitigation Plan states that if mitigation actions are not sufficient for the protection of species and aquatic habitat, pumping and injection would be suspended until appropriate mitigation measures are identified, implemented, and shown to be effective (McGinley and Associates 2021, p. 34).

We, along with other interested parties (*e.g.,* Department of the Navy, NDOW) provided comments to the BLM regarding the Monitoring and Mitigation Plan, which was first made available to the public in January 2021. We have low confidence in the ability of the Monitoring and Mitigation Plan to adequately detect and respond to changes because of the complexity and natural variability of the spring system, limited baseline data, and perceived inadequacies of the plan. We determined the Monitoring and Mitigation Plan is inadequate because of the inadequate time to collect relevant baseline information prior to beginning operation of the plant, limited monitoring locations, low frequency of monitoring and reporting, lack of a statistical approach for addressing variability and uncertainty, lack of information on how water quality would be addressed, interacting effects of climate change and extractive water use, and uncertainty about mitigation if measures ran counter to other operating goals of the plant.

The Dixie Valley toad is classified as protected by the State of Nevada under Nevada Administrative Code (NAC) 503.075(2)(b). Per NAC 503.090(1), there is no open season on those species of amphibian classified as protected. Per NAC 503.094, the State issues permits for the take and possession of any species of wildlife for strictly scientific or educational purposes. The State's Department of Conservation and Natural Resources includes the Nevada Division of Natural Heritage (NDNH), which tracks the species status of plants and animals in Nevada. The NDNH recognizes Dixie Valley toads as critically imperiled, rank *S1*. Ranks of *S1* are defined as species with very high risks of extirpation in the jurisdiction due to very restricted range, very few populations or occurrences, very steep declines, severe threats, or other factors.

Determination of Status for the Dixie Valley Toad

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of ''endangered species'' or ''threatened species.'' The Act defines an ''endangered species'' as a species in danger of extinction throughout all or a significant portion of its range and a ''threatened species'' as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of an ''endangered species'' or a ''threatened species'' because 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.

In conducting our status assessment of the Dixie Valley toad, we evaluated all identified threats under the Act's section 4(a)(1) factors and assessed how the cumulative impact of all threats acts on the viability of the species as a whole. That is, all the anticipated effects from both habitat-based and direct mortality-based threats are examined in total and then evaluated in the context of what those combined negative effects will mean to the future condition of the Dixie Valley toad.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we determined that the Dixie Valley toad is at risk of extinction throughout its range primarily due to the approval and commencement of geothermal development. Other threats identified in this status determination include increased severity of drought due to climate change (Factor A), the threat of chytrid fungus establishing itself in the population (Factor C), groundwater pumping associated with human consumption, agriculture, and county planning (Factor A), and predation by invasive bullfrogs (Factor C). These three threats will likely exacerbate the main threat of geothermal development. Existing regulatory mechanisms do not address the primary threat to the species (Factor D).

Construction of the Dixie Meadows Geothermal Utilization Project has begun, and geothermal production is assumed to begin before the end of 2022. Based upon the best available scientific and commercial information as described in this determination, the Service has a high degree of certainty that geothermal production will have severe, negative effects on the geothermal springs the species relies upon for habitat (Factor A). These negative effects include reductions in spring temperature and springflow, which directly affect the needs of the species (*i.e.,* adequate water temperature, sufficient wetted areas, sufficient wetland vegetation, including vegetation cover, and adequate water quality (see *Species Needs,* above)). The best available information indicates that a complete reduction in springflow and significant reduction of water temperature are plausible outcomes of the geothermal project, and these conditions could result in the species no longer persisting (*i.e.,* becoming extinct or functionally extinct as a result of significant habitat degradation, or no reproduction due to highly isolated, non-recruiting individuals).

The narrowly distributed, isolated nature of the single, small population of the species indicates that the Dixie Valley toad will have no ability to withstand stochastic or catastrophic events through dispersal. Because the species occurs in only one spring system and has experienced little historical variation, it has low potential to adapt to a fast-changing environment. As a single-site endemic with no dispersal opportunities outside the current range and low adaptive capacity, the species has inherently low redundancy and representation, and depends entirely on the continued availability of wetland habitat in Dixie Meadows. Low redundancy and representation make the Dixie Valley toad particularly vulnerable to fast-paced change to its habitat and catastrophic events, any of which could plausibly result from the permitted Dixie Meadows Geothermal Utilization Project.

The Dixie Valley toad exists in one population that will likely be directly affected to a significant degree by geothermal production in a short timeframe, resulting in a high risk that the species could become extinct.

In addition to the current development of the geothermal project,

a combination of threats will act synergistically to exacerbate effects from geothermal production on the Dixie Meadows spring system. A reduction in springflow could be exacerbated by the greater severity of droughts being experienced in the Southwestern United States, including Nevada (Snyder et al. 2019, pp. 2–4; Williams et al. 2020, pp. 1–5). Higher temperatures and drier conditions could result in greater evapotranspiration, leading to increased drying of wetland habitat. A reduction in water temperature could allow chytrid fungus to become established and negatively impact the Dixie Valley toad population. Chytrid fungus would likely be catastrophic to Dixie Valley toads, as it has caused severe declines in other amphibian species, and the fungus has been found in another known vector species (bullfrog) in Dixie Valley (Forrest 2013, p. 77). Bullfrogs themselves are a threat to the species, as Dixie Valley toads could be easily preyed upon because of their small size. If bullfrogs were to become established throughout Dixie Valley toad habitat, there would likely be a reduction in Dixie Valley toad abundance.

Thus, after assessing the best available information, we conclude that the Dixie Valley toad is currently in danger of extinction throughout all of its range due to the immediacy of the threat of geothermal production, including negative effects such as reductions in spring temperature and springflow, which would directly affect the needs of the species (*i.e.,* adequate water temperature, sufficient wetted areas, sufficient wetland vegetation, including vegetation cover, and adequate water quality), and low confidence in the ability of the Mitigation and Monitoring Plan to effectively minimize and mitigate for potential effects that are likely to manifest in the near term. We find that threatened species status is not appropriate because the threat of extinction is imminent as opposed to being likely to develop within the foreseeable future.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. We have determined that the Dixie Valley toad is in danger of extinction throughout all of its range and, accordingly, did not undertake an analysis of any significant portion of its range. Because the Dixie Valley toad warrants listing as endangered throughout all of its range, our determination does not conflict with the decision in *Center for Biological Diversity* v. *Everson,* 435 F. Supp. 3d 69 (D.D.C. 2020), because that decision related to SPR analyses for species that warrant listing as threatened, not endangered, throughout all of their range.

Determination of Status

Our review of the best available scientific and commercial information indicates that the Dixie Valley toad meets the definition of an endangered species. For the reasons discussed below, we further find that the threats facing the Dixie Valley toad at this time constitute an emergency posing a significant risk to the well-being of the Dixie Valley toad. Therefore, we are emergency listing the Dixie Valley toad as an endangered species in accordance with sections 3(6), 4(a)(1), and 4(b)(7) of the Act.

Reasons for Emergency Determination

Under section 4(b)(7) of the Act and regulations at 50 CFR 424.20, we may emergency list a species if the threats to the species constitute an emergency posing a significant risk to its well-being. An emergency listing expires 240 days following publication in the **Federal Register** unless, during this 240-day period, we list the species following the normal listing procedures. In accordance with the Act, if at any time after we publish this emergency rule, we determine that substantial evidence does not exist to warrant such a rule, we will withdraw it.

We conclude that emergency listing the Dixie Valley toad as endangered is warranted. In making this determination, we have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats faced by the Dixie Valley toad. As discussed above in detail, the Dixie Meadows Geothermal Utilization Project poses a high degree of threat to the Dixie Valley toad, such that it poses a significant risk to the well-being of the species. Moreover, the project has been permitted, construction has already begun, and power plant production is projected to begin this calendar year. Significant and possibly irreversible negative impacts to the species may occur before listing could become effective following completion of the usually required rulemaking procedures for listing a species. We therefore conclude that the current circumstances constitute an emergency.

By emergency listing the Dixie Valley toad as an endangered species, the protections of the Act (through sections 7, 9, and 10) and recognition that will immediately become available to the species will increase the likelihood that it can be saved from extinction.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan identifies site-specific management actions that set a trigger for review of the five factors that control whether a species remains endangered or may be downlisted or delisted and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental

organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*) (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education.

Following publication of a final listing rule, funding for recovery actions is available from a variety of sources, including Federal budgets, State programs, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Nevada will be eligible for Federal funds to implement management actions that promote the protection or recovery of the Dixie Valley toad. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the Dixie Valley toad is only emergency listed under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph may include, but are not limited to, management and any other landscape-altering activities on Federal lands: Aquatic habitat restoration, fire management plans, fire suppression, fuel reduction treatments, mining permits, integrated natural resources management plans, land resource management plans, oil and natural gas permits, renewable energy development, renewable and alternative energy projects, and geothermal project approvals and implementation.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) endangered wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any species listed as an endangered species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22. With regard to endangered wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed those activities that would or would not constitute a violation of section 9 of the Act. Based on the best available information, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

(1) Vehicle use on existing roads and trails in compliance with the BLM Carson City District's resource management plan.

(2) Recreational use with minimal ground disturbance (*e.g.,* hiking, walking).

Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act if they are not authorized in accordance with applicable law, including the Endangered Species Act; this list is not comprehensive:

(1) Unauthorized handling or collecting of the species;

(2) Unauthorized livestock grazing that results in direct mortality and direct or indirect destruction of vegetation and aquatic habitat;

(3) Destruction/alteration of the species' habitat by draining, ditching, stream channelization or diversion, or diversion or alteration of surface or ground water flow into or out of the wetland;

(4) Introduction of nonnative species that compete with or prey upon the Dixie Valley toad or wetland vegetation;

(5) The unauthorized release of biological control agents that attack any life stage of the Dixie Valley toad;

(6) Modification of the vegetation components on sites known to be occupied by the Dixie Valley toad; and

(7) Modification of spring and wetland water temperatures.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Reno Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994

(Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951, May 4, 1994), E.O. 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We requested information from the Paiute-Shoshone Tribe of the Fallon Reservation and Colony and have continued to coordinate during the SSA process. We are requesting the Tribe's partner review of the SSA report concurrent with the open comment period identified in the proposed rule that is published concurrently with this emergency rule and found in the Proposed Rules section of this issue of the **Federal Register** (see Docket No. FWS–R8–ES–2022–0024 in *https://www.regulations.gov*). We will continue to work with Tribal entities during the development of a final listing determination for the Dixie Valley toad.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Reno Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Reno Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11 in paragraph (h) by adding an entry for ''Toad, Dixie Valley'' to the List of Endangered and Threatened Wildlife in alphabetical order under Amphibians to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
AMPHIBIANS				
*	*	*	*	*
Toad, Dixie Valley	*Anaxyrus williamsi*	Wherever found	E	87 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS]; 4/7/2022.
*	*	*	*	*

* * * * *

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–07374 Filed 4–6–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 220404–0083]

RIN 0648–BL15

Fisheries of the Northeastern United States; Atlantic Spiny Dogfish Fishery; 2022 Specifications and Trip Limit Adjustment

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

ACTION: Final rule.

SUMMARY: NMFS issues final Atlantic spiny dogfish specifications for the 2022 fishing year, and an adjustment to the commercial trip limit, as recommended by the Mid-Atlantic and New England Fishery Management Councils. This action is necessary to establish allowable harvest levels and other management measures to prevent overfishing while enabling optimum yield, using the best scientific information available. This rule also informs the public of the final fishery 2022 specifications and management measures.

DATES: Effective on May 1, 2022.

ADDRESSES: The Mid-Atlantic Fishery Management Council prepared a Supplemental Information Report (SIR) for these specifications that describes the action, any changes from the original environmental assessment (EA), and analyses for this 2022 specifications trip limit adjustment action. Copies of the SIR, original EA, and other supporting documents for this action, are available upon request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the internet at *https://www.mafmc.org/supporting-documents.*

FOR FURTHER INFORMATION CONTACT: Cynthia Ferrio, Fishery Policy Analyst, (978) 281–9180.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic and New England Fishery Management Councils jointly manage the Atlantic Spiny Dogfish Fishery Management Plan (FMP), with the Mid-Atlantic Council acting as the administrative lead. Additionally, the Atlantic States Marine Fisheries Commission manages the spiny dogfish fishery in state waters from Maine to North Carolina through an interstate

fishery management plan. The Councils' FMP requires the specification of regulatory harvest limits, including: An acceptable biological catch (ABC); annual catch limit (ACL); annual catch target (ACT); total allowable landings value (TAL); and coastwide commercial quota. These limits and other management measures may be set for up to five fishing years at a time, with each fishing year running from May 1 through April 30. This action implements status quo specifications for fishing year 2022 and an increased commercial trip limit for the Atlantic spiny dogfish fishery, as recommended by the Councils.

The spiny dogfish fishery is currently operating under multi-year specifications for fishing years 2021 and 2022 based on a 2020 assessment update and the Mid-Atlantic Council's updated risk policy. The Councils found no reason to change the previously projected status quo specifications for fishing year 2022. However, both Councils did recommend an increase to the commercial trip limit based on requests from fishery stakeholders to provide more economic stability and opportunity to fully achieve the provided commercial quota.

The proposed rule for this action published in the **Federal Register** on February 25, 2022 (87 FR 10762), and comments were accepted through March 14, 2022. NMFS received five comments from the public, and no changes to the final rule are necessary as a result of those comments (see Comments and Responses for additional detail). Additional background information regarding the development of these specifications was provided in the proposed rule and is not repeated here.

Final Measures

This action implements the Councils' recommendations for status quo 2022 spiny dogfish catch limit specifications (Table 1), and a 25-percent increase to the commercial trip limit from 6,000 lb (2,722 kg) per trip to 7,500 lb (3,402 kg) per trip, as outlined in the proposed rule.

TABLE 1—FINAL SPINY DOGFISH FISHERY SPECIFICATIONS FOR FISHING YEAR 2022

	Million (lb)	Metric (tons)
ABC	38.58	17,498
ACL = ACT	38.48	17,453
TAL	29.68	13,461
Commercial Quota	29.56	13,408

There is a research track stock assessment in progress for Atlantic spiny dogfish. This assessment is expected to inform development of the next set of specifications, beginning in fishing year 2023.

Comments and Responses

The public comment period for the proposed rule ended on March 14, 2022, and NMFS received five comments from the public. No changes were made to final rule as a result of these comments.

Two commenters voiced similar concerns with the action, saying that increasing the trip limit only benefits the processors but not the harvesters. Both were also concerned that a higher limit will cause the price per pound to crash and ruin the market for dogfish. Another commenter agreed with the first two comments about the potential price drop, and also said that the trip limit should remain status quo until after the current stock assessment is complete. The fourth comment also disagrees with the trip limit increase, because there is no data showing that catch rates in the fishery have increased to warrant this change. This commenter is concerned that without these data, increasing the trip limit will cause a loss of industry jobs.

These concerns were discussed throughout the development of this action and in discussion of trip limit adjustments in recent years. There has been support for raising the trip limit from harvesters as well as processors during this action's development in 2021 by members of the public at meetings of the Advisory Panel, Committee, Atlantic Marine Fisheries Commission, and both Councils. Further, an increase of 25 percent (1,500 lb/680 kg) was recommended as a compromise when compared to other suggested alternatives that could have raised the limit even more. The change in this action is expected to provide some additional flexibility and opportunity to industry, with minimal negative impacts on the fishery, market, and other aspects of the human environment. Both Councils also plan to reconsider the trip limit after the results from the stock assessment become available.

The final comment was submitted by a college student and is primarily a brief history of Atlantic spiny dogfish management. This comment supports the action overall, but cautions that economic gain should not be valued more highly than the health of the stock. NMFS agrees with the sentiments of this comment, and will not implement catch limits or management measures that are likely to cause overfishing, in accordance with National Standard 1 of the Magnuson-Stevens Act.

Changes From the Proposed Rule

NMFS has not made any changes to the proposed regulatory text, and there are no substantive changes from the proposed rule.

Classification

Pursuant to section 304(b)(3) of the Magnuson Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator, Greater Atlantic Region, has determined that these final specifications are necessary for the conservation and management of the Atlantic spiny dogfish fishery, and that they are consistent with the Atlantic Spiny Dogfish FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

The Councils reviewed the regulations for this action and deemed them necessary and appropriate to implement consistent with section 303(c) of the Magnuson-Stevens Act.

The need to implement these measures in a timely manner to ensure that these final specifications and increased trip limit are in place for the start of the 2022 spiny dogfish fishing year constitutes good cause under the authority contained in 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date of this action. The 2022 fishing year begins on May 1, 2022. A delay in effectiveness beyond May 1 would be contrary to the public interest as it could create confusion in the spiny dogfish industry, and cause potential economic harm to the fishery through lost opportunity to fish under the higher

trip limit. NMFS has also received several direct requests from industry stakeholders that the higher trip limit be implemented as soon as possible, which supports the conclusion that any further delay is contrary to public interest.

Finally, regulated parties do not require any additional time to come into compliance with this rule, and thus, a 30-day delay before the final rule becomes effective does not provide any benefit. Unlike actions that require an adjustment period, vessels fishing for spiny dogfish will not have to purchase new equipment or otherwise expend time or money to comply with these management measures. Rather, complying with this action simply means adhering to the new, increased trip limit. Fishery stakeholders have also been involved in the development of this action and are anticipating this rule, even requesting it be effective as soon as practicable. Therefore, NMFS finds good cause not to delay this final rule's effectiveness, consistent with 5 U.S.C. 553(d)(3). As a result, there is good cause to implement this action on May 1, 2022.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification, and the initial certification remains unchanged. As a result, a final regulatory flexibility analysis is not required and none was prepared.

This final rule does not duplicate, conflict, or overlap with any existing Federal rules.

This action contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: April 4, 2022.

Carrie Robinson,

Acting Deputy Assistant Administrator for Regulatory Programs,National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.235, revise paragraph (a)(1) to read as follows:

§ 648.235 Spiny dogfish possession and landing restrictions.

(a) * * *

(1) Possess up to 7,500 lb (3,402 kg) of spiny dogfish per trip; and

* * * * *

[FR Doc. 2022–07417 Filed 4–6–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 67
Thursday, April 7, 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.

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 518

RIN 3141–AA72

Self-Regulation of Class II Gaming

AGENCY: National Indian Gaming Commission.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission (NIGC) proposes to amend its regulations regarding self-regulation of Class II gaming under the Indian Gaming Regulatory Act. The proposed rule will amend the regulations to address an ambiguity in the petitioning process and clarify and expand the Office of Self-Regulation's (OSR) role once the Commission issues a certificate. Notably, the proposed rule: Clarifies the NIGC may issue a final decision on issuing a certificate within 30 days instead of after 30 days; enumerates the OSR is the correct party to receive notifications of material changes from self-regulated tribes; clarifies the OSR will be the proponent of any case to revoke a certificate of self-regulation before the Commission; enables the OSR to obtain information from a self-regulated tribe; and clarifies that, in any revocation proceeding, the OSR has the burden to show just cause for the revocation and carry that burden by a preponderance of the evidence.

DATES: The agency must receive comments on or before June 6, 2022.

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

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: information@nigc.gov.*
- *Fax:* (202) 632–7066.
- *Mail:* National Indian Gaming Commission, 1849 C Street NW, MS 1621, Washington, DC 20240.
- *Hand Delivery:* National Indian Gaming Commission, 90 K Street NE, Suite 200, Washington, DC 20002, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: James A. Lewis, National Indian Gaming Commission; Telephone: (202) 632–7003.

SUPPLEMENTARY INFORMATION:

I. Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments providing the factual basis behind supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal.

II. 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 National Indian Gaming Commission (NIGC or Commission) and sets out a comprehensive framework for the regulation of gaming on Indian lands.

On January 31, 2012, the Commission published a notice of proposed rulemaking to promulgate part 518, the procedures controlling self-regulation. 77 FR 4714 (Jan. 31, 2012). Once promulgated, part 518 established the procedures for the Commission and the OSR to, among other things, receive, evaluate, recommend, issue, deny, or revoke a certificate of self-regulation.

On September 1, 2013, after initial publication, the Commission enacted minor revisions to part 518 to amend certain timelines and an incorrect section heading and reference to IGRA. 78 FR 37114 (Sept. 1, 2013).

III. Development of the Proposed Rule

On June 9, 2021, the National Indian Gaming Commission sent a Notice of Consultation announcing that the Agency intended to consult on several topics, including proposed changes to the procedures controlling self-regulation. Prior to consultation, the Commission released proposed discussion drafts of the regulations for review. The proposed amendments to the procedures controlling self-regulation are intended to improve the Agency's efficiency in evaluating petitions for self-regulation, reduce the time it takes to obtain a certificate of self-regulation and clarify the Office of Self-Regulation's functions. The Commission held two virtual consultation sessions in September and one virtual consultation in October of 2021 to receive tribal input on any proposed changes.

The Commission reviewed all comments received through consultation and now proposes these changes, which it believes will improve the procedures for self-regulation.

IV. 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 proposed rule does not unduly

burden the judicial system and meets the requirements of section 3(a) and 3(b)(2) of the order.

National Environmental Policy Act

The Commission has determined that the proposed 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 3141–0003.

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 to the public, announcing the Agency intended to consult on several topics, including proposed changes to the procedures for self-regulation. The Commission held two virtual consultation sessions in September and one virtual consultation session in October of 2021 to receive tribal input on proposed changes.

List of Subjects in 25 CFR Part 518

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

Therefore, for reasons stated in the preamble, 25 CFR part 518 is proposed to be amended as follows:

PART 518—SELF-REGULATION OF CLASS II GAMING

■ 1. The authority citation for part 518 is amended to read as follows:

Authority: 25 U.S.C. 2706(b)(10); 25 U.S.C. 2710(c).

■ 2. Revise §§ 518.1 through 518.7 to read as follows:

Sec.
518.1 What does this part cover?
518.2 Who will administer the self-regulation program for the Commission?
518.3 Who is eligible to petition for a certificate of self-regulation?
518.4 What must a tribe submit to the Commission as part of its petition?
518.5 What criteria must a tribe meet to receive a certificate of self-regulation?
518.6 What are the responsibilities of the Office of Self-Regulation in the certification process?
518.7 What process will the Commission use to review and certify petitions?

* * * * *

§ 518.1 What does this part cover?

This part sets forth requirements for obtaining a certificate of self-regulation of Class II gaming operations under 25 U.S.C. 2710(c). When the Commission issues a certificate of self-regulation, the certificate is issued to the tribe, not to a particular gaming operation. The certificate applies to all Class II gaming activity conducted by the tribe holding the certificate.

§ 518.2 Who will administer the self-regulation program for the Commission?

The self-regulation program will be administered by the Office of Self-Regulation. The Chair shall appoint a Director to administer the Office of Self-Regulation.

§ 518.3 Who is eligible to petition for a certificate of self-regulation?

A tribe is eligible to petition the Commission for a certificate of self-regulation of Class II gaming if, for a three (3)-year period immediately preceding the date of its petition:

(a) The tribe has continuously conducted such gaming;

(b) All gaming that the tribe has engaged in, or has licensed and regulated, on Indian lands within the tribe's jurisdiction, is located within a State that permits such gaming for any purpose by any person, organization or entity (and such gaming is not otherwise specifically prohibited on Indian lands by Federal law), in accordance with 25 U.S.C. 2710(b)(1)(A);

(c) The governing body of the tribe has adopted an ordinance or resolution that the Chair has approved, in accordance with 25 U.S.C. 2710(b)(1)(B);

(d) The tribe has otherwise complied with the provisions of 25 U.S.C. 2710; and

(e) The gaming operation and the tribal regulatory body have, for the three (3) years immediately preceding the date of the petition, maintained all records required to support the petition for self-regulation.

§ 518.4 What must a tribe submit to the Commission as part of its petition?

A petition for a certificate of self-regulation is complete under this part when it contains:

(a) Two copies on 8½″ x 11″ paper of a petition for self-regulation approved by the governing body of the tribe and certified as authentic by an authorized tribal official;

(b) A description of how the tribe meets the eligibility criteria in § 518.3, which may include supporting documentation; and

(c) The following information with supporting documentation:

(1) A brief history of each gaming operation(s), including the opening dates and periods of voluntary or involuntary closure;

(2) An organizational chart of the tribal regulatory body;

(3) A brief description of the criteria tribal regulators must meet before being eligible for employment as a tribal regulator;

(4) A brief description of the process by which the tribal regulatory body is funded, and the funding level for the three years immediately preceding the date of the petition;

(5) A list of the current regulators and employees of the tribal regulatory body, their complete resumes, their titles, the dates they began employment, and, if serving limited terms, the expiration date of such terms;

(6) A brief description of the accounting system(s) at the gaming operation which tracks the flow of the gaming revenues;

(7) A list of gaming activity internal controls at the gaming operation(s);

(8) A description of the record keeping system(s) for all investigations, enforcement actions, and prosecutions of violations of the tribal gaming ordinance or regulations, for the three (3)-year period immediately preceding the date of the petition; and

(9) The tribe's current set of gaming regulations, if not included in the approved tribal gaming ordinance.

§ 518.5 What criteria must a tribe meet to receive a certificate of self-regulation?

(a) The Commission shall issue a certificate of self-regulation if it determines that for a three (3)-year period, the tribe has:

(1) Conducted its gaming activity in a manner that:

(i) Has resulted in an effective and honest accounting of all revenues;

(ii) Has resulted in a reputation for safe, fair, and honest operation of the activity; and

(iii) Has been generally free of evidence of criminal or dishonest activity;

(2) Conducted its gaming operation on a fiscally and economically sound basis;

(3) Conducted its gaming activity in compliance with the Indian Gaming Regulatory Act (IGRA), Commission regulations in this chapter, and the tribe's gaming ordinance and gaming regulations; and

(4) Adopted and is implementing adequate systems for:

(i) Accounting of all revenues from the gaming activity;

(ii) Investigating, licensing and monitoring of all employees of the gaming activity;

(iii) Investigating, enforcing, prosecuting, or referring for prosecution violations of its gaming ordinance and regulations; and

(iv) Prosecuting criminal or dishonest activity or referring such activity for prosecution.

(b) A tribe may illustrate that it has met the criteria listed in paragraph (a) of this section by addressing factors such as those listed in paragraphs (b)(1) through (9) of this section. The list of factors is not all-inclusive; other factors not listed here may also be addressed and considered.

(1) The tribe adopted and is implementing minimum internal control standards which are at least as stringent as those promulgated by the Commission;

(2) The tribe requires tribal gaming regulators to meet the same suitability requirements as those required for key employees and primary management officials of the gaming operation(s);

(3) The tribe's gaming operation utilizes an adequate system for accounting of all gaming revenues from Class II gaming activity;

(4) The tribe has a dispute resolution process for gaming operation customers and has taken steps to ensure that the process is adequately implemented;

(5) The tribe has a gaming regulatory body which:

(i) Monitors gaming activities to ensure compliance with Federal and tribal laws and regulations;

(ii) Monitors the gaming revenues accounting system for continued effectiveness;

(iii) Performs routine operational or other audits of the Class II gaming activities;

(iv) Routinely receives and reviews gaming revenue accounting information from the gaming operation(s);

(v) Has access to, and may inspect, examine, photocopy and audit, all papers, books, and records of the gaming operation(s) and Class II gaming activities;

(vi) Monitors compliance with minimum internal control standards for the gaming operation;

(vii) Has adopted and is implementing an adequate system for investigating, licensing, and monitoring of all employees of the gaming activity;

(viii) Maintains records on licensees and on persons denied licenses, including persons otherwise prohibited from engaging in gaming activities within the tribe's jurisdiction;

(ix) Establishes standards for, and issues, vendor licenses or permits to persons or entities who deal with the gaming operation, such as manufacturers and suppliers of services, equipment and supplies;

(x) Establishes or approves the rules governing Class II games, and requires their posting;

(xi) Has adopted and is implementing an adequate system for the investigation of possible violations of the tribal gaming ordinance and regulations, and takes appropriate enforcement actions; and

(xii) Takes testimony and conducts hearings on regulatory matters, including matters related to the revocation of primary management officials, key employee and vendor licenses;

(6) The tribe allocates and appropriates a sufficient source of permanent and stable funding for the tribal regulatory body;

(7) The tribe has adopted and is implementing a conflict of interest policy for the regulators/regulatory body and their staff;

(8) The tribe has adopted and is implementing a system for adequate prosecution of violations of the tribal gaming ordinance and regulations or referrals for prosecution; and

(9) The tribe demonstrates that the operation is being conducted in a manner which adequately protects the environment and the public health and safety.

(c) The tribe assists the Commission with access and information-gathering responsibilities during the certification process.

(d) The burden of establishing self-regulation is upon the tribe filing the petition.

§ 518.6 What are the responsibilities of the Office of Self-Regulation in the certification process?

The Office of Self-Regulation shall be responsible for directing and coordinating the certification process. It shall provide a written report and recommendation to the Commission as to whether a certificate of self-regulation should be issued or denied, and a copy of the report and recommendation to the petitioning tribe.

§ 518.7 What process will the Commission use to review and certify petitions?

(a) Petitions for self-regulation shall be submitted by tribes to the Office of Self-Regulation.

(1) Within 30 days of receipt of a tribe s petition, the Office of Self-Regulation shall conduct a review of the tribe's petition to determine whether it is complete under § 518.4.

(2) If the tribe's petition is incomplete, the Office of Self-Regulation shall notify the tribe by letter, certified mail or return receipt requested, of any obvious deficiencies or significant omissions in the petition. A tribe with an incomplete petition may submit additional information and/or clarification within 30 days of receipt of notice of an incomplete petition.

(3) If the tribe's petition is complete, the Office of Self-Regulation shall notify the tribe in writing.

(b) Once a tribe's petition is complete, the Office of Self-Regulation shall conduct a review to determine whether the tribe meets the eligibility criteria in § 518.3 and the approval criteria in § 518.5. During its review, the Office of Self-Regulation:

(1) May request from the tribe any additional material it deems necessary to assess whether the tribe has met the criteria for self-regulation.

(2) Will coordinate an on-site review and verification of the information submitted by the petitioning tribe.

(c) Within 120 days of notice of a complete petition under § 518.4, the Office of Self-Regulation shall provide a recommendation and written report to the full Commission and the petitioning tribe.

(1) If the Office of Self-Regulation determines that the tribe has satisfied the criteria for a certificate of self-regulation, it shall recommend to the Commission that a certificate be issued to the tribe.

(2) If the Office of Self-Regulation determines that the tribe has not met the criteria for a certificate of self-regulation, it shall recommend to the Commission that it not issue a certificate to the tribe.

(3) The Office of Self-Regulation shall make all information, on which it relies

in making its recommendation and report, available to the tribe, subject to the confidentiality requirements in 25 U.S.C. 2716(a), and shall afford the tribe an opportunity to respond.

(4) The report shall include:

(i) Findings as to whether each of the eligibility criteria is met, and a summary of the basis for each finding;

(ii) Findings as to whether each of the approval criteria is met, and a summary of the basis for each finding;

(iii) A recommendation to the Commission as to whether it should issue the tribe a certificate of self-regulation; and

(iv) A list of any documents and other information received in support of the tribe's petition.

(5) A tribe shall have 30 days from the date of issuance of the report to submit to the Office of Self-Regulation a response to the report.

(d) After receiving the Office of Self-Regulation's recommendation and report, and a tribe's response to the report, the Commission shall issue preliminary findings as to whether the eligibility and approval criteria are met. The Commission's preliminary findings will be provided to the tribe within 45 days of receipt of the report.

(e) Upon receipt of the Commission's preliminary findings, the tribe can request, in writing, a hearing before the Commission, as set forth in § 518.8. Hearing requests shall be made to the Office of Self-Regulation and shall specify the issues to be addressed by the tribe at the hearing and any proposed oral or written testimony the tribe wishes to present.

(f) The Commission shall issue a final determination within 30 days after issuance of its preliminary findings if the tribe has informed the Commission in writing that the tribe does not request a hearing or within 30 days after the conclusion of a hearing, if one is held. The decision of the Commission to approve or deny a petition shall be a final agency action.

(g) A tribe may withdraw its petition and resubmit it at any time prior to the issuance of the Commission's final determination.

■ 3. Revise § 518.11 to read as follows:

§ 518.11 Does a tribe that holds a certificate of self-regulation have a continuing duty to advise the Commission of any additional information?

Yes. A tribe that holds a certificate of self-regulation has a continuing duty to advise the Office of Self-Regulation within ten business days of any changes in circumstances that are material to the approval criteria in § 518.5 and may reasonably cause the Commission to review and revoke the tribe's certificate of self-regulation. Failure to do so is grounds for revocation of a certificate of self-regulation.

■ 4. Revise §§ 518.13 and 518.14 to read as follows:

§ 518.13 When may the Commission revoke a certificate of self-regulation?

If the Office of Self-Regulation determines that the tribe no longer meets or did not comply with the eligibility criteria of § 518.3, the approval criteria of § 518.5, the requirements of § 518.10, or the requirements of § 518.11, the Office of Self-Regulation shall prepare a written recommendation to the Commission and deliver a copy of the recommendation to the tribe. The Office of Self-Regulation's recommendation shall state the reasons for the recommendation and shall advise the tribe of its right to a hearing under part 584 of this chapter or right to appeal under part 585 of this chapter. The Commission may, after an opportunity for a hearing, revoke a certificate of self-regulation by a majority vote of its members if it determines that the tribe no longer meets or did not comply with the eligibility criteria of § 518.3, the approval criteria of § 518.5, the requirements of § 518.10, or the requirements of § 518.11.

§ 518.14 May a tribe request a hearing on the Commission's proposal to revoke its certificate of self-regulation?

Yes. A tribe may request a hearing regarding the Office of Self-Regulation's recommendation that the Commission revoke a certificate of self-regulation. Such a request shall be filed with the Commission pursuant to part 584 of this chapter. Failure to request a hearing within the time provided by part 584 of this chapter shall constitute a waiver of the right to a hearing. At any hearing where the Commission considers revoking a certificate, the Office of Self-Regulation bears the burden of proof to support its recommendation by a preponderance of the evidence. The decision to revoke a certificate is a final agency action and is appealable to Federal District Court pursuant to 25 U.S.C. 2714.

Date: March 24, 2022.

E. Sequoyah Simermeyer,

Chairman.

Jeannie Hovland,

Vice Chair.

[FR Doc. 2022–06617 Filed 4–6–22; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–114339–21]

RIN 1545–BQ16

Affordability of Employer Coverage for Family Members of Employees

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; withdrawal of a notice of proposed rulemaking; notification of hearing.

SUMMARY: This document contains proposed regulations under section 36B of the Internal Revenue Code (the ''Code'') that would amend the existing regulations regarding eligibility for the premium tax credit (''PTC'') to provide that affordability of employer-sponsored minimum essential coverage (employer coverage) for family members of an employee is determined based on the employee's share of the cost of covering the employee and those family members, not the cost of covering only the employee. The proposed regulations also would add a minimum value rule for family members of employees based on the benefits provided to the family members. The proposed regulations would affect taxpayers who enroll, or enroll a family member, in individual health insurance coverage through a Health Insurance Exchange (''Exchange'') and who may be allowed a PTC for the coverage. This document also provides a notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by June 6, 2022. As of April 7, 2022, the notice of proposed rulemaking published in the **Federal Register** on September 1, 2015 (80 FR 52678), is withdrawn. A public hearing has been scheduled for Monday, June 27, 2022, at 10:00 a.m. EDT. The IRS must receive speakers' outlines of topics to be discussed at the public hearing by Monday, June 13, 2022. If no outlines are received by Monday, June 13, 2022, the public hearing will be cancelled.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–114339–21) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The IRS 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. The Department of the Treasury (''Treasury Department'') and the IRS will publish for public availability any comment submitted electronically, and, to the extent practicable any paper comments submitted, to its public docket. Send paper submissions to: CC:PA:LPD:PR (REG–114339–21), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Clara Raymond at (202) 317–4718; concerning submission of comments or outlines, the hearing, or any questions to attend the hearing by teleconferencing, Regina Johnson at (202) 317–5177 (not toll-free numbers) or preferably by email to *publichearings@irs.gov*. If emailing, please include the following information in the subject line: Attend, Testify, or Question and REG–114339–21.

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 36B of the Code.

Section 36B provides a PTC for applicable taxpayers who meet certain eligibility requirements, including that a member of the taxpayer's family enrolls in a qualified health plan (''QHP'') through an Exchange for one or more ''coverage months.'' Under § 1.36B–1(d) of the Income Tax Regulations, a taxpayer's family consists of the taxpayer, the taxpayer's spouse if filing jointly, and any dependents of the taxpayer.

Section 1.36B–3(d)(1) provides that the PTC for a coverage month is the lesser of: (i) The premiums for the month, reduced by any amounts that were refunded, for one or more QHPs in which a taxpayer or a member of the taxpayer's family enrolls (''enrollment premiums''); or (ii) the excess of the adjusted monthly premium for the applicable benchmark plan over 1/12 of the product of a taxpayer's household income and the applicable percentage for the taxable year (''taxpayer's contribution amount'').

Under section 36B(c)(2)(B) and § 1.36B–3(c), a month is a coverage month for an individual only if the individual is not eligible for minimum essential coverage (''MEC'') for that month (other than coverage under a health care plan offered in the individual market within a state). Under section 5000A(f)(1)(B) of the Code, the term MEC includes employer coverage. If an individual is eligible for employer coverage for a given month, no PTC is allowed for the individual for that month.

Section 36B(c)(2)(C) generally provides that an individual is not eligible for employer coverage if the coverage offered is unaffordable or does not provide minimum value. However, if the individual enrolls in employer coverage, the individual is eligible for MEC, irrespective of whether the employer coverage is affordable or provides minimum value. *See* section 36B(c)(2)(C)(iii) and § 1.36B–2(c)(3)(vii).

Section 36B(c)(2)(C)(i)(II) and § 1.36B–2(c)(3)(v)(A)(*1*) generally provide that employer coverage is unaffordable for an employee if the share of the annual premium the employee must pay for self-only coverage is more than the required contribution percentage of household income. The required contribution percentage is 9.5 percent and is indexed annually under section 36B(c)(2)(C)(iv).[1] Likewise, § 1.36B–2(c)(3)(v)(A)(*2*) generally provides that employer coverage is unaffordable for individuals eligible to enroll in employer coverage because of their relationship to the employee (related individuals) if the share of the annual premium the employee must pay for self-only coverage is more than the required contribution percentage of household income. Thus, the employee's share of the premium for family coverage, as defined in § 1.36B–1(m), is not considered in determining whether employer coverage is affordable for related individuals.

Under section 36B(c)(2)(C)(ii) and § 1.36B–6(a)(1), an eligible employer-sponsored plan provides minimum value only if the plan's share of the total allowed costs of benefits provided to an employee is at least 60 percent. On November 4, 2014, the IRS released Notice 2014–69, 2014–48 I.R.B. 903, which advised taxpayers of the intent to propose regulations providing that plans that fail to provide substantial coverage for inpatient hospitalization or physician services also do not provide minimum value. Notice 2014–69 noted that the Department of Health and Human Services (HHS) was concurrently issuing parallel guidance and also provided that, pending issuance of final Treasury regulations, an employee will not be required to treat a non-hospital/non-physician services plan as providing minimum value for purposes of an employee's eligibility for a PTC.

On November 26, 2014, HHS issued proposed regulations providing that an eligible employer-sponsored plan provides minimum value only if, in addition to covering at least 60 percent of the total allowed costs of benefits provided under the plan, the plan benefits include substantial coverage of inpatient hospital services and physician services. *See* 79 FR 70674. On February 27, 2015, HHS finalized this minimum value rule at 45 CFR 156.145(a). *See* 80 FR 10750, 10872. On September 1, 2015, the Treasury Department and the IRS issued proposed regulations under section 36B (REG–143800–14, 80 FR 52678) (2015 proposed regulations) incorporating the substance of the minimum value rule in the HHS final regulations. The rule in the 2015 proposed regulations issued by the Treasury Department and the IRS relating to substantial coverage of inpatient hospital services and physician services has not been finalized.

On January 28, 2021, President Biden issued Executive Order (E.O.) 14009, Strengthening Medicaid and the Affordable Care Act (ACA). Section 3(a) of E.O. 14009 directs the Secretary of the Treasury to review, as soon as practicable, all existing regulations and other agency actions to determine whether the actions are inconsistent with the policy to protect and strengthen the ACA. Section 3(a)(v) of E.O. 14009 also directs the Secretary of the Treasury, as part of this review, to examine policies or practices that may reduce the affordability of coverage or financial assistance for coverage, including for dependents. Consequently, the Treasury Department and the IRS have reviewed the regulations under section 36B, including § 1.36B–2(c)(3)(v)(A)(*2*), which provides that the affordability of employer coverage for related individuals is based on the employee's share of the annual premium for self-only coverage, not the cost of family coverage. The Treasury Department and the IRS have tentatively determined that the rule in § 1.36B–2(c)(3)(v)(A)(*2*) is not required by the relevant statutes and is inconsistent with the overall purpose of the ACA to expand access to affordable health care coverage.

[1] As adjusted, the required contribution percentage is 9.61 percent for 2022. *See* Rev. Proc. 2021–36, 2021–35 I.R.B. 357. For simplicity, this preamble refers to 9.5 percent as the required contribution percentage.

Explanation of Provisions

I. Reasons for Regulatory Changes to Affordability Rule

As explained in the Background section of this preamble, individuals generally are not allowed a PTC if they are eligible for non-individual market MEC, including employer coverage. However, individuals are not eligible for employer coverage if the coverage is unaffordable or does not provide minimum value, unless they enroll in the coverage. Coverage is not affordable for an employee if the portion of the premiums required to be paid by the employee for self-only coverage exceeds 9.5 percent of household income. The current regulations under section 36B provide that if self-only employer coverage is affordable for an employee, then the coverage is also affordable for a spouse with whom the employee is filing a joint return and any dependents of the employee who may be eligible to enroll in the employer coverage, regardless of the amount the employee must pay to cover the spouse and dependents. *See* § 1.36B–2(c)(3)(v)(A)(*2*).

Section 1.36B–2(c)(3)(v)(A)(*2*) was promulgated as a final regulation in 2013. *See* TD 9611 (78 FR 7264). The Treasury Department and the IRS explained in the preamble to the 2013 final regulation that the language of section 36B, through the cross-reference to section 5000A(e)(1)(B),[2] specifies that the affordability test for related individuals is based on the cost of self-only coverage. However, the approach in the current regulations has potentially impacted millions of Americans. Among those impacted are families with children, some of whom have suffered economic hardship. In addition, the current approach has undermined access to more affordable health care coverage by preventing access to lower-premium subsidized Exchange plans. Under the current regulations, a PTC is not allowed for children and other family members who have been offered employer coverage if the cost of the employee's self-only coverage is affordable, regardless of the employee's cost to cover those family members. Many of these families purchase health insurance, either through a family member's job or an Exchange, but pay high portions of their income towards premiums. Other families forgo coverage altogether due to the high premium costs. Several studies have analyzed this problem.[3]

Pursuant to E.O. 14009, the Treasury Department and the IRS have reexamined the current interpretation of section 36B(c)(2)(C)(i) in § 1.36B–2(c)(3)(v)(A)(*2*). The Treasury Department and the IRS have preliminarily determined that section 36B(c)(2)(C)(i) does not compel the result that if self-only employer coverage is affordable for an employee, then the coverage also is affordable for a spouse and any dependents. To the contrary, the Treasury Department and the IRS believe that the statute is better read to require a separate affordability determination for employees and for family members. Further, the Treasury Department and the IRS are now of the view that the interpretation in the current regulations unduly weakens the ACA by basing affordability solely on the premium cost for the employee's self-only coverage and, therefore, the interpretation in the current regulations is contrary to the policy of the ACA to expand access to affordable health care coverage.

As discussed more fully in part II of this Explanation of Provisions, the Treasury Department and the IRS believe that section 36B(c)(2)(C)(i) is best interpreted in a manner that requires consideration of the premium cost to the employee to cover not just the employee, but also other members of the employee's family who may enroll in the employer coverage. This interpretation would create consistency across parallel provisions of the Code enacted by the ACA, specifically with regard to the affordability tests in sections 36B and 5000A. Consequently, the Treasury Department and the IRS propose to exercise the regulatory authority granted in section 36B(h) to adopt an alternative reading of section 36B(c)(2)(C)(i). Under this alternative reading, affordability of employer coverage for related individuals in the employee's family is determined based on the cost of covering the employee and those related individuals.

II. Affordability Rule for Related Individuals

A. Approach in Current Regulations

When the Treasury Department and the IRS promulgated § 1.36B–2(c)(3)(v)(A)(*2*) as a final regulation in 2013, it was after considerable deliberation regarding the affordability rule for related individuals. The Treasury Department and the IRS first issued proposed regulations under section 36B in August 2011. *See* REG–131491–10 (76 FR 50931). In addition to proposing general rules on all aspects of the PTC, the 2011 proposed regulations provided that affordability for related individuals was based on the amount an employee must pay for self-only coverage. In response to the 2011 proposed regulations, the Treasury Department and the IRS received a significant number of comments on the proposed affordability rule for related individuals. To fully consider those comments and ensure a comprehensive analysis of the issue, the Treasury Department and the IRS promulgated final regulations in May 2012 that reserved with respect to the affordability rule for related individuals and stated that future regulations would address the issue. *See* TD 9590 (77 FR 30377). In February 2013, the Treasury Department and the IRS finalized the affordability rule for related individuals as initially proposed in 2011. *See* TD 9611 (78 FR 7264). In finalizing the rule as initially proposed in 2011—that is, providing that affordability for related individuals was based on the amount an employee must pay for self-only coverage—the Treasury Department and the IRS focused on the relevant statutory provisions in sections 36B(c)(2)(C)(i)(II), 5000A(e)(1)(B), and 5000A(e)(1)(C).

Under section 36B(c)(2)(C)(i)(II), an employee who does not enroll in employer coverage is not considered eligible for the coverage if ''the employee's required contribution (within the meaning of section 5000A(e)(1)(B)) with respect to the plan exceeds 9.5 percent of the applicable taxpayer's household income.'' The flush language following this provision provides that ''[t]his clause shall also apply to an individual who is eligible to enroll in the plan by reason of a relationship the individual bears to the employee.'' This flush language does not specify how the language in section 36B(c)(2)(C)(i)(II) is intended to apply with respect to related individuals or how the cross-reference to section 5000A(e)(1)(B) is to be understood with regard to coverage of related individuals.

Section 5000A(e)(1)(B)(i)[4] provides that, for an employee eligible to purchase employer coverage, the term ''required contribution'' means ''the portion of the annual premium which

[2] Section 5000A provides rules regarding the individual shared responsibility payment, including an exemption from the payment for individuals who have an offer of employer coverage that is unaffordable.

[3] For example, see *https://www.healthaffairs.org/do/10.1377/hblog20210520.564880/full/.*

[4] Section 5000A(e)(1) provides an exemption from the requirement to maintain MEC for individuals who are eligible only for coverage that is unaffordable. Under section 5000A(e)(1)(A), coverage is unaffordable for an individual if the individual's required contribution exceeds a certain percentage of the individual's household income for the taxable year.

would be paid by the individual . . . for self-only coverage.'' For related individuals, the definition of ''required contribution'' in section 5000A(e)(1)(B)(i) is modified by a ''special rule'' in section 5000A(e)(1)(C). Section 5000A(e)(1)(C) provides that ''[f]or purposes of [section 5000A(e)(1)](B)(i), if an . . . individual is eligible for minimum essential coverage through an employer by reason of a relationship to an employee, the determination under subparagraph (A) shall be made by reference to the required contribution of the employee.'' The regulations under section 5000A interpret section 5000A(e)(1)(C) as modifying the required contribution rule in section 5000A(e)(1)(B)(i) with regard to coverage for related individuals to take into account the cost of covering the employee and the related individuals, not just the employee. Specifically, with respect to related individuals, § 1.5000A–3(e)(3)(ii)(B) provides that the required contribution for related individuals is the amount an employee must pay to cover the employee and the related individuals. The affordability rule for related individuals in § 1.5000A–3(e)(3)(ii)(B) was proposed on the same day that the affordability rule for related individuals in § 1.36B–2(c)(3)(v)(A)(*2*) was finalized in TD 9611.

When § 1.36B–2(c)(3)(v)(A)(*2*) was promulgated as a final regulation in 2013, the Treasury Department and the IRS considered the statutory language of section 36B(c)(2)(C)(i)(II) and its cross-reference to section 5000A(e)(1)(B), as well as the statutory language of section 5000A(e)(1)(B) and the cross-reference in section 5000A(e)(1)(C) to section 5000A(e)(1)(B). Under one reading of section 36B(c)(2)(C)(i)(II), the affordability rule for related individuals is determined solely by reference to section 5000A(e)(1)(B), without the modification to that section for related individuals provided by section 5000A(e)(1)(C). This reading results in affordability being determined based on the cost of self-only coverage to the employee. Under an alternative reading, the affordability rule for related individuals is determined by reference to section 5000A(e)(1)(B) taking into account the modification by section 5000A(e)(1)(C). With the issuance of current § 1.36B–2(c)(3)(v)(A)(*2*), the Treasury Department and the IRS adopted the interpretation that affordability of employer coverage for related individuals is based on the cost of self-only coverage to the employee.

B. Approach in Proposed Regulations

The Treasury Department and the IRS recognize that the statutory language in section 36B(c)(2)(C)(i)(II) supports two different readings. Under one reading, reflected in current § 1.36B–2(c)(3)(v)(A)(*2*), the affordability rule for related individuals is determined solely by reference to section 5000A(e)(1)(B), without the modification to that section for related individuals provided by section 5000A(e)(1)(C). This reading results in affordability being determined based on the cost of self-only coverage to the employee. Under an alternative reading, however, the affordability rule for related individuals is determined by reference to section 5000A(e)(1)(B), but also encompasses the modification of 5000A(e)(1)(B) by section 5000A(e)(1)(C), which provides a special rule for related individuals.

These proposed regulations would adopt the alternative reading, which the Treasury Department and the IRS have now preliminarily concluded is the better reading of these provisions. Under this interpretation, because section 5000A(e)(1)(C) begins with the language ''[f]or purposes of [section 5000A(e)(1)](B)(i),'' the parenthetical cross reference in section 36B(c)(2)(C)(i)(II) to section 5000A(e)(1)(B)(i) is understood to incorporate the special rule in section 5000A(e)(1)(C) that modifies the required contribution rule in section 5000A(e)(1)(B)(i) when the coverage in question is for related individuals. Under this interpretation, a specific reference in the flush language of section 36B(c)(2)(C)(i) to section 5000A(e)(1)(C) is not necessary to require the consideration of section 5000A(e)(1)(C) in determining affordability for related individuals for section 36B purposes.[5]

This proposed amendment to the affordability rule for related individuals would create greater consistency between the affordability rules in section 36B(c)(2)(C)(i) and the affordability rules in section 5000A(e)(1). The proposed amendment would also promote consistency between the affordability rules in these provisions and 42 U.S.C. 18081(b)(4)(C), which requires Exchange applicants to separately provide the required contributions of employees and of related individuals in order to determine PTC eligibility; in the Treasury Department's and the IRS's view, the requirement to provide this information would make little sense if PTC eligibility depended only on the cost to the employee for self-only coverage. In addition, the proposed amendment would also support efforts to achieve the goal of the ACA to provide affordable, quality health care for all Americans. *See* H.R. Rep. No. 111–243 (2009).

The proposed regulations would provide that an eligible employer-sponsored plan is affordable for related individuals if the portion of the annual premium the employee must pay for family coverage, that is, the employee's required contribution, does not exceed 9.5 percent of household income. For this purpose, family coverage means all employer plans that cover any related individual other than the employee, including a self plus-one plan for an employee enrolling one other family member in the coverage. An employee's required contribution for family coverage is the portion of the annual premium the employee must pay for coverage of the employee and all other individuals included in the employee's family who are offered the coverage.

Some individuals who are not part of the tax family might nonetheless be offered the employer coverage. For example, children up to age 26 might be offered coverage by the taxpayer's employer, but those adult children might not be reported on the employee's tax return because they do not qualify as dependents of the employee. The cost of covering individuals who are offered the coverage but are not in the employee's family is not considered in determining whether the employee's family members have an offer of affordable employer coverage, regardless of whether the non-family member enrolls in the coverage. That is because, under § 1.36B–2(c)(4)(i), a related individual who is not a spouse filing jointly with the employee or a dependent of the employee, such as a child of the employee who is no longer the employee's dependent, is treated as

[5] In Joint Committee on Taxation, *Technical Explanation of the Revenue Provisions of the ''Reconciliation Act of 2010,'' as amended, in combination with the ''Patient Protection and Affordable Care Act,''* (JCX–18–10), March 21, 2010 (the JCT report), the Joint Committee staff initially explained that ''[u]naffordable is defined as coverage with a premium required to be paid by the employee that is 9.5 percent or more of the employee's household income, based on the type of coverage applicable (*e.g.,* individual or family coverage).'' The quoted language was later revised to state that ''[u]naffordable is defined as coverage with a premium required to be paid by the employee that is 9.5 percent or more of the employee's household income, based on self-only coverage.'' *See ERRATA for JCX–18–10,* (JCX–27–10), May 4, 2010. Although the JCT report does not compel any particular reading of section 36B(c)(2)(C)(i)(II) as it relates to family coverage, these differing interpretations by the Joint Committee staff further demonstrate the statutory ambiguity that renders either interpretation available under the ACA.

eligible for the employer coverage only if he or she is enrolled in the coverage. Consequently, a related individual who is not a spouse filing jointly with the employee or a dependent of the employee does not need a determination of unaffordable coverage to be eligible for the PTC. As a result, the cost of covering that individual should not be considered in determining whether other related individuals have an offer of affordable employer coverage.

The proposed regulations would make changes only to the affordability rule for related individuals; they would make no changes to the affordability rule for employees. As required by statute, employees continue to have an offer of affordable employer coverage if the employee's required contribution for self-only coverage of the employee does not exceed the required contribution percentage of household income. Accordingly, under the proposed regulations, a spouse or dependent of an employee may have an offer of employer coverage that is unaffordable even though the employee has an affordable offer of self-only coverage.

The proposed regulations also address situations in which an individual has offers of coverage from multiple employers. Under the proposed regulations, an individual with offers of coverage from multiple employers, either as an employee or a related individual, has an offer of affordable coverage if at least one of the offers is affordable.[6] Thus, for example, assume X is married and files a joint return with X's spouse, Y. If X has offers of coverage from X's employer and Y's employer, X has an offer of affordable coverage if the self-only cost of X's employer coverage is affordable or if the family cost of Y's employer coverage is affordable. This rule regarding multiple offers of coverage is consistent with section 36B(c)(2)(B), under which a month is not a coverage month for an individual if the individual is eligible for MEC for the month, including employer coverage that is affordable and provides minimum value. In this example, X is eligible for affordable employer coverage if one or both of the offers of coverage to X is affordable.

The proposed change to the affordability rule for related individuals in § 1.36B–2(c)(3)(v)(A)(*2*) requires a conforming change to § 1.36B–2(c)(3)(v)(B), which provides that the affordability of employer coverage for an employment period that is less than a full calendar year is based on the employee's required contribution for self-only coverage (''part-year period rule''). The proposed regulations would amend § 1.36B–2(c)(3)(v)(B) to provide a part-year period rule for employees that is based on the employee's required contribution for self-only coverage and a part-year period rule for related individuals that is based on the employee's required contribution for family coverage. Changes to other existing rules such as § 1.36B–2(c)(3)(v)(A)(*4*) (wellness incentive programs) and (*5*) (employer contributions to health reimbursement arrangements integrated with eligible employer-sponsored plans) are not necessary because those paragraphs refer to an ''employee's required contribution,'' which, under the proposed regulations, would cover both the required contribution for self-only coverage and the required contribution for family coverage.

III. Minimum Value

A. Minimum Value Cost of Benefits Rule for Related Individuals

Section 1.36B–6(a)(1) provides that an eligible employer-sponsored plan provides minimum value if the plan's share of the total allowed cost of benefits provided to an employee is at least 60 percent. The proposed regulations would expand § 1.36B–6(a) to provide a similar minimum value rule for related individuals that is based on the level of coverage provided to related individuals under an employer-sponsored plan.

Section 36B(c)(2)(C)(ii) provides that an employee is not eligible for employer coverage when the employer-sponsored plan does not provide minimum value. Section 36B(c)(2)(C)(ii) does not specifically mention related individuals. Section 36B(c)(2)(C)(ii) could be interpreted to mean that there is no minimum value requirement for related individuals so that a related individual is eligible for employer coverage as long as the coverage is affordable, regardless of whether the employer coverage provides minimum value. Under such an interpretation, if an employer offers coverage to an employee and related individuals that is affordable, but does not provide minimum value for the employee, an employee who does not enroll in the coverage would not be eligible for the coverage, but related individuals offered the coverage would be eligible because section 36B does not have a minimum value requirement for related individuals.

That approach, however, was not adopted with the issuance of § 1.36B–2(c)(3)(i)(A), which was promulgated in final regulations in 2012. *See* TD 9590 (77 FR 30377). Section 1.36B–2(c)(3)(i)(A) clarifies that there is a minimum value requirement for both employees and related individuals, stating that ''an employee who may enroll in an eligible employer-sponsored plan . . . that is minimum essential coverage, and . . . a related individual, are eligible for minimum essential coverage under the plan for any month only if the plan is affordable and provides minimum value.'' Under this long-standing rule, a related individual who receives an offer of employer-sponsored coverage that does not provide minimum value is ineligible for the coverage, provided that the related individual does not enroll in the coverage.

Section 1.36B–2(c)(3)(i)(A) clarifies that there is a minimum value requirement for related individuals; however, § 1.36B–6(a) provides the rule for determining whether an eligible employer-sponsored plan provides minimum value to related individuals. As explained in the Background section of this preamble, under § 1.36B–6(a)(1), an eligible employer-sponsored plan provides minimum value if the plan's share of the total allowed cost of benefits provided to an employee is at least 60 percent, regardless of the total allowed costs of benefits provided to the related individual. Thus, under this rule, if the plan's share of the total allowed cost of benefits provided to an employee is below 60 percent, the plan does not provide minimum value to employees nor to any related individuals offered the coverage. Without a separate minimum value rule for related individuals based on the costs of benefits provided to related individuals, a PTC would not be allowed for a related individual offered coverage under a plan that was affordable but that provided minimum value to employees and not to related individuals. This outcome would undermine the benefit a related individual would derive from the proposed amendment of the affordability rule for related individuals. That is, the affordability of employer coverage for related individuals would be based on the employee's cost of covering the related individuals, but there would be no assurance that affordable coverage offered to the related individuals provided a minimum value of benefits to the related individuals.

[6] The proposed rule for offers from multiple employers is consistent with the treatment under § 1.36B–2(c)(3)(i) for situations in which an employee or family member may choose from multiple plans offered by an employer. In those situations, an individual has an offer of affordable coverage if at least one of the plans offered by the employer is affordable.

The lack of a separate minimum value rule for related individuals also would be inconsistent with the overall goal of the ACA in providing comprehensive, affordable health coverage, as well as the goal of improving access to quality and affordable health care. Therefore, these proposed regulations provide in § 1.36B–6(a)(2)(i) that an eligible employer-sponsored plan satisfies the minimum value requirement only if the plan's share of the total allowed costs of benefits provided to related individuals is at least 60 percent, similar to the existing rule in § 1.36B–6(a)(1) for employees. Further, to be considered to provide minimum value under § 1.36B–6(a)(2)(ii) of these proposed regulations, an eligible-employer sponsored plan would have to include substantial coverage of inpatient hospital services and physician services, as discussed in more detail in section III.B. of this preamble.

B. Minimum Value Rule Regarding Inpatient Hospitalization and Physician Services

As noted earlier in the Background section of this preamble, the Treasury Department and the IRS issued proposed regulations in September 2015 incorporating the substance of the minimum value rule that was finalized by HHS in February 2015. The HHS final regulations and § 1.36B–6(a)(2) of the 2015 proposed regulations provide that an eligible employer-sponsored plan provides minimum value only if, in addition to covering at least 60 percent of the total allowed costs of benefits provided to an employee under the plan, the plan benefits include substantial coverage of inpatient hospital services and physician services. The Treasury Department and the IRS have not finalized these regulations. The Treasury Department and the IRS are withdrawing the 2015 proposed regulations and reproposing in § 1.36B–6(a)(1)(ii) without substantive change the minimum value rule regarding inpatient hospital services and physician services for employees. Pending issuance of final Treasury regulations, an employee will not be required to treat a non-hospital/non-physician services plan as providing minimum value for purposes of an employee's eligibility for a PTC. *See* Notice 2014–69.

In addition, the Treasury Department and the IRS are proposing in this document to expand the minimum value rule in § 1.36B–6(a)(2) of the 2015 proposed regulations to apply to related individuals. Thus, § 1.36B–6(a)(2)(ii) of the proposed regulations would provide that an eligible employer-sponsored plan provides minimum value to a related individual only if, in addition to covering at least 60 percent of the total allowed costs of benefits provided to the related individual, the plan benefits include substantial coverage of inpatient hospital services and physician services.

IV. Premium Refunds Affecting the PTC Computation

Section 1.36B–3(d)(1)(i) provides that, in determining a taxpayer's premium assistance amount [7] for a coverage month, the taxpayer's enrollment premiums for the month are the premiums for the month, reduced by any amounts that were refunded, for one or more QHPs in which a taxpayer or a member of the taxpayer's family enrolls. Questions have arisen concerning refunds paid to a taxpayer in a taxable year that is after the taxable year the premium is paid and whether those refunds should be considered in determining the taxpayer's premium assistance amount for the month to which the refund relates. A medical loss ratio rebate under section 2718 of the Public Health Service Act is an example of a premium refund that may be paid to a taxpayer in a taxable year that is after the taxable year the taxpayer paid the premium.

Tax liability for a taxable year generally is determined based on events occurring in that taxable year (the current taxable year). Events occurring in a later taxable year, such as a refund of a deductible amount paid in the current taxable year, generally don't affect the tax liability of the current taxable year. Thus, a taxpayer's premium assistance amount for a month in the current taxable year should not be affected by a premium refund that was paid in a later taxable year.

Consequently, the proposed regulations would clarify that, in computing the premium assistance amount for a coverage month, a taxpayer's enrollment premiums for the month are the premiums for the month, reduced by any amounts that were refunded in the same taxable year the taxpayer incurred the premium liability.

V. Severability

If any provision in this rulemaking is held to be invalid or unenforceable facially, or as applied to any person or circumstance, it shall be severable from the remainder of this rulemaking, and shall not affect the remainder thereof, or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

[7] The terms ''premium assistance amount'' and ''premium tax credit'' (or PTC) have the same meaning.

Statement of Availability of IRS Documents

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

Proposed Applicability Dates

The proposed regulations under §§ 1.36B–2, 1.36B–3, and 1.36B–6(a)(2) are proposed to apply for taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**. As of the publication date of these proposed regulations, the proposed regulations are expected to be finalized no later than the end of this year. The Treasury Department and the IRS have been working closely with HHS to ensure that the federally-facilitated Exchange would be ready to implement the proposed changes before the open enrollment for 2023 coverage. HHS, in coordination with the Treasury Department and the IRS, intends to take all necessary steps to support efforts by state-based Exchanges to implement any changes before the open enrollment for 2023 coverage.

The proposed regulations under § 1.36B–6(a)(1)(i) are proposed to apply for taxable years ending after December 31, 2013.

The proposed regulations under § 1.36B–6(a)(1)(ii) are proposed to apply for plan years beginning after November 3, 2014.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

E.O.s 12866 and 13563 direct agencies to assess 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.

These proposed regulations have been designated as subject to review under E.O. 12866 pursuant to the Memorandum of Agreement (April 11, 2018) (MOA) between the Treasury Department and the Office of Management and Budget (OMB) regarding review of tax regulations.

A. Background

1. Affordability of Employer Coverage for Family Members of an Employee

As noted earlier in this preamble, section 36B provides a PTC for applicable taxpayers who meet certain eligibility requirements, including that the taxpayer or one or more family members is enrolled in a QHP through an Exchange (Exchange coverage) for one or more months in which they are not eligible for other MEC. However, an individual who is eligible to enroll in employer coverage, but chooses not to, is not considered eligible for the employer coverage if it is ''unaffordable.'' Section 36B defines employer coverage as unaffordable for an employee if the employee's share of the self-only premium is more than 9.5 percent of the employee's household income.

Section 1.36B–2(c)(3)(v)(A)(*2*) provides that affordability of employer coverage for each related individual of the employee is determined by the cost of self-only coverage. Thus, the employee and any related individuals included in the employee's family, within the meaning of § 1.36B–1(d), are eligible for MEC and are ineligible for the PTC if (1) the plan provides minimum value and (2) the employee's share of the self-only coverage is not more than 9.5 percent of household income (that is, the self-only coverage for the employee is ''affordable'').

2. Description of the Proposed Regulations

The proposed regulations would revise § 1.36B–2(c)(3)(v)(A)(*2*) to provide a separate affordability test for related individuals based on the cost to the employee of family coverage. The proposed regulations do not change the affordability test for the employee. As a result, whenever a family applies for Exchange coverage and one or more family members has an offer of employer coverage, the Exchange will perform the following affordability determinations: One determination for the employee based on the cost of self-only coverage, one determination for the related individuals based on the cost of family coverage, and additional determinations for any related individuals who have an offer of coverage from another employer. It is therefore possible that family members would be eligible for PTC but the employee would not. In this case, if the entire family chooses to enroll in Exchange coverage with advance payments of the premium tax credit (APTC), the APTC would be paid only for coverage of the employee's family members but would not be paid for coverage of the employee.

B. Baseline

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

C. Affected Entities

Some families with an offer of employer coverage to the employee and at least one other family member would be newly eligible for a PTC for the Exchange coverage of the non-employee family members. The proposed regulations would have no effect on families for whom self-only employer coverage costs more than 9.5 percent of household income—given that family coverage is more expensive than self-only coverage—because the affordability status of their employer coverage is unchanged. Similarly, the proposed regulations would not affect families for whom the cost of family employer coverage does not exceed 9.5 percent of household income because their coverage is determined to be affordable either way. In contrast, the proposed regulations would affect only family members—other than the employee—for whom the employee's cost for the available employer coverage does not exceed 9.5 percent of household income for a self-only plan but exceeds 9.5 percent of household income for a family plan or for whom the offer of the family plan is affordable but doesn't provide minimum value. The Treasury Department and the IRS are unable to estimate the size of the population affected by the proposed regulations because contribution amounts for family coverage are not observed in the tax data.

Employers may see a shift for some of their employees from family coverage to self-only coverage when family members newly qualify for PTC. The cost per enrollee could increase or decrease depending on the characteristics of those that remain covered. However, this shift would likely lead to a decrease in the total amount employers are spending on health insurance as the Federal government increases spending on PTC for the non-employee family members.

D. Economic Analysis of the Proposed Regulations

1. Overview

For some families, the proposed regulations would lower the premium contributions required to purchase coverage for all family members by allowing family members other than the employee to qualify for a PTC. For some families with offers of employer coverage who will be newly eligible for the PTC, the combined cost of split coverage (self-only employer coverage for the employee plus PTC-subsidized Exchange coverage for related individuals) would be lower than what they pay for family coverage through the employer. Some low-income families with uninsured individuals where the employee is offered low-cost, self-only employer coverage and relatively high-cost family employer coverage would gain access to a lower-cost option through eligibility for the PTC on behalf of one or more related individuals.

However, the cost for families to purchase Exchange coverage with APTC is determined in part by the applicable percentage and household income, which are the same regardless of the number of individuals actually covered. Therefore, if the number of individuals needing Exchange coverage is small—such as when some family members have access to other MEC—the cost of Exchange coverage per enrollee is relatively high when added to the cost of the employee share of self-only employer coverage. Furthermore, split coverage also means multiple deductibles and maximum out-of-pocket limits for the family, which potentially increases out-of-pocket costs for families. As a result of these features, many families with offers of employer coverage who would be newly eligible for the PTC under the proposed regulations—including families with some uninsured individuals—would not see any savings in the combined cost of out-of-pocket premiums and cost sharing. Lastly, many families may prefer the benefits and provider networks of employer coverage, compared to Exchange coverage. Taking all these factors into account, the Treasury Department and the IRS have determined that new take-up of Exchange coverage may be modest for eligible families because many would either still prefer employer coverage or prefer to purchase other goods and services, or save or invest, rather than insure all family members.

2. Benefits

Gain of health insurance coverage. For those individuals who are uninsured because the premiums for family coverage through a family member's employer are unaffordable, gaining access to PTC for the purchase of Exchange coverage may be more affordable and prompt some of them to take up coverage.

Additional health insurance option. For those individuals who are covered by family coverage through a family member's employer that costs more than 9.5 percent of their household income, the proposed regulations would, by providing access to a PTC, give them an additional option that could provide coverage at a lower cost or with more comprehensive benefits.

The Treasury Department and the IRS are unable to estimate the size of the benefits of the proposed regulations because contribution amounts for family coverage are not observed in the tax data. The Treasury Department and the IRS request comments that provide data, other evidence, or models that provide insight on this issue.

3. Costs

Administrative costs. Adding this new option for eligibility for PTC increases the cost to the IRS to evaluate PTC claims. The IRS's PTC infrastructure will require one-time changes to certain processes, forms, and instructions to be implemented in time for the 2023 tax year, and the cost of these changes is expected to be negligible. The Centers for Medicare & Medicaid Services (''CMS''), as the administrator of the Federally-facilitated Exchanges and the federal Exchange eligibility and enrollment platform, and the State-based Exchanges that operate their own Exchange eligibility and enrollment platforms will also incur administrative costs as the Exchanges will have primary responsibility for implementing the rule as part of the eligibility and enrollment process when families are applying for Exchange coverage with APTC. Exchanges will incur one-time costs to update Exchange eligibility systems to account for the new treatment of family contribution amounts for employer coverage for purposes of determining eligibility for APTC, and CMS, State-based Exchanges, State Medicaid Agencies, and CMS-approved Enhanced Direct Enrollment partners will incur administrative costs to make conforming updates to their respective consumer applications and consumer-facing affordability tools. The Treasury Department and the IRS anticipate total administrative costs to CMS, Exchanges, State Medicaid Agencies, and Enhanced Direct Enrollment partners associated with the proposed regulation to be modest, and request comments from impacted stakeholders to inform administrative cost estimates.

4. Transfers

Increased PTC costs for new Exchange enrollees. Because some individuals may be newly eligible for PTC, some individuals may move from employer coverage or uninsured status to Exchange coverage. Thus, the proposed regulations may increase the amount of PTC being paid by the government and reduce employer contributions.

Decreased employer exclusion for people who drop employer coverage. If individuals drop their employer coverage, or do not enroll when they otherwise would have, to take up Exchange coverage, the amount of money that was going toward their employer coverage, which provides tax-preferred health benefits, will go into the employee's wages, other employees' wages, and employer profits and will no longer be tax exempt. Thus, the proposed regulations may increase the amount of tax revenue received from income and payroll taxes.

The Treasury Department and the IRS are unable to estimate the size of the population affected by the proposed regulations because contribution amounts for family coverage are not observed in the tax data. The Treasury Department and the IRS request comments that provide data, other evidence, or models that provide insight on this issue.

5. Impact on Small Entities

When an agency issues a proposed rulemaking, the Regulatory Flexibility Act (5 U.S.C. chapter 6) (the ''Act'') requires the agency to ''prepare and make available for public comment an initial regulatory flexibility analysis'' that ''describe[s] the impact of the proposed rule on small entities.'' *See* 5 U.S.C. 603(a). The term ''small entities'' is defined in 5 U.S.C. 601 to mean ''small business,'' ''small organization,'' and ''small governmental jurisdiction,'' which are also defined in 5 U.S.C. 601. Small business size standards define whether a business is ''small'' and have been established for types of economic activities, or industry, generally under the North American Industry Classification System (NAICS). *See* title 13, part 121 of the Code of Federal Regulations (titled ''Small Business Size Regulations''). The size standards look at various factors, including annual receipts, number of employees, and amount of assets, to determine whether the business is small. *See* title 13, § 121.201 of the Code of Federal Regulations for the Small Business Size Standards by NAICS Industry.

Section 605 of the Act provides an exception to the requirement to prepare an initial regulatory flexibility analysis if the agency certifies that the proposed rulemaking will not have a significant economic impact on a substantial number of small entities. The Treasury Department and the IRS hereby certify that these proposed regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the majority of the effect of the proposed regulations falls on individual taxpayers, and entities will experience only small changes.

6. Impact on Small Business

Pursuant to section 7805(f) of the Code, these proposed regulations have been submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on their impact on small business.

II. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million (updated annually for inflation). This proposed rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

III. Executive Order 13132: Federalism

E.O. 13132 (titled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the E.O. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the E.O.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to comments that are submitted timely to the IRS as prescribed in this preamble in the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations, including the economic impact of the proposed regulations. Any electronic comments submitted, and to the extent practicable any paper comments submitted, will be made

available at *www.regulations.gov* or upon request.

A public hearing has been scheduled for June 27, 2022, beginning at 10:00 a.m. EDT. Announcement 2020–4, 2020–17 IRB 1, provides that until further notice, public hearings conducted by the IRS will be held telephonically.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Individuals who wish to testify (by telephone) at the public hearing must send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number (REG–114339–21) for the hearing and the word TESTIFY. For example, the subject line may say: Request to TESTIFY at Hearing for REG–114339–21. The email should also include a copy of the speaker's outline of topics. The email requesting to speak must be received by June 13, 2022. Speakers will have up to ten minutes to testify and may be asked questions by the panel.

Individuals who want to attend the public hearing by telephone must also send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number (REG–114339–21) and the word ATTEND. For example, the subject line may say: Request to ATTEND Hearing for REG–114339–21. Email requests to attend the public hearing must be received by 5:00 p.m. EDT on June 23, 2022.

The telephonic hearing will be made accessible to people with disabilities. To request special assistance during the telephonic hearing, please contact the Publications and Regulations Branch of the Office of Associate Chief Counsel (Procedure and Administration) by sending an email to *publichearings@irs.gov* (preferred) or by telephone at (202) 317–5177 (not a toll-free number) by June 22, 2022. Any questions regarding speaking at or attending the public hearing may also be emailed to *publichearings@irs.gov.*

Drafting Information

The principal author of these proposed regulations is Suzanne R. Sinno of the Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the Treasury Department and the IRS participated in the development of the regulations.

Withdrawal of Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, the notice of proposed rulemaking (REG–143800–14) that was published in the **Federal Register** on September 1, 2015 (80 FR 52678), is withdrawn.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

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 1.36B–2 is amended by:

■ 1. Revising the first sentence and adding a sentence following the first sentence of paragraph (c)(3)(v)(A)(*2*).

■ 2. Adding paragraph (c)(3)(v)(A)(*8*).

■ 3. Revising the second sentence of paragraph (c)(3)(v)(B).

■ 4. In paragraph (c)(3)(v)(D), Examples 1 through 9 are designated as paragraphs (c)(3)(v)(D)(*1*) through (*9*), respectively.

■ 5. In newly designated paragraphs (c)(3)(v)(D)(*3*), (*5*), (*6*), (*7*), and (*9*), redesignating the paragraphs in the first column as the paragraphs in the second column:

Old paragraphs	New paragraphs
(c)(3)(v)(D)(*3*)(i) through (ii).	(c)(3)(v)(D)(*3*)(*i*) through (*ii*).
(c)(3)(v)(D)(*5*)(i) through (ii).	(c)(3)(v)(D)(*5*)(*i*) through (*ii*).
(c)(3)(v)(D)(*6*)(i) through (ii).	(c)(3)(v)(D)(*6*)(*i*) through (*ii*).
(c)(3)(v)(D)(*7*)(i) through (iv).	(c)(3)(v)(D)(*7*)(*i*) through (*iv*).
(c)(3)(v)(D)(*9*)(i) through (ii).	(c)(3)(v)(D)(*9*)(*i*) through (*ii*).

■ 6. Revising newly designated paragraphs (c)(3)(v)(D)(*1*) and (*2*).

■ 7. Redesignating paragraphs (c)(3)(v)(D)(*3*) through (*9*) as paragraphs (c)(3)(v)(D)(*7*) through (*13*), respectively.

■ 8. Adding new paragraphs (c)(3)(v)(D)(*3*) through (*6*);

■ 9. Revising the heading for newly redesignated paragraph (c)(3)(v)(D)(*7*), the heading and first sentence of newly redesignated paragraph (c)(3)(v)(D)(*8*), the heading of newly redesignated paragraph (c)(3)(v)(D)(*9*), and the first sentence of newly redesignated paragraph (c)(3)(v)(D)(*9*)(*i*).

■ 10. In the headings for newly redesignated paragraphs (c)(3)(v)(D)(*10*) through (*13*), removing the first period and adding a colon in its place.

■ 11. Revising paragraph (e)(1).

■ 12. Adding paragraph (e)(5).

The revisions and additions read as follows:

§ 1.36B–2 Eligibility for premium tax credit.

* * * * *

(c) * * *

(3) * * *

(v) * * *

(A) * * *

(*2*) * * * Except as provided in paragraph (c)(3)(v)(A)(*3*) of this section, an eligible employer-sponsored plan is affordable for a related individual if the employee's required contribution for family coverage under the plan does not exceed the required contribution percentage, as defined in paragraph (c)(3)(v)(C) of this section, of the applicable taxpayer's household income for the taxable year. For purposes of this paragraph (c)(3)(v)(A)(*2*), an employee's required contribution for family coverage is the portion of the annual premium the employee must pay for coverage of the employee and all other individuals included in the employee's family, as defined in § 1.36B–1(d), who are offered coverage under the eligible employer-sponsored plan. * * *

* * * * *

(*8*) *Multiple offers of coverage.* An individual who has offers of coverage under eligible employer-sponsored plans from multiple employers, either as an employee or a related individual, has an offer of affordable coverage if at least one of the offers of coverage is affordable under paragraph (c)(3)(v)(A)(*1*) or (*2*) of this section.

(B) * * * Coverage under an eligible employer-sponsored plan is affordable for a part-year period if the annualized required contribution for self-only coverage, in the case of an employee, or family coverage, in the case of a related individual, under the plan for the part-year period does not exceed the required contribution percentage of the applicable taxpayer's household income for the taxable year. * * *

* * * * *

(D) * * *

(*1*) *Example 1: Basic determination of affordability.* For all of 2023, taxpayer C works for an employer, X, that offers its employees and their spouses a health insurance plan under which, to enroll in self-only coverage, C must contribute an amount for 2023 that does not exceed the required contribution percentage of C's 2023 household income. Because C's required contribution for self-only

coverage does not exceed the required contribution percentage of C's household income, under paragraph (c)(3)(v)(A)(*1*) of this section, X's plan is affordable for C, and C is eligible for minimum essential coverage for all months in 2023.

(*2*) *Example 2: Basic determination of affordability for a related individual.* (*i*) The facts are the same as in paragraph (c)(3)(v)(D)(*1*) of this section (Example 1), except that C is married to J, they file a joint return, and to enroll C and J, X's plan requires C to contribute an amount for coverage for C and J for 2023 that exceeds the required contribution percentage of C's and J's household income. J does not work for an employer that offers employer-sponsored coverage.

(*ii*) J is a member of C's family as defined in § 1.36B–1(d). Because C's required contribution for coverage of C and J exceeds the required contribution percentage of C's and J's household income, under paragraph (c)(3)(v)(A)(*2*) of this section, X's plan is unaffordable for J. Accordingly, J is not eligible for minimum essential coverage for 2023. However, under paragraph (c)(3)(v)(A)(*1*) of this section, X's plan is affordable for C, and C is eligible for minimum essential coverage for all months in 2023.

(*3*) *Example 3: Multiple offers of coverage.* The facts are the same as in paragraph (c)(3)(v)(D)(*2*) of this section (Example 2), except that J works all year for an employer that offers employer-sponsored coverage to employees. J's required contribution for the cost of self-only coverage from J's employer does not exceed the required contribution percentage of C's and J's household income. Although the coverage offered by C's employer for C and J is unaffordable for J, the coverage offered by J's employer is affordable for J. Consequently, under paragraphs (c)(3)(v)(A)(*1*) and (*8*) of this section, J is eligible for minimum essential coverage for all months in 2023.

(*4*) *Example 4: Cost of covering individuals not part of taxpayer's family.* (*i*) D and E are married, file a joint return, and have two children, F and G, under age 26. F is a dependent of D and E, but G is not. D works all year for an employer that offers employer-sponsored coverage to employees, their spouses, and their children under age 26. E, F, and G do not work for employers offering coverage. D's required contribution for self-only coverage under D's employer's coverage does not exceed the required contribution percentage of D's and E's household income. D's required contribution for coverage of D, E, F, and G exceeds the required contribution percentage of D's and E's household income, but D's required contribution for coverage of D, E, and F does not exceed the required contribution percentage of the household income.

(*ii*) E and F are members of D's family as defined in § 1.36B–1(d). G is not a member of D's family under § 1.36B–1(d), because G is not D's dependent. Under paragraph (c)(3)(v)(A)(*1*) of this section, D's employer's coverage is affordable for D because D's required contribution for self-only coverage does not exceed the required contribution percentage of D's and E's household income. D's employer's coverage also is affordable for E and F, because, under paragraph (c)(3)(v)(A)(*2*) of this section, D's required contribution for coverage of D, E, and F does not exceed the required contribution percentage of D's and E's household income. Although D's cost to cover D, E, F, and G exceeds the required contribution percentage of D's and E's household income, under paragraph (c)(3)(v)(A)(*2*) of this section, the cost to cover G is not considered in determining whether D's employer's coverage is affordable for E and F, regardless of whether G actually enrolls in the plan, because G is not in D's family. D, E, and F are eligible for minimum essential coverage for all months in 2023. Under paragraph (c)(4)(i) of this section, G is considered eligible for the coverage offered by D's employer only if G enrolls in the coverage.

(*5*) *Example 5: More than one family member with an employer offering coverage.* (*i*) K and L are married, file a joint return, and have one dependent child, M. K works all year for an employer that offers coverage to employees, spouses, and children under age 26. L works all year for an employer that offers coverage to employees only. K's required contribution for self-only coverage under K's employer's coverage does not exceed the required contribution percentage of K's and L's household income. Likewise, L's required contribution for self-only coverage under L's employer's coverage does not exceed the required contribution percentage of K's and L's household income. However, K's required contribution for coverage of K, L, and M exceeds the required contribution percentage of K's and L's household income.

(*ii*) L and M are members of K's family as defined in § 1.36B–1(d). Under paragraph (c)(3)(v)(A)(*1*) of this section, K's employer's coverage is affordable for K because K's required contribution for self-only coverage does not exceed the required contribution percentage of K's and L's household income. Similarly, L's employer's coverage is affordable for L, because L's required contribution for self-only coverage does not exceed the required contribution percentage of K's and L's household income. Thus, K and L are eligible for minimum essential coverage for all months in 2023. However, under paragraph (c)(3)(v)(A)(*2*) of this section, K's employer's coverage is unaffordable for M, because K's required contribution for coverage of K, L, and M exceeds the required contribution percentage of K's and L's household income. Accordingly, M is not eligible for minimum essential coverage for 2023.

(*6*) *Example 6: Multiple offers of coverage for a related individual.* (*i*) The facts are the same as in paragraph (c)(3)(v)(D)(*5*) of this section (Example 5), except that L works all year for an employer that offers coverage to employees, spouses, and children under age 26. L's required contribution for coverage of K, L, and M does not exceed the required contribution percentage of K's and L's household income.

(*ii*) Although M is not eligible for affordable employer coverage under K's employer's coverage, paragraph (c)(3)(v)(A)(*8*) of this section dictates that L's employer coverage must be evaluated to determine whether L's employer coverage is affordable for M. Under paragraph (c)(3)(v)(A)(*2*) of this section, L's employer's coverage is affordable for M, because L's required contribution for K, L, and M does not exceed the required contribution percentage of K's and L's household income. Accordingly, M is eligible for minimum essential coverage for all months in 2023.

(*7*) *Example 7: Determination of unaffordability at enrollment.* * * *

(*8*) *Example 8: Determination of unaffordability for plan year.* The facts are the same as in paragraph (c)(3)(v)(D)(*7*) of this section (Example 7), except that X's employee health insurance plan year is September 1 to August 31. * * *

(*9*) *Example 9: No affordability information affirmatively provided for annual redetermination.* (i) The facts are the same as in paragraph (c)(3)(v)(D)(*7*) of this section (Example 7), except the Exchange redetermines D's eligibility for advance credit payments for 2015. * * *

* * * * *

(e) * * *

(1) Except as provided in paragraphs (e)(2) through (5) of this section, this section applies to taxable years ending after December 31, 2013.

* * * * *

(5) The first two sentences of paragraph (c)(3)(v)(A)(*2*), paragraph (c)(3)(v)(A)(*8*), the second sentence of paragraph (c)(3)(v)(B), paragraphs (c)(3)(v)(D)(*1*) through (*6*), and the first sentences of paragraphs (c)(3)(v)(D)(*8*) and (*9*) of this section apply to taxable years beginning after [date final regulations are published in the **Federal Register**].

■ **Par. 3.** Section 1.36B–3 is amended by revising paragraphs (d)(1)(i) and (n)(1) and adding paragraph (n)(3) to read as follows:

§ 1.36B–3 Computing the premium assistance credit amount.

* * * * *

(d) * * *

(1) * * *

(i) The premiums for the month, reduced by any amounts that were refunded in the same taxable year as the premium liability is incurred, for one or more qualified health plans in which a taxpayer or a member of the taxpayer's family enrolls (enrollment premiums); or

* * * * *

(n) * * * (1) Except as provided in paragraphs (n)(2) and (3) of this section, this section applies to taxable years ending after December 31, 2013.

* * * * *

(3) Paragraph (d)(1)(i) of this section applies to taxable years beginning after [the date final regulations are published in the **Federal Register**].

■ **Par. 4.** Section 1.36B–6 is amended by revising paragraphs (a) and (g)(2) to read as follows:

§ 1.36B–6 Minimum value.

(a) *In general*—(1) *Employees.* An eligible employer-sponsored plan provides minimum value (MV) for an employee of the employer offering the coverage only if—

(i) The plan's MV percentage, as defined in paragraph (c) of this section, is at least 60 percent based on the plan's share of the total allowed costs of benefits provided to the employee; and

(ii) The plan provides substantial coverage of inpatient hospital services and physician services.

(2) *Related individuals.* An eligible employer-sponsored plan provides MV for an individual who may enroll in the plan because of a relationship to an employee of the employer offering the coverage (a related individual) only if—

(i) The plan's MV percentage, as defined in paragraph (c) of this section, is at least 60 percent based on the plan's share of the total allowed costs of benefits provided to the related individual; and

(ii) The plan provides substantial coverage of inpatient hospital services and physician services.

* * * * *

(g) * * *

(2) *Exceptions.* (i) Paragraph (a)(1)(ii) of this section applies for plan years beginning after November 3, 2014; and

(ii) Paragraph (a)(2) of this section applies to taxable years beginning after [date final regulations are published in the **Federal Register**].

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2022–07158 Filed 4–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2022–0179]

RIN 1625–AA08

Special Local Regulation; St. Mary's River, St. George's Creek, Piney Point, MD

AGENCY: Coast Guard, Homeland Security (DHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish temporary special local regulations for certain waters of the St. Mary's River. This action is necessary to provide for the safety of life on these navigable waters located at Piney Point, MD, during a high-speed power boat demonstration event on June 4, 2022, and June 5, 2022. This proposed rulemaking would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port, Maryland-National Capital Region or the Coast Guard Event Patrol Commander. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 9, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0179 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email MST3 Melissa Kelly, U.S. Coast Guard Sector Maryland-National Capital Region; telephone 410–576–2596, email *Melissa.C.Kelly@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
PATCOM Coast Guard Patrol Commander
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Southern Maryland Boat Club of Leonardtown, MD, notified the Coast Guard that it will be conducting the Southern Maryland Boat Club Piney Point Rumble on the River Regatta from 8 a.m. to 4 p.m. on June 4, 2022, and from 8 a.m. to 4 p.m. on June 5, 2022. The high-speed power boat demonstration event consists of approximately 55 participating vintage and historic race boats—including runabouts, v-bottoms, tunnel hulls, and hydroplanes—8 to 21 feet in length. The vessels will be participating in an exhibition, operating in heats along a marked racetrack-type course 1 mile in length and 200 feet in width, located in the St. George Creek at Piney Point, MD. The regatta is not a competition, but rather a demonstration of vintage race craft. Hazards from the high-speed power boat demonstration event include participants operating within and adjacent to designated navigation channels and interfering with vessels intending to operate within those channels, as well as operating near approaches to local public boat landings. The COTP Maryland-National Capital Region has determined that potential hazards associated with the high-speed power boat event would be a safety concern for anyone intending to participate in this event and for vessels that operate within specified waters of St. George Creek.

The purpose of this rulemaking is to protect event participants, non-participants, and transiting vessels before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70041.

III. Discussion of Proposed Rule

The COTP Maryland-National Capital Region proposes to establish special local regulations from 7:30 a.m. on June 4, 2022, through 5 p.m. on June 5, 2022. The regulations would be enforced from

7:30 a.m. to 5 p.m. on June 4, 2022, and from 7:30 a.m. to 5 p.m. on June 5, 2022. The regulated area would cover all navigable waters of St. George Creek, within an area bounded by a line connecting the following points: From the shoreline at Cedar Point at position latitude 38°09′03.4″ N, longitude 076°29′55.7″ W; thence south along the shoreline to Coade Bar at latitude 38°08′22.5″ N, longitude 076°29′19.9″ W; thence southeast across St. George Creek to Dodson Point at latitude 38°08′03.8″ N, longitude 076°29′44.6″ W; thence north along the shoreline and the eastern extent of the St. George Island (SR–249) Bridge to Long Bar (at the entrance to St. George Harbor) at latitude 38°08′50.6″ N, longitude 076°30′13.0″ W; thence northeast across St. George Creek to and terminating at the point of origin. The regulated area is approximately 1,750 yards in length and 940 yards in width.

This proposed rule provides additional information about areas within the regulated area, and their definitions and the restrictions that would apply to mariners. These areas include ''Race Area,'' ''Buffer Area,'' and ''Spectator Area.''

The proposed duration of the special local regulations and size of the regulated area are intended to ensure the safety of life on these navigable waters before, during, and after the high-speed power boat event scheduled to take place from 8 a.m. to 4 p.m. on June 4, 2022, and from 8 a.m. to 4 p.m. on June 5, 2022. The COTP and the Coast Guard Event PATCOM would have authority to forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area would be required to immediately comply with the directions given by the COTP or Event PATCOM. If a person or vessel fails to follow such directions, the Coast Guard may expel them from the area, issue them a citation for failure to comply, or both.

Except for Southern Maryland Boat Club Piney Point Rumble on the River Regatta participants and vessels already at berth, a vessel or person would be required to get permission from the COTP or Event PATCOM before entering the regulated area. Vessel operators would be able to request permission to enter and transit through the regulated area by contacting the Event PATCOM on VHF–FM channel 16. Vessel traffic would be able to safely transit the regulated area once the Event PATCOM deems it safe to do so. A vessel within the regulated area must operate at safe speed that minimizes wake. A person or vessel not registered with the event sponsor as a participant or assigned as official patrols would be considered a spectator. Official Patrols are any vessel assigned or approved by the Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign. Official Patrols enforcing this regulated area can be contacted on VHF–FM channel 16 and channel 22A.

If permission is granted by the COTP or Event PATCOM, a person or vessel would be allowed to enter the regulated area or pass directly through the regulated area as instructed. Vessels would be required to operate at a safe speed that minimizes wake while within the regulated area in a manner that would not endanger event participants or any other craft. A spectator vessel must not loiter within the navigable channel while within the regulated area. Official patrol vessels would direct spectators to the designated spectator area. Only participant vessels and official patrol vessels would be allowed to enter the race area. The Coast Guard would publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF–FM marine band radio announcing specific event dates and times.

The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size and duration of the regulated area, which would impact a small designated area of St. George Creek for 19 total enforcement hours. This waterway supports mainly recreational vessel traffic, which at its peak, occurs during the summer season. Although this regulated area extends across the entire width of the waterway, the rule would allow vessels and persons to seek permission to enter the regulated area, and vessel traffic able to do so safely would be able to transit the regulated area on the eastern portion of the waterway away from the event area as instructed by Event PATCOM. Such vessels must operate at safe speed that minimizes wake and not loiter within the navigable channel while within the regulated area. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the status of the regulated area.

B. Impact on Small Entities

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

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed 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 preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves implementation of regulations within 33 CFR part 100 applicable to organized marine events on the navigable waters of the United States that could negatively impact the safety of waterway users and shore side activities in the event area for 19 total enforcement hours. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to 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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2022–0179 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T05–0179 to read as follows:

§ 100.T05–0179 Southern Maryland Boat Club Piney Point Regatta, St. Mary's River, St. George Creek, Piney Point, MD.

(a) *Locations.* All coordinates are based on datum NAD 1983.

(1) *Regulated area.* All navigable waters of St. George Creek, within an area bounded by a line connecting the following points: From the shoreline at Cedar Point at position latitude 38°09′03.4″ N, longitude 076°29′55.7″ W; thence south along the shoreline to Coade Bar at latitude 38°08′22.5″ N, longitude 076°29′19.9″ W; thence southeast across St. George Creek to Dodson Point at latitude 38°08′03.8″ N, longitude 076°29′44.6″ W; thence north along the shoreline and the eastern extent of the St. George Island (SR–249) Bridge to Long Bar (at the entrance to St. George Harbor) at latitude 38°08′50.6″ N, longitude 076°30′13.0″ W; thence northeast across St. George Creek to and terminating at the point of origin. The race area, buffer area, and spectator area are within the regulated area.

(2) *Race area.* The race area is a polygon in shape measuring approximately 700 yards in length by 240 yards in width. The area is bounded by a line commencing near Hodgson Point at position latitude 38°08′39.80″ N, longitude 076°30′3.13″ W, thence

southeast to latitude 38°08′21.95″ N, longitude 076°29′49.31″ W; thence southwest to latitude 38°08′18.20″ N, longitude 076°29′56.98″ W, thence northwest to latitude 38°08′36.10″ N, longitude 076°30′10.84″ W; thence northeast to and terminating at the point of origin.

(3) *Buffer area.* The buffer area is a polygon in shape measuring approximately 90 yards in all directions surrounding the entire race area described in paragraph (a)(2) of this section. The area is bounded by a line commencing near Hodgson Point at position latitude 38°08′43.58″ N, longitude 076°30′02.12″ W; thence southeast to latitude 38°08′21.12″ N, longitude 076°29′44.81″ W, thence southwest to latitude 38°08′14.68″ N, longitude 076°29′58.24″ W; thence northwest to latitude 38°08′35.95″ N, longitude 076°30′14.33″ W, thence northeast to and terminating at the point of origin.

(4) *Spectator area.* The designated spectator area is a polygon in shape with its length measuring approximately 700 yards and its width measuring approximately 300 yards at its northern portion and 150 yards at it southern portion. The area is bounded by a line commencing at position latitude 38°08′46.86″ N, longitude 076°29′51.07″ W; thence southeast to latitude 38°08′38.11″ N, longitude 076°29′44.27″ W; thence south to latitude 38°08′26.81″ N, longitude 076°29′43.01″ W; thence southwest to latitude 38°08′23.50″ N, longitude 076°29′46.50″ W, thence northwest to latitude 38°08′41.28″ N, longitude 076°30′00.18″ W, thence northeast to and terminating at the point of origin.

(b) *Definitions.* As used in this section—

Buffer area is a neutral area that surrounds the perimeter of the race area within the regulated area described by this section. The purpose of a buffer area is to minimize potential collision conflicts with marine event participants or high-speed powerboats and spectator vessels or nearby transiting vessels. This area provides separation between a race area and a specified spectator area or other vessels that are operating in the vicinity of the regulated area established by the special local regulations in this section.

Captain of the Port (COTP) Maryland-National Capital Region means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region or any Coast Guard commissioned, warrant or petty officer who has been authorized by the COTP to act on his behalf.

Event Patrol Commander or *Event PATCOM* means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Commander, Coast Guard Sector Maryland-National Capital Region.

Official patrol means any vessel assigned or approved by Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

Participant means all persons and vessels registered with the event sponsor as participating in the ''Southern Maryland Boat Club Piney Point Rumble on the River Regatta'' event, or otherwise designated by the event sponsor as having a function tied to the event.

Race area is an area described by a line bound by coordinates provided in latitude and longitude that outlines the boundary of a race area within the regulated area defined by this section.

Spectator means a person or vessel not registered with the event sponsor as participants or assigned as official patrols.

Spectator area is an area described by a line bound by coordinates provided in latitude and longitude that outlines the boundary of a spectator area within the regulated area defined by this section.

(c) *Special local regulations.* (1) The COTP Maryland-National Capital Region or Event PATCOM may forbid and control the movement of all vessels and persons, including event participants, in the regulated area described in paragraph (a)(1) of this section. When hailed or signaled by an official patrol, a vessel or person in the regulated area shall immediately comply with the directions given by the patrol. Failure to do so may result in the Coast Guard expelling the person or vessel from the area, issuing a citation for failure to comply, or both. The COTP Maryland-National Capital Region or Event PATCOM may terminate the event, or a participant's operations at any time the COTP Maryland-National Capital Region or Event PATCOM believes it necessary to do so for the protection of life or property.

(2) Except for participants and vessels already at berth, a person or vessel within the regulated area at the start of enforcement of this section must immediately depart the regulated area.

(3) A spectator must contact the Event PATCOM to request permission to either enter or pass through the regulated area. The Event PATCOM, and official patrol vessels enforcing this regulated area, can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz) and channel 22A (157.1 MHz). If permission is granted, the spectator must enter the designated spectator area or pass directly through the regulated area as instructed by Event PATCOM. A vessel within the regulated area must operate at safe speed that minimizes wake. A spectator vessel must not loiter within the navigable channel while within the regulated area.

(4) Only participant vessels and official patrol vessels are allowed to enter and remain within the race area.

(5) Only participant vessels and official patrol vessels are allowed to enter and transit directly through the buffer area, in order to arrive at or depart from the race area.

(6) A person or vessel that desires to transit, moor, or anchor within the regulated area must obtain authorization from the COTP Maryland-National Capital Region or Event PATCOM. A person or vessel seeking such permission can contact the COTP Maryland-National Capital Region at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz) or the Event PATCOM on Marine Band Radio, VHF–FM channel 16 (156.8 MHz).

(7) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF–FM marine band radio announcing specific event dates and times.

(d) *Enforcement officials.* The Coast Guard may be assisted with marine event patrol and enforcement of the regulated area by other Federal, state, and local agencies.

(e) *Enforcement period.* This section will be enforced from 7:30 a.m. to 5 p.m. on June 4, 2022, and from 7:30 a.m. to 5 p.m. on June 5, 2022.

Dated: March 30, 2022.

David E. O'Connell,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2022–07404 Filed 4–6–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2022–0329; FRL–9699–01–R7]

Air Plan Approval; Missouri; Start-Up, Shutdown, and Malfunction Conditions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Missouri State

Implementation Plan (SIP) received on February 11, 2020. In the submission, Missouri requests to revise a regulation related to reporting of start-up, shutdown, and malfunction (SSM) events. The revisions to this rule include adding incorporations by reference to other State rules, including definitions specific to the rule and making administrative wording changes. These revisions do not impact the stringency of the SIP or air quality. Approval of these revisions will ensure consistency between State and federally approved rules.

DATES: Comments must be received on or before May 9, 2022.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R07–OAR–2022–0329 to *https://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Written Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Allie Donohue, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7986; email address: *donohue.allie@epa.gov.*

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

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I. Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–OAR–2022–0329, at *https://www.regulations.gov.* 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 *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. What is being addressed in this document?

The EPA is proposing to approve Missouri's revisions to 10 Code of State Regulation (CSR) 10–6.050, *Start-Up, Shutdown, and Malfunction Conditions,* which relate to reporting of SSM events in the Missouri SIP. These provisions in the SIP require the reporting of SSM events to the Missouri Department of Natural Resources (MoDNR). Specifically, the provisions set the time by which such notification must occur, define what constitutes an SSM event, and establish the required contents of the written report including but not limited to measures taken to mitigate the extent and duration of the excess emissions, measures taken to remedy the situation which caused the excess emissions and the measures taken or planned to prevent the recurrence of these situations.

The EPA received the MoDNR's SIP revision submission on February 11, 2020. The EPA's full analysis of the revisions can be found in the technical support document (TSD) included in this docket.

In 10 CSR 10–6.050 Section (2) Definitions, the State incorporated definitions for ''excess emissions'' into subsection (A), ''malfunction'' into subsection (B), ''shutdown'' into subsection (C), and start-up into subsection (D). The definitions in the revision are the same as the definitions in the SIP approved 10 CSR 10–6.020. The revisions to Section (2) Definitions also move language about definitions not included in 10 CSR 10–6.050 into subsection (E). Because the language was already SIP-approved, and because the definitions relate to requirements related to informational reporting on SSM events, EPA finds that these revisions do not affect the stringency of the SIP. The rule revisions also include minor word changes, which are administrative in nature and do not affect the stringency of the SIP.

EPA finds that approving these revisions into the Missouri SIP is consistent with EPA's policy as further described in Section III.

III. Background

On February 22, 2013, the EPA issued a **Federal Register** notice of proposed rulemaking outlining EPA's policy at the time with respect to SIP provisions related to periods of SSM. EPA analyzed specific SSM SIP provisions and explained how each one either did or did not comply with the Clean Air Act (CAA) with regard to excess emission events.[1] EPA finalized this proposed action on June 12, 2015, in ''State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls To Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown and Malfunction'' (80 FR 33839, June 12, 2015), hereafter referred to as the ''2015 SSM SIP Action.''

As described in section IX.H.3 of the February 2013 proposal, EPA reviewed the Missouri rule at issue in this action because it was included in a Sierra Club petition.[2] Sierra Club argued that this Missouri provision gave State personnel authority to determine where enforcement action should be taken based on information a source submits about excess emissions resulting from a malfunction, start-up, or shutdown. EPA denied the petition on this provision and affirmatively found the provision to be consistent with the 2015 policy ''on the basis that the provision is on its face clearly applicable only to Missouri state enforcement personnel and that the provision thus could not reasonably be read by a court to foreclose enforcement by the EPA or through a citizen suit where Missouri state personnel elect to exercise enforcement discretion.'' As a result, Missouri rule, 10 Code of State Regulation (CSR) 10–6.050, *Start-Up, Shutdown, and Malfunction Conditions,* was not included in the 2015 SSM SIP Call. Because the Missouri submittal does not substantively alter this rule, EPA's previous conclusions relating to

[1] State Implementation Plans: Response to Petition for Rulemaking; Findings of Substantial Inadequacy; and SIP Calls To Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction, 78 FR 12460 (Feb. 22, 2013).

[2] Petition to Find Inadequate and Correct Several State Implementation Plans under section 110 of the Clean Air Act Due to Startup, Shutdown, Malfunction, and/or Maintenance Provisions (June 30, 2011).

this provision's compliance with EPA's SSM policy remain unchanged.

IV. Have the requirements for approval of a SIP revision been met?

The State submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision from June 3, 2019 to July 3, 2019 and received 6 comments. Five comments were from industry groups and one comment was from EPA. The industry comments all related to reporting excess emissions as soon as possible. Ultimately, the State opted not to include additional language to this effect and maintained that notification must occur within two days. The EPA comment letter indicated that EPA did not have comments on the rule changes. Therefore, the State adequately addressed each comment. In addition, as explained above, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

V. What action is the EPA proposing?

The EPA is proposing to approve Missouri's revisions to 10 CSR 10–6.050, *Start-Up, Shutdown, and Malfunction Conditions,* which relate to reporting of SSM events in the Missouri SIP as submitted to EPA on February 11, 2020. We are soliciting comments on this proposed action. Because this rule was previously approved into Missouri's SIP, we are soliciting comments solely on the proposed revisions to the rule and not on the existing text that is approved into Missouri's SIP. Final rulemaking will occur after consideration of any comments.

VI. Incorporation by Reference

In this document, the EPA is proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the Missouri Regulations described in Section II of this preamble and set forth in the proposed amendments to 40 CFR part 52 below. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VII. Statutory and Executive Order Reviews

Under the Clean Air Act (CAA), the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely 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);
- Is not subject to requirements of the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

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

Dated: March 31, 2022.

Meghan A. McCollister,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend 40 CFR part 52 as set forth below:

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 AA—Missouri

■ 2. In § 52.1320, the table in paragraph (c) is amended by revising the entry ''10–6.050'' to read as follows:

§ 52.870 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
* * *	*	*	*	*
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri				
* * *	*	*	*	*
10–6.050	Start-Up, Shutdown, and Malfunction Conditions.	1/30/2020	[Date of publication of the final rule in the **Federal Register**], [**Federal Register** citation of the final rule].	
* * *	*	*	*	*

* * * * *

[FR Doc. 2022–07292 Filed 4–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2021–0411; FRL–9547–01–R5]

Air Plan Approval; Minnesota; Bulk Silos FESOP Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a site-specific revision to the Minnesota State Implementation Plan (SIP) for particulate matter less than 10 microns (PM_{10}) for the portland cement distribution terminal owned and operated by Bulk Silos, LLC (Bulk Silos), formerly known as Lafarge North America Corporation on Childs Road Terminal (Lafarge-Childs Road Terminal) located in Saint Paul, Ramsey County, Minnesota. In its June 16, 2021, submittal, the Minnesota Pollution Control Agency (MPCA) requested that EPA approve certain conditions contained in Bulk Silos' federally enforceable state operating permit (FESOP) into the Minnesota PM SIP. The request is approvable because it satisfies the requirements of the Clean Air Act (CAA). MPCA's submission included an updated modeling demonstration to show the construction changes incorporated in the Title I SIP Conditions will not interfere with the ability to maintain the National Ambient Air Quality Standards (NAAQS), as Bulk Silos' allowable PM_{10} emissions limits will be decreased with this action.

DATES: Comments must be received on or before May 9, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2021–0411 at *http://www.regulations.gov,* or via email to *arra.sarah@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Olivia Davidson, Physical Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0266, *davidson.olivia@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives such comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: March 31, 2022.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2022–07287 Filed 4–6–22; 8:45 am]

BILLING CODE 6560–50–P

SURFACE TRANSPORTATION BOARD

49 CFR Chapter X

[Docket No. EP 768]

Petition for Rulemaking To Adopt Rules Governing Private Railcar Use by Railroads

AGENCY: Surface Transportation Board.

ACTION: Petition for rulemaking.

SUMMARY: The Board seeks public comment on a petition by the North America Freight Car Association, The National Grain and Feed Association, The Chlorine Institute, and The National Oilseed Processors Association to adopt regulations governing railroads' use of private freight cars and several specific related issues.

DATES: Comments are due by June 30, 2022; replies are due by August 1, 2022.

FOR FURTHER INFORMATION CONTACT: Amy Ziehm at (202) 245–0391. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On July 26, 2021, the North America Freight Car Association (NAFCA), The National Grain and Feed Association (NGFA), The Chlorine Institute (CI), and The National Oilseed Processors Association (NOPA) (collectively, Petitioners) filed a joint petition for rulemaking proposing that the Board adopt regulations allowing private railcar providers [1] to assess a ''private railcar delay charge'' if railroads delay private freight cars beyond a specified period of time. (Pet. 18.)

Petitioners assert that the Board may adopt their proposed regulations pursuant to its authority under 49 U.S.C. 11122(a)(2), which provides that the Board's car service regulations may include, in addition to the compensation to be paid, ''the other terms of any arrangement for the use by a rail carrier of a locomotive, freight car, or other vehicle not owned by the rail carrier using the locomotive, freight car, or other vehicle, whether or not owned by another carrier, shipper, or third person.''

After receiving a number of replies and notices of intent to participate in response to the petition, the Board opened a proceeding in this docket on November 23, 2021.

Background

Petitioners' Proposed Regulations. The regulations that Petitioners propose would allow private railcar providers to assess a charge when a private freight car does not move for more than 72 hours at any point on a railroad's system between the time it is ''released for transportation'' and the time it is ''either constructively placed or actually placed at the private railcar provider's facility or designated location.'' [2] (Pet. 24.) Petitioners propose that Car Location Message (CLM) Event Sighting Codes published by Railinc [3] would be used to measure time, and charges would be assessed when the ''CLM location city of CLM Sighting Code has not changed for more than [72] hours.'' (*Id.* at 18.) Petitioners suggest that the amount of the charge would be equivalent to the greater of the carrier's applicable demurrage or storage charge. (*Id.* at 24.) Charges would be assessed unless ''the rail carrier demonstrates that it was not a cause of the allowable transit idle time being exceeded despite exercising due diligence.'' (*Id.*) Furthermore, carriers would be able to dispute the amount of the charges in ''an appropriate proceeding in which the rail carrier shall bear the burden of proof to demonstrate that the private railcar delay charge is unreasonable and inappropriate.'' (*Id.*) Petitioners also argue that the Board should explore monetary penalties for noncompliance. (*Id.* at 17, 24.)

Petitioners argue that their proposed regulations are necessary to encourage the efficient use of private freight cars because carriers do not presently have sufficient incentives to use private freight cars efficiently. (*Id.* at 8–10.) Petitioners assert that there are no Board regulations and few tariff provisions that provide such incentives. (*Id.* at 9–10.) Petitioners also contend that carriers ''have little or no commercial incentive (other than revenue generation)'' to use private freight cars efficiently because most private railcar providers do not have the necessary commercial strength to negotiate service-standard contract provisions. (*Id.* at 11.) Moreover, petitioners argue that the ''lack of clarity and guidance as to the definition of the common carrier obligation, and the circumstances in which it is considered violated'' deter private railcar providers from pursuing formal complaints. (*Id.*) Petitioners contend that their proposal uses ''existing principles governing demurrage and accessorial charges'' to incentivize carriers to use private freight cars more efficiently. (*Id.* at 2.)

Petitioners also argue that their proposed regulations are necessary to compensate private railcar providers for the costs they incur when carriers use private freight cars inefficiently. (*Id.* at 12–13.) Petitioners state that private freight cars comprise most of the national fleet and that the costs of owning and maintaining private freight cars have increased significantly over the past 10 years. (*Id.* at 5–7.) Although Petitioners acknowledge that private railcar providers receive compensation from carriers for the use of their private freight cars, they argue that carriers' inefficient use of private freight cars deprives them of the use of their assets and makes it harder for them to earn a reasonable return on their investment. (*Id.* at 2, 12–13, 20–21.) Petitioners offer examples of carriers' inefficient use of private freight cars, including one in which a shipper's private freight cars were held by Class I carriers for periods of between eight and 61 days, as well as examples of the resulting harm to private railcar providers, including one in which a shipper incurred increased costs for trucks and special switches. (*Id.* at 13–14.)

Replies. The Board received replies to the petition from AAR; CSX Transportation, Inc. (CSXT); Union Pacific Railroad Company (UP); the Institute for Scrap Recycling Industries, Inc. (ISRI); a group of several shipper associations including the American Chemistry Council, The Fertilizer Institute, and the National Industrial Transportation League (collectively, Joint Shippers); the National Association of Chemical Distributors (NACD); the National Coal Transportation Association (NCTA); the Private Railcar Food and Beverage Association (PRFBA); American Fuel & Petrochemical Manufacturers (AFPM); the Freight Rail Customer Alliance (FRCA); and the Canadian Oilseed Processors Association (COPA), as well as notices of intent to participate from NGFA and the American Short Line and Regional Railroad Association. AAR, CSXT, and UP oppose the petition, while ISRI, Joint Shippers, NACD, NCTA, PRFBA, AFPM, FRCA, and COPA support it.

UP and AAR claim that the Board lacks the statutory authority under § 11122(a)(2) to adopt Petitioners' proposed regulations.[4] (UP Reply 2–3, Aug. 30, 2021; AAR Reply 3–6, Aug. 30, 2021.) UP argues that the Board must ''disregard the reference to 'freight cars' '' in the current version of § 11122(a)(2) because, prior to 1978, the relevant part of this paragraph (allowing the agency to regulate ''the other terms'' of arrangements) did not reference

[1] Petitioners define a ''private railcar provider'' as ''a shipper, receiver, or other party who owns or leases a private railcar and provides it to a railroad for transportation.'' (Pet. 23.)

[2] Constructive placement occurs when a railcar is available for delivery but cannot actually be placed at the receiver's destination because of a condition attributable to the receiver, such as lack of room on the tracks in the receiver's facility. *See Pol'y Statement on Demurrage & Accessorial Rules & Charges,* EP 757, slip op. at 8 n.22 (STB served Apr. 30, 2020).

[3] Railinc, a subsidiary of the Association of American Railroads (AAR), provides rail data and messaging services to the freight rail industry.

[4] CSXT states that it joins AAR's comments. (CSXT Reply 2.)

freight cars specifically but rather only locomotives and other vehicles.[5] (UP Reply 2–3, Aug. 30, 2021.) UP contends that although the current language of § 11122(a)(2) may suggest a broader authority to regulate arrangements for railroads' use of freight cars, substantive differences between the two versions of the provision must be resolved in favor of the pre-1978 Recodification statute because Congress expressly indicated that the 1978 Recodification may not be construed as making a substantive change to the existing laws. (UP Reply 3, Aug. 30, 2021 (citing *N. Am. Freight Car Ass'n* v. *Union Pac. R.R.,* NOR 42144, slip op. at 5 (STB served Mar. 22, 2021).)

AAR argues that the Board does not have the authority to adopt Petitioners' proposed regulations under § 11122(a)(2) because the Board's authority to regulate car service does not extend to the regulation of the transportation services railroads provide. (AAR Reply 4, Aug. 30, 2021.) In support, AAR cites to *Peoria & Pekin Union Railway* v. *United States,* 263 U.S. 528 (1923), and *Atchison, Topeka & Santa Fe Railway* v. *ICC,* 607 F.2d 1199 (7th Cir. 1979). (AAR Reply 4–5, Aug. 30, 2021.) In *Peoria,* the Supreme Court found that the ICC could not use its car service authority to require switching because the term ''car service'' means ''the use to which the vehicles of transportation are put; not the transportation service rendered by means of them.'' *Peoria,* 263 U.S. at 533–35. Pursuant to this definition, the court in *Atchison* determined that the ICC could not require tariff publication of operating schedules under its car service authority because tariff operating schedules were ''directly related to transportation service and do not fall within the definition of car service.'' *Atchison,* 607 F.2d at 1205. According to AAR, Petitioners' proposal would regulate transportation service because it would ''establish rigid standards relating to the details of how railroads provide transportation during the course of a car's movement across the network'' and essentially establish ''transportation service guarantees under another name.'' (AAR Reply 3–4, Aug. 30, 2021.) Moreover, AAR contends that, although the Board may establish regulations to ensure an adequate supply of freight cars, Petitioners have not demonstrated that a freight car shortage exists. (*Id.* at 5.)

AAR, CSXT, and UP additionally contend that Petitioners' proposed regulations are unnecessary because (1) carriers already have ample incentives to move private freight cars efficiently, as delays hinder operations and reduce revenue, (CSXT Reply 3–4; UP Reply 7–8, Aug. 30, 2021; AAR Reply 8–9, Aug. 30, 2021); (2) a significant portion of traffic moves under contract and would not be covered by Petitioners' proposed regulations, (CSXT Reply 7); (3) no freight car shortage exists justifying Board intervention, (UP Reply 4–6, Aug. 30, 2021; AAR Reply 5, Aug. 30, 2021); (4) private railcar providers have other avenues to pursue relief, such as through specific service commitments in contracts and the complaint process, (UP Reply 10–11, Aug. 30, 2021); and (5) private freight car ownership already conveys benefits, such as greater control over equipment and economic compensation from carriers, (AAR Reply 7, 10, Aug. 30, 2021). They also argue that Petitioners' proposed regulations will have a negative impact on the efficiency of the rail network by incentivizing carriers to move cars inefficiently to avoid the charges and by reducing cooperation between carriers during periods of network stress. (CSXT Reply 6; UP Reply 9, Aug. 30, 2021; AAR Reply 16, Aug. 30, 2021.)

Several respondents indicate that they support the petition because Petitioners' proposed regulations would provide appropriate financial incentives for Class I carriers to use private freight cars more efficiently, (*see, e.g.,* NCTA Comments 1–2; PRFBA Comments 1; FRCA Comments 1), and offer reciprocity for demurrage charges (*see, e.g.,* NACD Comments 1; AFPM Comments 2; COPA Comments 1–2). ISRI contends that carriers have essentially forced scrap metal companies to lease or own private freight cars after carriers reduced the number of system cars available to scrap steel shippers and shifted those available system cars to more profitable products. (ISRI Reply 5.) Joint Shippers ask the Board to solicit comments on ways to achieve greater reciprocity for the treatment of private freight cars during first-mile and last-mile service,[6] and on how Petitioners' proposed regulations would be implemented, including whether carriers would be responsible for monitoring railcar delays and crediting amounts owed under the proposed regulations against their demurrage invoices. (Joint Shippers Reply 3, 5.)

On September 10, 2021, Petitioners submitted a surreply to the replies, along with a motion for leave to file. Petitioners argue that the cases cited by AAR cannot be analogized to their proposal because Petitioners do not ''ask the Board to directly order the Railroads to take any action regarding their provision of transportation services.'' (Petitioners Surreply 4.) Furthermore, Petitioners assert that UP's argument contravenes the language of the 4R Act § 1(14)(a), 90 Stat. at 46, in which Congress expressed the clear intent to ''encourage the purchase, acquisition, and efficient utilization of freight cars'' and, ''[i]n order to carry out such intent,'' authorized the agency to ''establish reasonable rules, regulations, and practices with respect to car service.'' (Petitioners Surreply 5.) Petitioners also contend that prior agency decisions have construed § 11122(a) as authorizing the regulation of the terms of railroads' use of freight cars. (Pet. 15–17 (citing *Shippers Comm., OT–5* v. *Ann Arbor R.R.,* 5 I.C.C. 2d 856, 863–64 (1989) (determining, pursuant to § 11122(a), that carriers may not restrict the access of private freight cars except under exceptional circumstances), *aff'd sub nom. Shippers Comm., OT–5* v. *ICC,* 968 F.2d 75 (D.C. Cir. 1992); Petitioners Surreply 6.)

On September 23, 2021, AAR and UP submitted replies to Petitioners' motion for leave. AAR contends that Petitioners' efforts to distinguish *Peoria* and *Atchison* are unavailing since ''the proposed Board action would dictate how railroads perform transportation services, namely switching services.'' (AAR Reply 1–2, Sept. 23, 2021.) UP argues that the Board should reject Petitioners' claim that the agency has construed § 11122(a) as allowing it to regulate the terms of railroads' use of

[5] The predecessor to § 11122(a) stated, in relevant part:

It is the intent of the Congress to encourage the purchase, acquisition, and efficient utilization of freight cars. In order to carry out such intent, the Commission may, upon complaint of an interested party or upon its own initiative without complaint, and after notice and an opportunity for a hearing, establish reasonable rules, regulations, and practices with respect to car service by common carriers by railroad subject to this part, including (i) the compensation to be paid for the use of any locomotive, freight car, or other vehicle, (ii) the other terms of any contract, agreement, or arrangement for the use of any locomotive or other vehicle not owned by the carrier by which it is used (and whether or not owned by another carrier, shipper, or third party), and (iii) the penalties or other sanctions for nonobservance of such rules, regulations, or practices.

Railroad Revitalization and Regulatory Reform Act of 1976 (4R Act), Public Law 94–210, 1(14)(a), 90 Stat. 31, 46–47. In 1978, Congress recodified the Interstate Commerce Act, enacting it as Title 49 of the U.S. Code, and stated that the agency's car service regulations may include ''the other terms of any arrangement for the use by a rail carrier of a locomotive, freight car, or other vehicle not owned by the rail carrier using the locomotive, freight car, or other vehicle, whether or not owned by another carrier, shipper, or third person.'' Act of Oct. 17, 1978, Public Law 95–473, 11122(a)(2), 92 Stat. 1337, 1421–22 (1978 Recodification).

[6] ISRI states that it supports Joint Shippers' request for comments on first-mile and last-mile service. (ISRI Comments 3.)

freight cars. (UP Reply 1, Sept. 23, 2021.)

On November 23, 2021, the Board granted Petitioners' motion for leave to file a surreply, opened a proceeding to consider Petitioners' proposal, and stated that it would establish procedures for public comment in a subsequent decision.

Request for Comments

The Board invites comment on the issues raised in the petition generally as well as on the following specific questions:

1. Petitioners assert that the Board's current regulations and policies do not create sufficient incentives for Class I carriers to use private freight cars efficiently. (Pet. 2.) The Board invites commenters to provide detailed, concrete examples of carriers' inefficient use of private freight cars (*i.e.,* the carriers and car owners involved, relevant dates and times, etc.). They may also wish to provide context for their comments by including information about the quantity of private freight cars owned or leased, volume of traffic shipped, storage capacity, and seasonality of shipments (if any). If requested, a protective order may be issued that would allow sensitive information to be filed under seal. In particular, the Board asks commenters to address the following:

a. How frequently do carriers hold private freight cars for more than 72 consecutive hours? The Board requests that commenters provide supporting data on the frequency of this occurrence, where available.

b. To the extent known by the commenter, why do carriers hold private freight cars for more than 72 consecutive hours?

c. To the extent known by the commenter, at which location(s) on the rail system are private freight cars held for more than 72 consecutive hours?

d. How are rail users' operations, facilities, production, and/or finances affected?

e. Has the frequency and severity of the issue changed with the implementation of operating changes by Class I railroads?

2. UP asserts that Petitioners' proposed regulations are unnecessary because private railcar providers have other avenues to pursue relief, such as through specific service commitments in contracts. (UP Reply 10–11, Aug. 30, 2021.) Do such contract service commitments include similar terms to the regulations proposed by Petitioners?

3. How, if at all, would Petitioners' proposal regulate ''car service'' within the meaning of 49 U.S.C. 11122(a) by ''encourag[ing] the purchase, acquisition, and efficient use of freight cars''?

a. The Board invites commenters to address AAR's argument that Petitioners' proposal would regulate the ''transportation services'' that railroads provide, rather than ''car service'' within the meaning of § 11122(a). (*See* AAR Reply 3–6, Aug. 30, 2021.)

b. To what extent is a finding of inadequate car supply a prerequisite for the Board to adopt Petitioners' proposed regulations?

c. Do rail users currently lack access to an adequate supply of freight cars or anticipate a future freight car shortage?

i. If so, how would the proposed regulations help solve or mitigate the issue? The Board requests that commenters provide supporting data on any claim of a current or future inadequacy of car supply, where available.

d. Petitioners contend that their proposed regulations would ''result in the national railcar fleet being of a more rational size to utilize existing rail system capacity and meet demand.'' (Pet. 2.)

i. How would the proposed regulations lead to a more rationally sized freight car fleet?

ii. How, if at all, would a more rationally sized freight car fleet ensure an adequate supply of freight cars?

4. How would Petitioners' proposed regulations affect rail users that do not use private freight cars? For example, CSXT, UP, and AAR argue that Petitioners' proposed regulations would create incentives for carriers to prioritize private freight cars to the disadvantage of rail users that use railroad-owned freight cars. (CSXT Reply 2; UP Reply 8 n.26, Aug. 30, 2021; AAR Reply 16, Aug. 30, 2021.)

5. Petitioners propose that charges would be assessed unless ''the rail carrier demonstrates that it was not a cause of the [72 hours] being exceeded despite exercising due diligence.'' (Pet. 24.)

a. In what kinds of circumstances should carriers be able to show that they were not ''a cause'' of the 72 hours being exceeded?

b. What kind of actions should constitute ''due diligence''?

c. How would this standard account for the possibility raised by AAR that carriers may hold private freight cars longer than 72 consecutive hours to improve the overall efficiency of the rail network (*i.e.,* to prevent congestion at terminals during times of peak demand or to recover from network disruptions caused by weather events)? (*See* AAR Reply 16, Aug. 30, 2021.)

d. How would this standard account for rail users' own car supply decisions? For example, UP argues that Petitioners' proposed regulations would ''incentivize shippers to acquire additional freight cars and deploy them during service disruptions, despite their potential to contribute to congestion problems.'' (UP Reply 13–14, Aug. 30, 2021.)

6. How would rail network efficiency be affected by the proposal?

a. The Board requests that commenters provide data, where available, to support claims that the rail network would be more (or less) efficient as a result of Petitioners' proposed rule.

b. Under Petitioners' approach, to what extent would carriers have incentives to make potentially inefficient movements solely to avoid charges? (*See* CSXT Reply 6; AAR Reply 16, Aug. 30, 2021; UP Reply 9, Aug. 30, 2021.)

7. Under Petitioners' proposed regulations, private railcar providers would be able to assess charges if the ''CLM location city of CLM Sighting Code'' of a private freight car has not changed for more than 72 consecutive hours. (Pet. 18.)

a. Why is 72 hours an appropriate timeframe and not, for example, 48 hours or 96 hours?

b. Why should charges be based on when cars are idle for more than 72 consecutive hours, as opposed to, for example, overall transit idle times for the entire trip or when the placement of private freight cars exceeds projected transit times?

c. Are CLM Event Sighting Codes a practical way to measure idle time?

i. If not, what metric, if any, would be more useful as the basis for assessing delay charges?

d. At what point should the timeframe begin (*i.e.,* as soon as a rail user releases a private freight car, when the carrier picks up the private freight car, or some other point)?

i. And if the 72-hour timeframe begins when private freight cars are released, how would this timeframe apply to rail users that receive service only once or twice per week?

8. Petitioners' proposal contemplates that the amount of the ''private railcar delay charge'' would correspond to the carrier's applicable demurrage or storage charge unless the carrier could demonstrate that such a charge would be ''unreasonable and inappropriate'' in a particular situation. (Pet. 24.)

a. Is it appropriate for the Board to equate the amount of the ''private railcar delay charge'' to a demurrage or storage charge in most cases?

b. To what extent are there practical alternatives to equating Petitioners' proposed ''private railcar delay charge'' to a demurrage or storage charge and what are the merits of those alternatives?

9. Commenters should address the following questions about how the regulations proposed by Petitioners would be implemented:

a. Which party would be responsible for tracking the CLM Event Sighting Codes for private freight cars and invoicing in accordance with the proposed regulations?

b. Joint Shippers suggest that the Board could require carriers to credit charges against their demurrage invoices. (Joint Shippers Reply 5.) How would compensation be handled under this proposal for rail users that do not incur demurrage charges or incur fewer charges than would be owed pursuant to the proposed regulations?

10. Petitioners suggest that the proposed regulations should apply only to Class I carriers. (Pet. 1–2.) How, if at all, would Class II and Class III carriers be impacted by the proposed regulations, if limited to Class I carriers?

Interested persons may file comments by June 30, 2022. Replies will be due by August 1, 2022.

It is ordered:

1. Comments are due by June 30, 2022; replies are due by August 1, 2022.

2. Notice of this decision will be published in the **Federal Register**.

3. This decision is effective on its service date.

Decided: April 1, 2022.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2022–07349 Filed 4–6–22; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2022–0024; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BG21

Endangered and Threatened Wildlife and Plants; Endangered Species Status for the Dixie Valley Toad

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Dixie Valley toad (*Anaxyrus williamsi*), a toad species from Nevada, as an endangered species under the Endangered Species Act of 1973, as amended (Act). This determination also serves as our 12-month finding on a petition to list the Dixie Valley toad. After a review of the best available scientific and commercial information, we find that listing the species is warranted. An temporary rule (emergency action) listing this species as endangered for 240 days is published concurrently in this issue of the **Federal Register**. We find that the designation of critical habitat for the Dixie Valley toad is not determinable at this time. We solicit additional data, information, and comments that may assist us in making a final decision on this action. We also are notifying the public that we have scheduled an informational meeting followed by a public hearing on the proposed rule.

DATES: We will accept comments received or postmarked on or before June 6, 2022. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. *Public informational meeting and public hearing:* On May 9, we will hold a public informational meeting 5 p.m. to 5:35 p.m., Pacific Time, followed by a public hearing 5:35 to 7 p.m., Pacific Time.

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

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R8–ES–2022–0024, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R8–ES–2022–0024, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

FOR FURTHER INFORMATION CONTACT: Marc Jackson, Field Supervisor, U.S. Fish and Wildlife Service, Reno Fish and Wildlife Office, 1340 Financial Blvd., Suite 234, Reno, Nevada 89502; telephone 775–861–6300. 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.

SUPPLEMENTARY INFORMATION:

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) The species' biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current population levels, and current and projected trends; and

(d) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, additional information on the potential effects of geothermal plants on amphibians or wetland ecosystems, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status of this species.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information,

although noted, do not provide substantial information necessary to support a determination.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *https://www.regulations.gov.*

Because we will consider all comments and information we receive during the comment period, our final determinations may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that the species is threatened instead of endangered, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. At this time, we have preemptively scheduled a public informational meeting and public hearing on this proposed rule. We will hold the public informational meeting and public hearing on the date and at the times listed above under *Public informational meeting and public hearing* in **DATES**. We are holding the public informational meeting and public hearing via the Zoom online video platform and via teleconference so that participants can attend remotely. For security purposes, registration is required. To listen and view the meeting and hearing via Zoom, listen to the meeting and hearing by telephone, or provide oral public comments at the public hearing by Zoom or telephone, you must register. For information on how to register, or if you encounter problems joining Zoom the day of the meeting, visit *https://www.fws.gov/office/reno-fish-and-wildlife.* Registrants will receive the Zoom link and the telephone number for the public informational meeting and public hearing. If applicable, interested members of the public not familiar with the Zoom platform should view the Zoom video tutorials (*https://support.zoom.us/hc/en-us/articles/206618765-Zoom-video-tutorials*) prior to the public informational meeting and public hearing.

The public hearing will provide interested parties an opportunity to present verbal testimony (formal, oral comments) regarding this proposed rule to list the Dixie Valley toad as an endangered species. The public hearing is a forum for accepting formal verbal testimony and is not an opportunity for open dialogue. In the event there is a large attendance, the time allotted for oral statements may be limited. Therefore, anyone wishing to make an oral statement at the public hearing for the record is encouraged to provide a prepared written copy of their statement to us through the Federal eRulemaking Portal, or U.S. mail (see **ADDRESSES**, above). There are no limits on the length of written comments submitted to us. Anyone wishing to make an oral statement at the public hearing must register before the hearing *https://www.fws.gov/office/reno-fish-and-wildlife.* The use of a virtual public hearing is consistent with our regulations at 50 CFR 424.16(c)(3).

Reasonable Accommodation

The Service is committed to providing access to the public informational meeting and public hearing for all participants. Closed captioning will be available during the public informational meeting and public hearing. Further, a full audio and video recording and transcript of the public hearing will be posted online at *https://www.fws.gov/office/reno-fish-and-wildlife* after the hearing. Participants will also have access to live audio during the public informational meeting and public hearing via their telephone or computer speakers. Persons with disabilities requiring reasonable accommodations to participate in the meeting and/or hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the date of the meeting and hearing to help ensure availability. An accessible version of the Service's public informational meeting presentation will also be posted online at *https://www.fws.gov/office/reno-fish-and-wildlife* prior to the meeting and hearing (see **DATES**, above). See *https://www.fws.gov/office/reno-fish-and-wildlife* for more information about reasonable accommodation.

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Dixie Valley toad. The SSA team was composed of Service biologists, in consultation with other scientific experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species and its habitat. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we will seek expert opinions of at least three appropriate specialists regarding the SSA. The SSA report and other materials related to this proposed rule can be found at *https://www.regulations.gov* under Docket No. FWS–R8–ES–2022–0024.

I. Proposed Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of the Dixie Valley toad (*Anaxyrus williamsi*) is presented in the SSA report (Service 2022, entire).

The Dixie Valley toad was described as a distinct species in the western toads (*Anaxyrus boreas*) species complex in 2017 due to morphological differences, genetic information, and its isolated distribution (Gordon et al. 2017, entire). Forrest et al. (2017, entire) also published a paper describing Dixie Valley toad and came up with similar results but stopped short of concluding that it is a unique species. We evaluated both papers and concluded the Gordon et al. (2017, entire) paper provided a better sampling design to answer species-level genetic questions and conducted a more thorough morphological analysis. Additionally, the Dixie Valley toad has been accepted as a valid species by the two leading authoritative amphibian internet sites: (1) Amphibiaweb.org (AmphibiaWeb 2022, website) and (2) Amphibian Species of the World (Frost 2021, website). Because both the larger scientific community and our own analysis of the best available scientific information indicate that the findings of Gordon et al. (2017 entire) are well supported, we are accepting their conclusions that the Dixie Valley toad is a unique species (*Anaxyrus williamsi*). Therefore, we have determined that the Dixie Valley toad is a listable entity under the Act.

Fourteen different morphological characteristics of Dixie Valley toads were measured and compared to several other species within the western toads species complex (Gordon et al. 2017, pp. 125–131). While all 14 morphological characteristics measured for Dixie Valley toad were significantly different from the other species within the western toads species complex, the most striking differences were the average size of adults (mean snout-to-vent length (SVL) of 54.6 millimeters (mm) (2.2 inches (in)), which makes it the smallest species within the *A. boreas* species complex), the close-set eyes and perceptively large tympanum (eardrum), and its unique coloration (Gordon et al. 2017, pp. 125–131).

Limited information is available specific to the life history of the Dixie Valley toad; therefore, closely associated species are used as surrogates where appropriate. Breeding (denoted by observing a male and female in amplexus, egg masses, or tadpoles) occurs annually between March and May (Forrest 2013, p. 76). Breeding appears protracted due to the thermal nature of the habitat and can last up to 3 months (March–May) with toads breeding early in the year in habitats closer to the thermal spring sources and then moving downstream into habitats as they warm throughout spring and early summer. Other toad species typically have a much more contracted breeding season of 3–4 weeks (*e.g.,* Sherman 1980, pp. 18–19, 72–73). Dixie Valley toad tadpoles hatch shortly after being deposited; time to hatching is not known but is likely dependent on water temperature (*e.g.,* black toad (*Anaxyrus exsul*) tadpoles hatch in 7 to 9 days; Sherman 1980, p. 97). Fully metamorphosed Dixie Valley toadlets were observed 70 days after egg laying (Forrest 2013, pp. 76–77).

The Dixie Valley toad is a narrow-ranging endemic (highly local and known to exist only in their place of origin) known from one population in the Dixie Meadows area of Churchill County, Nevada. The species occurs primarily on Department of Defense (Fallon Naval Air Station) lands (90 percent) and Bureau of Land Management (BLM) lands (10 percent). The wetlands located in Dixie Meadows cover 307.6 hectares (ha) (760 acres (ac)) and are fed by geothermal springs. The potential area of occupancy is estimated to be 146 ha (360 ac) based on the extent of wetland-associated vegetation. The species is heavily reliant on these wetlands, as it is rarely encountered more than 14 meters (m) (46 feet (ft)) from aquatic habitat (Halstead et al. 2021, p. 7).

The Nevada Department of Wildlife received approval by the Legislative Council Bureau to add Dixie Valley toads as a protected amphibian by the State of Nevada under Nevada Administrative Code (NAC) 503.075(2)(b). The revised list of protected amphibians is expected to be finalized in 2022. Per NAC 503.090(1), there is no open season on those species of amphibian classified as protected. Per NAC 503.094, the State issues permits for the take and possession of any species of wildlife for strictly scientific or educational purposes. The Nevada Department of Conservation and Natural Resources includes the Nevada Division of Natural Heritage (NDNH), which tracks the species status of plants and animals in Nevada. The NDNH recognizes Dixie Valley toads as critically imperiled, rank *S1.* Ranks of *S1* are defined as species with very high risks of extirpation in the jurisdiction due to very restricted range, very few populations or occurrences, very steep declines, severe threats, or other factors.

For an extensive discussion of biological background information, previous Federal actions, biological status, the threats analysis, conservation efforts and regulatory mechanisms, our determination of status under the Act, and conservation measures available to listed and proposed species, consult the temporary rule, emergency action, for the Dixie Valley toad published concurrently in this issue of the **Federal Register**. The temporary rule further contains the rationale for this proposal to list the Dixie Valley toad as an endangered species under the Act.

II. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals). Additionally, our regulations at 50 CFR 424.02 define the word ''habitat,'' for the purposes of designating critical habitat only, as the abiotic and biotic setting that currently or periodically contains the resources and conditions necessary to support one or more life processes of a species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives''

to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat).

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. The implementing regulations at 50 CFR 424.12(b)(2) further delineate unoccupied critical habitat by setting out three specific parameters: (1) When designating critical habitat, the Secretary will first evaluate areas occupied by the species; (2) the Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species; and (3) for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

As the regulatory definition of ''habitat'' reflects (50 CFR 424.02), habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

As discussed in the SSA report, there is currently no imminent threat of collection or vandalism (identified under Factor B) for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In our SSA report and emergency listing rule for the Dixie Valley toad, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to Dixie Valley toad and that those threats in some way can be addressed by section 7(a)(2) consultation measures. The species occurs wholly in the jurisdiction of the United States, and we are able to identify areas that meet the definition of critical habitat. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) have been met and because the Secretary has not identified other circumstances for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for the Dixie Valley toad.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the Dixie Valley toad is determinable.

Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. Careful assessments of the economic impacts that may occur due to a critical habitat designation are not yet complete. Therefore, data sufficient to perform required analyses are lacking, and we conclude that the designation of critical habitat for the Dixie Valley toad is not determinable at this time. The Act allows the Service an additional year to publish a critical habitat designation that is not determinable at the time of listing (16 U.S.C. 1533(b)(6)(C)(ii)).

Required Determinations

Clarity of the Rule

We are required by E.O.s 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951, May 4, 1994), E.O. 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We requested information from the Paiute-Shoshone Tribe of the Fallon Reservation and Colony and have continued to coordinate during the SSA process. We are requesting the Tribe's partner review of the draft SSA report concurrent with the comment period identified in this proposed rule, which is published concurrently with the temporary rule found in the Rules and Regulations section of this issue of the **Federal Register** (see Docket No. FWS–R8–ES–2022–0024 at *https://www.regulations.gov*). We will continue to work with Tribal entities during the development of a final listing rule for the Dixie Valley toad, and for a designation of critical habitat if found to be prudent and determinable.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Reno Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Reno Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Published concurrently in the Rules and Regulations section of this issue of the **Federal Register**, we are exercising our authority pursuant to section 4(b)(7) of the Endangered Species Act of 1973, as amended, to emergency list for 240 days the Dixie Valley toad (*Anaxyrus williamsi*) as an endangered species due to the imminent development of a geothermal project in Dixie Meadows, Nevada, and the potential resulting effects to the geothermal springs relied upon by the Dixie Valley toad. For the reasons discussed in the preamble of that temporary rule, we propose to make the emergency listing permanent.

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–07375 Filed 4–6–22; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register

Vol. 87, No. 67

Thursday, April 7, 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

Agricultural Research Service

Notice of Intent To Seek OMB Approval To Collect Information: Forms Pertaining to the Scientific Peer Review of ARS Research Projects

AGENCY: Agricultural Research Service (ARS), USDA.

ACTION: Notice and request for comments.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act of 1995 and OMB implementing regulations. The Department is soliciting public comments on the subject proposal.

DATES: Written comments on this notice should be submitted on or before June 6, 2022.

ADDRESS: All comments concerning this notice should be directed to the Director & Program Coordinator listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Dr. Marquea D. King, Director & Program Coordinator, Office of Scientific Quality Review (OSQR); ARS, USDA; 5601 Sunnyside Avenue, Beltsville, Maryland; 20705; Phone: 301–504–3283; Fax: 301–504–1251; email: *marquea.king@usda.gov*.

SUPPLEMENTARY INFORMATION: The OSQR will seek approval from OMB to update six existing forms that will ensure the ARS efficiently manages data associated with the peer review of agricultural research. All forms are transferred and received electronically and may include on-line submission in the future.

Abstract: The OSQR was established in September of 1999 as a result of the Agricultural Research, Extension, and Education Reform Act 1998 (''The Act'') (Pub. L. 105–185). The Act included mandates to perform scientific peer reviews of all research activities conducted by the USDA. The Office manages the ARS peer review system by centrally coordinating all of the intramural peer review functions for ARS research projects on a 5-year cycle.

Each set of reviews is assigned a chairperson to govern the panel review process. Peer reviewers are external to the Agency and non-ARS scientists. Peer review panels are convened to assess the technical/scientific quality and correctness of each research project plan. Each panel reviewer receives information on a range of 2–5 ARS research projects.

On average, 150 research projects are reviewed annually by an estimated 185 reviewers; whereby approximately 130 are reviewed by panel and approximately 20 are reviewed through an ad hoc (written review) process. The management and execution of this peer review process is vastly dependent on the use of these forms.

The OSQR will seek OMB approval of the following forms:

1. Confidentiality Agreement Form—USDA uses this form to document that a selected reviewer is responsible for keeping confidential any information learned during the subject peer review process. The Confidentiality Agreement is signed prior to the reviewer's involvement in the peer review process. This form requires an original signature and can be submitted electronically.

2. Panelist Information Form—USDA uses this form to gather the most recent background information, diversity and inclusion data about the reviewer as well as information relevant to the paying of an honorarium and for travel, when needed. Sensitive information is transmitted on this form and destroyed after payment is received.

3. Peer Review of an ARS Research Project Form (Peer Review Form)—USDA uses this form to guide the reviewer's expert comments in written form on the assigned project plan. The form contains the criteria for plan review and seeks the reviewer's narrative comments and evaluation.

4. Additional Reviewer Comment Form—This form is supplied to members of a panel not assigned as a primary nor secondary reviewer on a particular project plan, however it encourages additional expert comments or recommendations for any plan regardless of the reviewers' assignment as primary or secondary.

5. Ad Hoc Review Form—USDA uses this in select cases (for Reviewers not participating in a panel review), a check-off listing of action classes at the end of the form allows them to provide an overall rating of the plan.

6. Recommendations for ARS Research Project Form—USDA uses this form to guide the panel's evaluation and critique of the review process. The form combines both primary and secondary reviewers' recommendations of the research project plan.

7. Panel Expense Report Form (Expense Report)—USDA uses this form to document a panel reviewer's expense incurred traveling to and attending a peer review meeting. The Expense Report includes lodging, meals, and transportation expenses. When completed, the form contains sensitive information and is held in compliance with the ARS travel guidelines. This form is used only in the rare circumstance that a panel meeting requires travel of the participants.

USDA's collection of information on the Confidentiality Agreement Form is needed to document that a selected reviewer is responsible for keeping confidential any information learned during the subject peer review process. The Confidentiality Agreement would be signed prior to the reviewer's involvement in the peer review process.

USDA's collection of information on the Panelist Information Form is needed to collect the most recent background information along with diversity and inclusion data about the reviewer. It contains sensitive information.

USDA's collection of information on the Peer Review Form and Reviewer Comment Form is needed to guide the reviewer's comments on the subject project. Both contain review guidance and space to insert comments.

USDA's collection of information on the Ad Hoc Review Form is needed to guide reviewer comments of those not participating in a chaired panel and affords a place to select an overall Action Class rating for the plan.

USDA's collection of information on the Recommendations Form is needed to guide the panel's critique of the review process. It contains the recommendations of the panel for the subject research project.

USDA's collection of information on the Expense Report Form is needed to document a panel reviewer's expenses

incurred by attending a peer review meeting. The Expense Report includes lodging, meals, and transportation expenses. It includes sensitive information.

Estimate of Burden: The burden associated with this approval process is the minimum required to successfully achieve program objectives. The information collection frequency is the minimum consistent with program objectives. The following estimates of time required to complete the forms, based on previous OSQR's experience with our current business model.

1. Confidentiality Agreement Form: (10 minutes completion time). The reviewer must read and consider the terms of the agreement and then sign and date the form.

2. Panelist Information Form: (30 minutes completion time). The reviewer provides standard personal and diversity information, similar to that found in grant review programs.

3. Panelist Peer Review of an ARS Research Project Form: (4–7 hours completion time). As the review page length varies. Reviewers freely write as much as they wish and complete the form. To adequately evaluate a research project plan that may exceed 60–70 pages in length, each reviewer must thoroughly read each plan.

4. Reviewer Comment Form: (60 minutes completion time). General assessment of the plan with brief comments on the approach and feasibility of the project and about one page.

5. Panel Recommendation for ARS Research Project Form: (30–60 minutes completion time). The page length significantly varies among Panelist Peer Reviews and Reviewer Comments. All recommendation forms are completed by the OSQR and further discussed and revised by the reviewers as part of their panel discussions. In-person panels are handled in the same manner.

6. Panel Expense Report Form: (30 minutes completion time).

Respondents and Estimated Number of Respondents: Selected scientific experts, currently working in the same discipline as the research projects being peer reviewed. These external experts are credible peers to the ARS. Annually, about 185 peer reviewers complete these forms. Most plans are discussed and deliberated via webinar and telephone conferencing. Travel is not generally necessary thus reviewers are not expected to complete Panel Expense Reports.

Frequency of Response:

Form	Number of respondents	Annual frequency
Confidentiality Agreement	185	1 per respondent (Total = 185).
Peer Review Forms (required and assigned 2 plans)	200	2 per panel respondent (Total = 400).
Reviewer Comment Form (reviewer is not assigned as primary or secondary review)	6	2 per panel respondent (Total = 12).
Expense Report (in-person reviewers)	6	1 per respondent (Total = 6).
Panelist Information Forms	185	1 per respondent/per form (Total = 185).
Recommendations Form (non-online project reviews)	82	2 per respondent (Total = 164).

Estimated Total Annual Burden on Respondents:

Form (time required to complete)	Number completed annually	Total burden (hours)
Confidentiality Agreement (10 minutes)	185	31
Panelist Information Forms (30 minutes)	185	93
Peer Review Forms (~6 hours)	200	1,200
Recommendations Form (2 hour)	82	164
Reviewer Comment Form (1 hour)	6	6
Expense Report (30 minutes)	6	3

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. chap. 35.

Comments: The Notice is soliciting comments from members of the public and impacted agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of ARS functions, including whether the information will have practical utility; (2) Evaluate the accuracy of the estimated burden from proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. All responses to this notice will be summarized and included in the request for OMB approval.

All comments will become a matter of public record.

Simon Y. Liu,

Associate Administrator, ARS.

[FR Doc. 2022–07407 Filed 4–6–22; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Notice of Request for Emergency Approval

In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Department of Agriculture (USDA) has submitted a request to the Office of Management and Budget (OMB) for a 6-month emergency approval of the following information collection: ICR 0560–0307, Emergency Livestock Relief Program (ELRP). Due to the Notice of Funding Availability notice published on April 4, 2022, FSA received OMB approval for the Emergency Request to allow FSA to begin distributing payments under the ELRP to eligible livestock producers who faced increased supplemental feed costs as a result of forage losses due to a qualifying drought or wildfire in calendar year 2021.

Farm Service Agency

Title: Emergency Livestock Relief Program.

OMB Control Number: 0560–0307.

Summary of Collection: The Farm Service Agency (FSA) is requested emergency clearance and review through 5 CFR 1320.13 for a new

information collection for the. FSA is using the Extending Government Funding and Delivering Emergency Assistance Act (Division B, Title 1, Pub. L. 117–43), to assist producers of livestock for losses incurred during calendar 2021 due to qualifying droughts or wildfires.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–07409 Filed 4–6–22; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Office of the Chief Financial Officer

Agency Programs Subject to Intergovernmental Review

AGENCY: Office of the Chief Financial Officer, USDA.

ACTION: Notice.

SUMMARY: The United States Department of Agriculture (USDA) is publishing an updated list of USDA financial assistance programs which States may choose to review under their Single Point of Contact (SPOC) intergovernmental review processes. These programs are also eligible for intergovernmental review by directly affected State, areawide, regional, and local entities if a State does not have a SPOC or chooses not to review an application for USDA financial assistance. USDA is streamlining the intergovernmental review process.

DATES: The list of financial assistance programs will be posted on the USDA website beginning April 7, 2022 and updated annually.

FOR FURTHER INFORMATION CONTACT: Tyson P. Whitney, Office of the Chief Financial Officer, Director, Transparency and Accountability Reporting Division, United States Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–9011, 202–720–8978, *tyson.whitney@usda.gov.*

SUPPLEMENTARY INFORMATION: As provided in 2 CFR 415.5, USDA published a notice in the **Federal Register** on December 4, 1987 (52 FR 46109) which listed USDA financial assistance programs subject to review under Executive Order 12372 and Section 204 of the Demonstration Cities and Metropolitan Development Act (Section 204) and Section 401(a) of the Intergovernmental Cooperation Act of 1968 (Section 401). This notice advises the public of the availability of a current list of USDA programs which States may choose to (1) review under their official Executive Order 12372 SPOC process or (2) are subject to the review process described at 2 CFR 415.9(a) if it does not have a SPOC or elects not to include an USDA program in the SPOC process. Executive Order 12372 exempts tribal programs from intergovernmental review.

As part of a streamlining initiative, rather than posting changes to the list in **Federal Register** notices, USDA's list of financial assistance programs subject to intergovernmental review will be posted on the USDA Office of the Chief Financial Officer website at *https://www.ocfo.usda.gov/FederalFinancialAssistancePolicy.* USDA will provide updates to the website annually.

Tyson P. Whitney,

Director, Transparency and Accountability Reporting Division.

[FR Doc. 2022–07399 Filed 4–6–22; 8:45 am]

BILLING CODE 3410–KS–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Supplemental Nutrition Assistance Program: Reporting of Lottery and Gambling, and Resource Verification

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a revision of a currently approved collection and existing burden in use without a valid OMB control number in the Supplemental Nutrition Assistance Program (SNAP). This information collection captures the burden associated with the requirement that States make ineligible SNAP participants with substantial lottery or gambling winnings and establish cooperative agreements with gaming entities within their States to identify SNAP participants with substantial winnings. Individuals and households are required to report substantial winnings. This revision removes the one-time start-up burden hours that were associated with establishing the collection of this information and modifies the ongoing burden hours associated with SNAP State agency eligibility workers in addition to bringing other burden activities associated with resource verification requirements into compliance.

DATES: Written comments must be received on or June 6, 2022.

ADDRESSES: Comments may be sent to: Program Design Branch, Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314. Comments may also be submitted via email to Jessica Luna at 703–305- 4391 or via email to *SNAPPDBRules@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Jessica Luna at 703–305–4391.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were 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 those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Supplemental Nutrition Assistance Program: Reporting of Lottery and Gambling, and Resource Verification.

Form Number: N/A.

OMB Control Number: 0584–0621.

Expiration Date: November 30, 2022.

Type of Request: Revision of a currently approved collection and addition of an existing collection in use without an OMB control number.

Abstract:

Lottery and Gambling

In accordance with section 4009 of the Agricultural Act of 2014, households in which members receive substantial lottery and gambling winnings are ineligible for SNAP until

they meet allowable financial resources and income eligibility requirements. Substantial winnings are defined as winnings that are equal to or greater than the resource limit for elderly or disabled households as defined in 7 CFR 273.8(b). States are also required to work cooperatively with entities responsible for gaming in their State to identify individuals and households with substantial winnings. SNAP households must report substantial winnings to State SNAP agencies. These requirements at 7 CFR 273.11(r) were implemented in 2019 through final rulemaking titled ''Supplemental Nutrition Assistance Program: Student Eligibility, Convicted Felons, Lottery and Gambling, and State Verification Provisions of the Agricultural Act of 2014'', published on April 15, 2019 (84 FR 15083, RIN 0584–AE41). A technical correction to the 60-Day Notice associated with this rulemaking was published on June 21, 2019 (84 FR 29029, RIN 0584–AE41).

In the process of renewing this information collection, FNS modified the reporting burden to remove the one-time start-up burden hours associated with the initial implementation of the requirements, such as establishing cooperative agreements. FNS also adjusted its calculation of burdens on State agency eligibility workers. Therefore, the burden for this set of requirements represents a decrease of −408,406.25 burden hours from the previous approval for this collection.

In the previous approval for this collection, the Agency assumed that 3 State SNAP agencies do not have lottery or gambling entities and are not likely to incur burden related to the lottery and gambling requirements. Because there is not an authoritative and comprehensive source of lottery and gambling legality information nationwide, and given wide variation across States, the Agency maintains this assumption for the purposes of this renewal.

The Agency assumes that the 50 State SNAP agencies subject to this requirement (the Agency assumes 3 State SNAP agencies do not have lottery or gambling entities) have already established cooperative agreements with the public agency gaming entities (1 per State, 50 total) and private gaming entities (4 per State, 200 total) in their State. These agreements use computerized data matching to identify winners within the SNAP participation list. The gaming entities must input data on each individual with winnings over the winnings threshold into the matching system, which FNS estimates to take 5 minutes (.0835 hours). There is no national database of how many people win large amounts of money in State lotteries or through gaming activities. Therefore, FNS will continue to use the previously approved estimates as there has been no indication that they require adjustment. The Agency assumes that each of the public and private gaming entities would have 6,000 individuals (members of the general public) who win over the threshold each year and whose data would need to be uploaded to the matching system. The information technology staff from each State SNAP agency maintains the matching system, which the Agency estimates takes 320 hours per year. Once the data is uploaded, the Agency assumes that matches occur automatically.

FNS estimates that 27,500 SNAP households will receive substantial lottery winnings per year, with most instances identified via the matching systems. FNS assumes that the matching systems will identify approximately 36,000 SNAP participants (average 720 per State agency) nationally each year. Of these, the State agencies will find that approximately 23,000 (average 460 per State agency) have actual substantial winnings (the others may be simply misidentified because of a similar name, inaccurate reporting, etc.). These matches are hereinafter referred to as ''substantive matches.'' Under 7 CFR 272.17 and 7 CFR 273.11(r), FNS anticipates that the 50 State SNAP agencies will receive approximately 13,000 records (average 260 per State agency) annually with misidentified participants. It will take about 40 minutes (.668 hours) for eligibility workers to identify each misidentification.

For each substantive match, an eligibility worker will do the following:

- The eligibility worker will generate a request for contact (RFC) requesting more information. The burden associated with RFCs is already accounted for in OMB Control Number 0584–0064 (expiration 2/29/2024) and is not counted in the total burden of this information collection.
- If the participant returns the RFC, the worker will review the returned information from the participant and engage in any additional verification. Under 7 CFR 272.17 and 7 CFR 273.11(r), FNS estimates that this will take eligibility workers approximately 20 minutes (.334 hours) and that approximately 80 percent of participants will return the RFCs. This estimate for the rate of return is based on a prior estimate in OMB Control Number 0584–0064 (expiration 2/29/2024) regarding RFCs. Therefore, FNS estimates that eligibility workers will handle approximately 18,400 returned RFCs (average 368 per State agency) from substantive matches.
- If the matched participant responds to the RFC and the eligibility worker finds them to be a substantial winner, the worker will close the case and send a notice of adverse action. If the participant does not return the RFC (an estimated 20 percent), the worker will close the case and send a notice of adverse action for failure to return the RFC. The burden associated with notices of adverse action is accounted for in OMB Control Number 0584–0064 (expiration 2/29/2024) and is not counted in the total burden of this collection.

Under 7 CFR 273.11(r), households are also required to report their substantial winnings to their State SNAP agency. Out of the 27,500 SNAP participants who will receive substantial lottery winnings, FNS estimates 23,000 substantial winners will be identified through the matching process and 4,500 households will self-report lottery and gambling winnings.

In response to the 4,500 (average 90 per State agency) households that self-report winnings, State eligibility workers will do the following:

- Under 7 CFR 272.17 and 7 CFR 273.11(r), Eligibility workers will review the information submitted by the participant. FNS estimates that this will take eligibility workers approximately 11 minutes (0.1837 hours). This estimate is based on a prior estimate in OMB Control Number 0584–0064 (expiration 2/29/2024) for a similar simplified reporting requirement for able-bodied adults without dependents.
- If the eligibility worker finds the participant to be a substantial winner, the worker will close the case, and send notice of adverse action. Again, this burden is accounted for in OMB Control Number 0584–0064 (expiration 2/29/2024) and is not counted in the total burden of this collection.

Under 7 CFR 273.11(r), SNAP households identified as substantial lottery winners via the matching process will receive and potentially respond to RFCs and notices of adverse action. The participant burdens associated with RFCs and notices of adverse action are accounted for in OMB Control Number 0584–0064 (expiration 2/29/2024) and are not counted in the total burden of this collection. FNS estimates that self-reporting households will spend 10 minutes (.167 hours) per response to report their substantial winnings to the State SNAP agency. FNS utilized the estimate of 10 minutes based on a prior estimate in OMB Control Number 0584–

0064 (expiration 2/29/2024) for the time it takes a household to complete a periodic report.

FNS recognizes that households who previously lost eligibility for SNAP due to lottery or gambling winnings may later re-apply to the program. The burden associated with submitting and processing applications is accounted for in OMB Control Number 0584–0064 (expiration 2/29/2024) and is not counted in the total burden of this collection.

This section of the information collection does not require any recordkeeping burden.

Resource Verification

Per Section 5(g) of the Food and Nutrition Act, all applicant households must meet the SNAP resource limits unless they are considered categorically eligible (Section 5(j) of the Food and Nutrition Act) for SNAP benefits. State eligibility workers must evaluate the resources available to each household to determine whether these households meet the SNAP resource limits as defined by 7 CFR 273.8(b). Resources are one of several criteria that SNAP State agencies use to determine SNAP eligibility and States may elect to mandate verification of resources (7 CFR 273.2(f)(3)). All States must verify any resource information that appears to be questionable, in accordance with 7 CFR 273.2(f)(2)(i).

With this information collection request, FNS is seeking OMB approval for the burden hours associated with resource verification information that is currently being collected in violation without a valid OMB control number or approved by OMB. Therefore, the burden hours for this requirement represent an additional 2,913,736.63 burden hours not included in the previous approval of this collection.

Households are considered categorically eligible for SNAP if each member receives certain cash assistance benefits, including Supplemental Security Income (SSI) and Temporary Assistance for Needy Families (TANF) assistance. States also have the option to implement broad-based categorical eligibility policies to deem recipients of non-cash or in-kind TANF benefits or services to be categorically eligible for SNAP. Out of 53 SNAP State agencies, 44 have adopted broad-based categorical eligibility policies. Therefore, only 9 States currently collect resource information as part of the SNAP eligibility determination process. State agencies conducting this process may need to contact financial institutions, Departments of Motor Vehicles, and other entities to obtain documentation of a household's resources. Households may need to submit proof of their available resources.

In 2018, FNS consulted with 8 States operating the resource test to estimate the amount of time that State agency staff spent verifying resources with clients at initial certification and subsequent recertifications. Through this consultation with States, FNS learned that 4 States verify resources when reported resources are close to the limit or questionable (hereinafter referred to as ''High Limit'' States), 2 States only verify when the report is questionable (''Self-Attestation'' States), and 2 States always verify resources (''Always'' States). For the purposes of this estimate, FNS assumes the 9th State verifies when a household is close to the asset limit or questionable (''High Limit''). In 2021, FNS confirmed that the following estimates remained accurate by consulting with States that verify resources.

Using the estimates obtained during State consultation on resource verification, FNS estimates that State SNAP agency staff spend the following average times on resource verification:

- *''High Limit'' or ''Self-Attestation'' Staff:* 12.3 minutes (0.205 hours) per case at initial certification and 7.4 minutes (0.123 hours) per case at recertification.
- *''Always'' Staff:* 43.75 minutes (0.729 hours) per case at initial certification and 26.25 minutes (0.438 hours) per case at recertification.

To estimate the total burden hours on State agencies, FNS applied these average times to the most recently available participation data (FY20) for SNAP initial and recertification applicant households in the 9 States that verify resources.[1]

FNS then estimated the burden hours for households to provide verification using the same FY20 participation data. The Agency estimates that providing verification would take 4 minutes (0.0668 hours) per household at initial certification and 6 minutes (.1002 hours) at recertification. These time estimates come from other verification activities in OMB Control Number 0584–0064 (expiration 2/29/2024). Using the estimates above for the number of households in each State subject to verification requirements, FNS then calculated the total number of households in each State that would have to participate in this annual burden in the chart below.

[1] National Data Bank data from FY2020, FNS 366–B, Total Initial Applications and Total Recertification Applications. OMB Control Number 0584–0594 (expiration 7/31/2023).

This section of the information collection does not require any new recordkeeping burden. The related recordkeeping burden for State agencies is currently covered under the approved information collection burden for application processing, OMB Control Number 0584–0064 (expiration 2/29/2024), which accounts for the casefile documentation that States maintain for each SNAP household at 7 CFR 273.2(f)(6).

Reporting

Affected Public Individuals/Household

Respondent Type: SNAP households.
Estimated Number of Respondents: 30,977,197.
Estimated Number of Responses per Respondent: 1.00.
Estimated Total Annual Responses: 30,977,197.
Estimated Time per Response: 0.078.
Estimated Total Annual Burden on Respondents: 2,421,974.31.

Affected Public State Agencies

Respondent Type: State SNAP agencies (50), State gambling and gaming entities (50).
Estimated Number of Respondents: 100.
Estimated Number of Responses per Respondent: 21,740.38.
Estimated Total Annual Responses: 2,174,038.
Estimated Time per Response: 0.252.
Estimated Total Annual Burden on Respondents: 548,170.07.

Affected Public Business

Respondent Type: Business private gambling and gaming entities.
Estimated Number of Respondents: 200.
Estimated Number of Responses per Respondent: 6,000.
Estimated Total Annual Responses: 1,200,000.
Estimated Time per Response: 0.08.
Estimated Total Annual Burden on Respondents: 96,000.00.

Total Affected Public

Respondent Type: SNAP households, State SNAP agencies, State gambling and gaming entities, and business private gambling and gaming entities.
Estimated Number of Respondents: 30,977,497.
Estimated Number of Responses per Respondent: 1.11.
Estimated Total Annual Responses: 34,351,235.
Estimated Time per Response: 0.089.
Estimated Total Annual Burden on Respondents: 3,066,144.38.

REFERENCE BURDEN TABLE BELOW

Burden activities	Reg. section	Respondent type	Description of activity	Estimated number of respondents	Estimated frequency of response	Estimated total annual responses	Estimated number of burden hours per response	Estimated total burden hours	Burden hours in use without a valid OMB control number	Previously approved burden hours	Difference due to adjustments	Differences due to program changes
Lottery & Gambling.	7 CFR 273.11(r)	SNAP Individuals/ Households.	*Self-report lottery or gambling winnings to State SNAP Agency.	4,500	1	4,500	0.167	751.50	0.00	4,593.00	-3,841.50	0.00
Resource Verification.	7 CFR 273.2(f)(1) & (2).	SNAP Individuals/ Households.	Verification of resources at initial application.	20,426,390	1	20,426,390	0.0668	1,364,482.85	1,364,482.85	0.00	N/A	0.00
	7 CFR 273.2(f)(8)(i).	SNAP Individuals/ Households.	Verification of resources at recertification.	10,546,307	1	10,546,307	0.1002	1,056,739.96	1,056,739.96	0.00	N/A	0.00
SNAP Individual/Household Subtotal Reporting				30,978,697	1.00	30,978,697	0.078	2,422,224.81	2,421,222.81	4,593.00	−3,841.50	0.00
Lottery & Gambling.	7 CFR 272.17(a) & (b).	State SNAP Agency Managers.	** Establish cooperative agreements with State public agency and private business gaming entities.	0	0	0	0	0.00	0.00	80,000.00	−80,000.00	0.00
	7 CFR 272.17(c)	State Public Agency Gaming Entity Managers.	** Establish cooperative agreements with State SNAP agency.	0	0	0	0	0.00	0.00	16,000.00	−16,000.00	0.00
	7 CFR 272.17(c)	State SNAP IT Staff.	** Create a data matching system with State public agency and private business gaming entities.	0	0	0	0	0.00	0.00	208,000.00	−208,000.00	0.00
	7 CFR 272.17 and 7 CFR 273.11(r).	State SNAP Agency Eligibility Worker.	Eligibility worker follow-up (matched, misidentified).	50	260	13,000	0.668	8,684.00	0.00	8,671.00	13.00	0.00
	7 CFR 272.17 and 7 CFR 273.11(r).	State SNAP Agency Eligibility Worker.	Eligibility worker follow-up (matched, substantive).	50	368	18,400	0.334	6,145.60	0.00	23,000	−16,027.75	0.00
	7 CFR 272.17 and 7 CFR 273.11(r).	State SNAP Agency Eligibility Worker.	Eligibility worker follow-up (self-reported winners).	50	90	4,500	0.184	826.65	0.00			
	7 CFR 272.17(c)	State Public Agency Gaming Entity Staff Member.	Input data into data matching system for use by State SNAP agency.	50	6,000	300,000	0.08	24,000.00	0.00	24,000	0.00	0.00

	7 CFR 272.17(c)	State SNAP IT Staff.	Maintain a data matching system with State public agency and private business gaming entities.	50	1	50	320	16,000.00	0.00	16,000	0.00	0.00
Resource Verification.	7 CFR 273.2(f)(1) & (2).	State SNAP Agency Eligibility Worker.	Verification of resources at initial application (States verifying all resources).	2	119,172	238,344	0.729	173,752.78	173,752.78	0.00	N/A	0.00
	7 CFR 273.2(f)(1) & (2).	State SNAP Agency Eligibility Worker.	Verification of resources at initial application (States verifying resources if questionable).	2	119,172	238,344	0.205	48,860.52	48,860.52	0.00	N/A	0.00
	7 CFR 273.2(f)(1) & (2).	State SNAP Agency Eligibility Worker.	Verification of resources at initial application (States verifying resources if close to the limit).	5	119,172	595,860	0.205	122,151.30	122,151.30	0.00	N/A	0.00
	7 CFR 273.2(f)(8)(i).	State SNAP Agency Eligibility Worker.	Verification of resources at recertification (States verifying all resources).	2	85,060	170,120	0.438	74,512.56	74,512.56	0.00	N/A	0.00
	7 CFR 273.2(f)(8)(i).	State SNAP Agency Eligibility Worker.	Verification of resources at recertification (States verifying resources if questionable).	2	85,060	170,120	0.123	20,924.76	20,924.76	0.00	N/A	0.00
	7 CFR 273.2(f)(8)(i).	State SNAP Agency Eligibility Worker.	Verification of resources at recertification (States verifying resources is close to the limit).	5	85,060	425,300	0.123	52,311.90	52,311.90	0.00	N/A	0.00
State Agency Subtotal Reporting				100	21,740.38	2,174,038	0.252	548,170.07	492,513.82	375,671.00	−320,014.75	0.00
Lottery & Gambling.	7 CFR 272.17(a) & (b).	Private Business Gaming Entity Managers.	** Establish cooperative agreements with State SNAP agency.	0	0	0	0	0.00	0.00	64,000	−64,000.00	0.00
	7 CFR 272.17(c)	Private Business Gaming Entity Staff Member.	Input data into data matching system for use by State SNAP agency.	200	6,000	1,200,000	0.08	96,000.00	0.00	96,000	0.00	0.00
Business Subtotal Reporting				200	6,000.00	1,200,000	0.08	96,000.00	0.00	160,000.00	−64,000.00	0.00

REFERENCE BURDEN TABLE BELOW—Continued

Burden activities	Reg. section	Respondent type	Description of activity	Estimated number of respondents	Estimated frequency of response	Estimated total annual responses	Estimated number of burden hours per response	Estimated total burden hours	Burden hours in use without a valid OMB control number	Previously approved burden hours	Difference due to adjustments	Differences due to program changes
Reporting Grand Total Burden Estimates				30,978,997	1.11	34,352,735	0.089	3,066,394.88	2,913,736.63	540,264.00	−387,856.25	0.00

* FNS assumes that all participants reporting lottery and gambling winnings will also have either an initial or recertification application in the same year. To avoid double counting, these households are not separately included in the total number of respondents for this section.

** The start-up burden from the previous approval for this collection has been removed from the renewal.

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–07419 Filed 4–6–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket #RUS–22–ELECTRIC–0008]

Next Era Energy Resources, LLC, Notice of Availability of a Final Environmental Impact Statement

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of availability of a final environmental impact statement.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS), an agency within the Department of Agriculture (USDA), has prepared a Final Environmental Impact Statement (FEIS) to meet its responsibilities under the National Environmental Policy Act (NEPA), RUS's implementing regulations, and other applicable environmental requirements related to providing financial assistance for Next Era Energy Resources, LLC's (NEER or the Applicant) proposed Skeleton Creek Solar and Battery Storage Project (Project). The Project is a proposed 250-megawatt (MW) solar array, plus 200-MW/800-megawatt-hour (MWh) storage facility using photovoltaic (PV) modules on private lands in Garfield County. RUS will also use the FEIS to meet its responsibilities under Section 106 of the National Historic Preservation Act, and its implementing regulations, ''Protection of Historic Properties''.

DATES: Written comments on this FEIS will be accepted no later than 30 days following the publication of the U.S. Environmental Protection Agency's notice of receipt of the FEIS in the **Federal Register** (EPA Publication Date April 8, 2022).

ADDRESSES: Submit comments to *SkeletonCreekSolarPublicComments@usda.gov.* The FEIS and other Project-related information is available at the Rural Utilities Service website located at *https://www.rd.usda.gov/environmentalstudy/skeleton-creek-solar-and-battery-storage-project-garfield-county-oklahoma.*

All information related to the Project is available at this website. In addition, a hardcopy of the FEIS is available at the Enid Public Library, located at 120 W Maine St., Enid, OK 73701. Parties wishing to be placed on the mailing list for future information or to receive hard or electronic copies of the EIS should send an email to *SkeletonCreekSolarPublicComments@usda.gov*

FOR FURTHER INFORMATION CONTACT: To receive copies of the FEIS or request information on the Project, the FEIS process, contact: Kristen Bastis, Archeologist, USDA, Rural Utilities Service, 1400 Independence Ave. SW, Mail Stop 1570, Washington, DC 20250, by phone at 202–692–4910, or email *SkeletonCreekSolarPublicComments@usda.gov.*

SUPPLEMENTARY INFORMATION: RUS is serving as the lead Federal agency, as defined at 40 CFR 1501.7, for preparation of the FEIS. Cooperating agencies for this Project include the United States Army Corps of Engineers, the Bureau of Land Management, and the Bureau of Indian Affairs. The United States Fish and Wildlife Service is a participating agency for this Project. The following three federal agencies will use this FEIS to inform decisions about funding, authorizing, or permitting various components of the Project:

- RUS will evaluate whether or not to provide Project financial assistance.
- The U.S. Army Corps of Engineers will review the Applicant's permit application, as required by Section 404 under the Clean Water Act.
- The U.S. Fish and Wildlife Service will determine the likelihood of Project effects on listed species, as required under Section 7 of the Endangered Species Act.

The FEIS addresses the construction and operation of the Project, which consists of a 250-MW solar array, plus 200-MW/800-MWh storage facility in Garfield County, Oklahoma. The Project consists of four major components: Photovoltaic solar arrays, energy storage facilities, linear facilities, and transmission interconnection facilities (Proposed Action). The energy storage facilities consist of batteries, solar trackers, and solar power inverters. Linear facilities include a network of internal access roads, communication cables or lines, and a distribution power network for construction and operations control systems. The transmission interconnection facilities include a substation/switchyard that interconnects to the existing OG&E 345-kV Woodring Substation via a gen-tie line. These components are explained in detail in the FEIS.

The Applicant is a utility company with more than 180 MW of battery energy storage systems in operation across the United States and Canada. Since the Applicant entered into a power purchase agreement with Western Farmers Electric Cooperative (WFEC) for the Project, the Project's purpose and need is focused on meeting the energy buyer's (WFEC) needs. WFEC's objective is to provide safe, adequate, and reliable power to its members at the lowest reasonable cost. The Project would allow the Applicant to provide the additional generation capacity needed by WFEC to achieve these goals within the service territories of their member cooperatives. Specifically, the Project would provide a source of non-dispatchable power via solar panels that increase capacity, whereas battery storage would provide a source of dispatchable power that increases the reliability of generated power to the grid. The pairing of battery storage with solar panels would further allow WFEC to meet peak demand needs without adding additional fossil fuel consumption to the system. In addition, the Project would help WFEC and the Southwest Power Pool to continue to comply with Oklahoma legislative declarations to facilitate the delivery of renewable energy.

Two additional alternatives, the Other Action Alternative and the No Action alternative, were evaluated in the FEIS. Under the No Action alternative, the Project would not be undertaken. Under the Other Action Alternative, the Project would be situated on buildable land located east of the Proposed Action.

RUS used input provided by government agencies, private organizations, and the public in the preparation of the FEIS. RUS has considered all comments received on the Draft EIS and revised the EIS accordingly. Following the 30-day comment period for the FEIS, RUS will prepare a Record of Decision (ROD). A Notice announcing the availability of the ROD will be published in the **Federal Register** and in local newspapers.

In accordance with Section 106 of the National Historic Preservation Act and its implementing regulation, ''Protection of Historic Properties'' (36 CFR 800) and as part of its broad environmental review process, RUS must take into account the effect of the proposed project on historic properties. Pursuant to 36 CFR 800.2(d)(3), RUS is using its procedures for public involvement under NEPA to meet its responsibilities to solicit and consider the views of the public during Section 106 review. Any party wishing to participate more directly with RUS as a ''consulting party'' in Section 106 review may submit a written request to the RUS contact provided in this notice.

The proposed project involves unavoidable impacts to wetlands and floodplains; this Notice of Availability also serves as a statement of no

practicable alternatives to impacts on wetlands and floodplains, in accordance with Executive Orders 11990 and 11988, respectively.

Any final action by RUS related to the Project will be subject to, and contingent upon, compliance with all relevant executive orders and federal, state, and local environmental laws and regulations in addition to the completion of the environmental review requirements as prescribed in Rural Utilities Service Environmental Policies and Procedures, 7 CFR part 1970.

Christopher A. McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2022–07390 Filed 4–6–22; 8:45 am]

BILLING CODE 3410–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Kansas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Kansas Advisory Committee (Committee) will hold a meeting via web conference on, April 21, 2022, at 12:00 p.m. Central Time. The purpose of the meeting is for the committee to discuss potential topics and panelists for the upcoming briefing(s).

DATES: The meetings will be held on:

- Thursday, April 21, 2022, at 12:00 p.m. Central Time *https://civilrights.webex.com/civilrights/j.php?MTID=meb853689b6701f585e54f11d03c45add* or Join by phone: 800–360–9505 USA Toll Free, Access code: 2764 924 9371.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 656–8937

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Kansas Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Chair's Comments
IV. Committee Discussion
V. Next Steps
VI. Public Comment
VII. Adjournment

Dated: April 3, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–07357 Filed 4–6–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that the Arizona Advisory Committee (Committee) to the Commission will hold a meeting via Webex on Monday, April 18, 2022, from 11 a.m. to 12 p.m. Arizona Time, for the purpose of discussing potential civil rights topics to study.

DATES: The meeting will be held on:

- Monday, April 18, 2022, from 11 a.m.–12 p.m. Arizona Time

Access Information:

To join by web conference (audio/visual), visit: *https://tinyurl.com/4a35adzx.*

To join by phone (audio only), dial 1–800–360–9505; enter access code: 2766 434 1207.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, Designated Federal Officer, (DFO) at *kfajota@usccr.gov* or by phone at (434) 515–2395.

SUPPLEMENTARY INFORMATION: Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Kayla Fajota (DFO) at *kfajota@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl2AAA.*

Please click on the ''Committee Meetings'' tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome and Roll Call
II. Approval of Minutes
III. Discussion and Possible Vote: Healthcare Disparities Subtopic
IV. Public Comment
V. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of the immediacy of the subject matter.

Dated: April 4, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–07446 Filed 4–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

National Advisory Committee

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of public virtual meeting.

SUMMARY: The Census Bureau is giving notice of a virtual meeting of the National Advisory Committee (NAC). The Committee will address policy, research, and technical issues relating to a full range of Census Bureau programs and activities, including the decennial census, demographic and economic statistical programs, field operations, and information technology. Last minute changes to the schedule are possible, which could prevent giving advance public notice of schedule adjustments. Please visit the Census Advisory Committees website at *http://www.census.gov/cac* for the NAC meeting information, including the agenda, and how to join the meeting.

DATES: The virtual meeting will be held on:

- Thursday, May 5, 2022, from 11:00 a.m. to 5:00 p.m. EDT, and
- Friday, May 6, 2022, from 11:00 a.m. to 5:00 p.m. EDT.

ADDRESSES: The meeting will be held via the WebEx platform at the following presentation links:

- May 5, 2022—*https://uscensus.webex.com/uscensus/j.php?MTID=me3d64e29670d4725c5084cbd160ab8ab*
- May 6, 2022—*https://uscensus.webex.com/uscensus/j.php?MTID=m0612c4d7af229194b03d3db3c8b00d72*

For audio, please call the following number: 1–888–603–9745. When prompted, please use the following Password: Census#1 and Passcode: 8154908#.

FOR FURTHER INFORMATION CONTACT: Shana Banks, Advisory Committee Branch Chief, Office of Program, Performance and Stakeholder Integration (PPSI), *shana.j.banks@census.gov,* Department of Commerce, Census Bureau, telephone 301–763–3815. For TTY callers, please use the Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The NAC provides technical expertise to address Census Bureau program needs and objectives. The members of the NAC are appointed by the Director of the Census Bureau. The NAC has been established in accordance with the Federal Advisory Committee Act (title 5, United States Code, appendix 2, section 10).

All meetings are open to the public. A brief period will be set aside during the virtual meeting for public comments on May 6, 2022. Individuals with extensive questions or statements may submit them in writing to *shana.j.banks@census.gov,* (subject line ''2022 NAC Spring Virtual Meeting Public Comment'').

Robert L. Santos, Director, Census Bureau, approved the publication of this Notice in the **Federal Register**.

Dated: April 1, 2022.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–07356 Filed 4–6–22; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–80–2021]

Foreign-Trade Zone (FTZ) 27—Boston, Massachusetts, Authorization of Production Activity, Wyeth Pharmaceuticals, LLC (mRNA Bulk Drug Substance), Andover, Massachusetts

On December 3, 2021, Wyeth Pharmaceuticals, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 27R, in Andover, Massachusetts.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (86 FR 70439, December 10, 2021). On April 4, 2022, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: April 4, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–07367 Filed 4–6–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Technical Advisory Committees; Notice of Recruitment of Members

The Bureau of Industry and Security (BIS), Department of Commerce is announcing its recruitment of candidates to serve on one of its six Technical Advisory Committees (''TACs'' or ''Committees''). TAC members advise the Department of Commerce on the technical parameters for export controls applicable to dual-use items (commodities, software, and technology) and on the administration of those controls. The TACs are composed of representatives from industry, academia, and the U.S. Government and reflect diverse points of view on the concerns of the exporting community. Industry representatives are selected from firms producing a broad range of items currently controlled for national security, non-proliferation, foreign policy, and short supply reasons or that are proposed for such controls. Representation from the private sector is balanced to the extent possible among large and small firms.

Six TACs are responsible for advising the Department of Commerce on the technical parameters for export controls and the administration of those controls within specified areas: Information Systems TAC: Control List Categories 3 (electronics), 4 (computers), and 5 (telecommunications and information security); Materials and Equipment TAC: Control List Categories 1 (materials, chemicals, microorganisms, and toxins) and 2 (materials processing); Sensors and Instrumentation TAC: Control List Category 6 (sensors and lasers); Transportation and Related Equipment TAC: Control List Categories 7 (navigation and avionics), 8 (marine), and 9 (propulsion systems, space vehicles, and related equipment); and the Emerging Technology TAC (identification of emerging and foundational technologies that may be developed over a period of five to ten years with potential dual-use applications). The sixth TAC, the Regulations and Procedures TAC, focuses on the Export Administration Regulations (EAR) and procedures for implementing the EAR.

TAC members are appointed by the Secretary of Commerce and serve terms of not more than four consecutive years. TAC members must obtain secret-level clearances prior to their appointment. These clearances are necessary so that members may be permitted access to classified information that may be

needed to formulate recommendations to the Department of Commerce. Applicants are strongly encouraged to review materials and information on each Committee website, including the Committee's charter, to gain an understanding of each Committee's responsibilities, matters on which the Committee will provide recommendations, and expectations for members. Members of any of the six TACs may not be registered as foreign agents under the Foreign Agents Registration Act. No TAC member may represent a company that is majority owned or controlled by a foreign government entity (or foreign government entities). TAC members will not be compensated for their services or reimbursed for their travel expenses.

If you are interested in becoming a TAC member, please provide the following information: 1. Name of applicant; 2. affirmation of U.S. citizenship; 3. organizational affiliation and title, as appropriate; 4. mailing address; 5. work telephone number; 6. email address; 7. summary of qualifications for membership; 8. An affirmative statement that the candidate will be able to meet the expected commitments of Committee work. Committee work includes: (a) Attending in-person/teleconference Committee meetings roughly four times per year (lasting 1–2 days each); (b) undertaking additional work outside of full Committee meetings including subcommittee conference calls or meetings as needed, and (c) frequently drafting, preparing or commenting on proposed recommendations to be evaluated at Committee meetings. Finally, candidates must provide an affirmative statement that they meet all Committee eligibility requirements.

The Department of Commerce is committed to equal opportunity in the workplace and seeks diverse Advisory Committee membership.

To respond to this recruitment notice, please send a copy of your resume to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov.*

Deadline: This Notice of Recruitment will be open for 60 days from its date of publication in the **Federal Register**.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2022–07359 Filed 4–6–22; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–880]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2019–2020

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

SUMMARY: The Department of Commerce (Commerce) determines that producers and/or exporters subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR), September 1, 2019, through August 31, 2020.

DATES: Applicable April 7, 2022.

FOR FURTHER INFORMATION CONTACT: Alice Maldonado or Jacob Garten, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4682 or (202) 482–3342, respectively.

SUPPLEMENTARY INFORMATION:

Background

This review covers two producers and exporters of the subject merchandise.[1] Commerce selected Dong-A Steel Co., Ltd., (DOSCO) and HiSteel Co., Ltd., (HiSteel) for individual examination. On October 6, 2021, Commerce published the *Preliminary Results*.[2] In November and December 2021, the petitioner,[3] DOSCO, and HiSteel submitted case and rebuttal briefs.[4] For a description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[5] On January 14, 2022, Commerce extended the deadline for the final results of this administrative review until April 1, 2022.[6]

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order[7]

The products covered by the *Order* are certain heavy walled rectangular welded steel pipes and tubes from the Republic of Korea (Korea). Products subject to the order are currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) item number 7306.61.1000. Subject merchandise may also be classified under 7306.61.3000. Although the HTSUS numbers and ASTM specification are provided for convenience and for customs purposes, the written product description remains dispositive.[8]

[1] We received a timely submission withdrawing all review requests for 27 companies; we rescinded the review with respect to these companies. *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea: Rescission of Antidumping Duty Administrative Review; 2019–2020, in Part,* 86 FR 14075 (March 12, 2021).

[2] *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 55582 (October 6, 2021) (*Preliminary Results*).

[3] The petitioner is Nucor Tubular Products Inc.

[4] *See* Petitioner's Letter, ''Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from South Korea: Nucor Tubular's Case Brief,'' dated November 17, 2021; DOSCO's Letter, ''Administrative Review of the Antidumping Order on Heavy Walled Rectangular Carbon Steel Pipe and Tube from Korea—Case Brief of Dong-A-Steel Co., Ltd and SeAH Steel Corporation,'' dated November 17, 2021; HiSteel's Letter, ''Administrative Review of the Antidumping Order on Heavy Walled Rectangular Carbon Steel Pipe and Tube from Korea—Case Brief of HiSteel Co., Ltd.,'' dated November 17, 2021; DOSCO and HiSteel's Joint Letter, ''Administrative Review of the Antidumping Order on Heavy Walled Rectangular Carbon Steel Pipe and Tube from Korea—Rebuttal Brief of Dong-A-Steel Co., Ltd and HiSteel Co. Ltd.,'' dated December 3, 2021; DOSCO's Letter, ''Administrative Review of the Antidumping Order on Heavy Walled Rectangular Carbon Steel Pipe and Tube from Korea—Rebuttal Brief of Dong-A-Steel Co., Ltd and SeAH Steel Corporation,'' dated December 3, 2021; HiSteel's Letter, ''Administrative Review of the Antidumping Order Heavy Walled Rectangular Carbon Steel Pipe and Tube from Korea—Rebuttal Brief of HiSteel Co. Ltd.,'' dated December 3, 2021. In February 2022, DOSCO and HiSteel, and the petitioner filed redacted briefs based on Commerce's request to remove untimely new factual information. *See* DOSCO and HiSteel's Letter, ''Administrative Review of the Antidumping Order on Heavy Walled Rectangular Carbon Steel Pipe and Tube from Korea—Redacted Case Brief of Dong-A-Steel Co., Ltd. and HiSteel Co. Ltd.,'' dated February 25, 2022; and Petitioner's Letter, ''Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from South Korea: Nucor Tubular's Rebuttal Brief Resubmission,'' dated February 24, 2022.

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2019–2020 Administrative Review of the Antidumping Duty Order on Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea,'' dated concurrently with, and hereby adopted by, these results (Issues and Decision Memorandum).

[6] *See* Memorandum, ''Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea: Extension of Deadline for Final Results of the 2019–2020 Antidumping Duty Administrative Review,'' dated January 14, 2022.

[7] *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey: Antidumping Duty Orders,* 81 FR 62865 (September 13, 2016) (*Order*).

[8] For a full description of the scope of the *Order, see* Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are listed in the appendix to this notice and addressed in the Issues and Decision Memorandum. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain changes to the preliminary weighted-average margin calculations for DOSCO and HiSteel. For a discussion of these changes, *see* the ''Margin Calculations'' section of the Issues and Decision Memorandum.[9]

Final Results of the Review

We assigned the following weighted-average dumping margins to the firms listed below for the period September 1, 2019, through August 31, 2020:

Producer/exporter	Weighted-average dumping margin (percent)
Dong-A Steel Co., Ltd [10]	1.61
HiSteel Co., Ltd	10.24

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Pursuant to 19 CFR 351.212(b)(1), where the respondent did not report entered value, we calculated the entered value in order to calculate the assessment rate. Where the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. In accordance with Commerce's practice, for entries of subject merchandise during the POR for which the reviewed companies did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate if there is no company-specific rate for the intermediate company(ies) involved in the transaction.[11]

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[12] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for each specific company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 3.24 percent, the all-others rate established in the LTFV investigation.[13] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: April 1, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Margin Calculations
V. Discussion of Issues
General Issues
Comment 1: Existence of a Particular Market Situation (PMS)
Comment 2: Differential Pricing
DOSCO-Specific Issues

[9] *See* Issues and Decision Memorandum.

[10] In the prior administrative review, Commerce collapsed Dong-A Steel Co., Ltd., with its affiliated producer SeAH Steel Corporation, and we continue to treat these companies as a single entity, in accordance with 19 CFR 351.401(f). *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2018–2019,* 86 FR 35060, 35061 (July 1, 2021).

[11] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[12] *See* section 751(a)(2)(C) of the Act.

[13] *See Order.*

Comment 3: Valuation of SeAH Steel Corporation (SeAH Steel)'s Hot Rolled Coil (HRC) Purchases
Comment 4: Calculation of DOSCO's General and Administrative (G&A) Expenses
Comment 5: Calculation of DOSCO's Scrap Offset Adjustment
Comment 6: SeAH Steel's Headquarters Inventory Valuation Losses
Comment 7: Error in Calculating Value of Services DOSCO Obtained from SeAH Steel Holdings Corporation (SSHC)
Comment 8: Treatment of Unrecovered Expenses of DOSCO's Corporate Parent
Comment 9: Treatment of Unrecovered Expenses of SeAH Holdings Corporation (SHC) and Other Affiliates
Comment 10: Allocation of Expenses between G&A and Indirect Selling Expenses (ISE)
Comment 11: Treatment of Miscellaneous Income in Calculation of DOSCO's G&A Expense Ratio
Comment 12: Adjustments to SeAH Steel's Costs Due to Reconciliation Discrepancy
Comment 13: Adjustments to the Calculation of the Consolidated Financial Expense Ratio
Comment 14: Adjustments to DOSCO's and SeAH Steel's Reported Scrap Offsets
Comment 15: Adjustments to DOSCO's G&A Expense Calculation
Comment 16: Calculation of DOSCO's Consolidated Financial Expense Ratio
Comment 17: Treatment of Reworked Merchandise in Regard to SeAH Steel's Reported Costs
HiSteel-Specific Issues
Comment 18: Allocation of Common Expenses for HiSteel
Comment 19: Financial Expense Ratio
Comment 20: Transactions-Disregarded Rule
Comment 21: Adjustment to HiSteel's Reported Scrap Offset
Comment 22: HiSteel's G&A Expense Ratio
VI. Recommendation

[FR Doc. 2022–07445 Filed 4–6–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB933]

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 Research Steering Committee of the Mid-Atlantic Fishery Management Council (Council) will hold a meeting. See **SUPPLEMENTARY INFORMATION** for agenda details.

DATES: The meeting will be held on Wednesday, April 27, 2022, from 8:45 a.m. to 3:45 p.m.

ADDRESSES: The meeting will be conducted in a hybrid format, with options for both in-person and webinar participation. The meeting will be held at Sheraton BWI, 1100 Old Elkridge Landing Road, Linthicum, MD 21090. Webinar details, including a telephone-only connection option, 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 the meeting is for the Research Steering Committee to review all the input received from the four previous Research Set-Aside (RSA) exploration workshops and make recommendations regarding the potential redevelopment of the Council's RSA program. The Committee's recommendations will then be considered by the Council during their June 2022 meeting. 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: April 4, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–07383 Filed 4–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB927]

South Atlantic 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 South Atlantic Fishery Management Council will hold a meeting of the Socio-Economic Panel (SEP) on April 25–26, 2022 and the Scientific and Statistical Committee (SSC) on April 26–28, 2022.

DATES: The SEP meeting will be held April 25–26, 2022. The meeting will be held from 1 p.m. until 5 p.m. EDT on April 25, and from 9 a.m. until 12 p.m. on April 26. The SSC meeting will be held April 26–28, 2022. The SSC meeting will be held from 1:30 p.m. until 5:30 p.m. EDT on April 26, from 8 a.m. until 5:30 p.m. on April 27, and from 8 a.m. until 12 p.m. on April 28, 2022.

ADDRESSES:

Meeting address: The meetings will be held at the Town and Country Inn, 2008 Savannah Highway, Charleston, SC 29407; phone: (884) 201–3033.

The meetings will also be available via webinar. Registration is required. Webinar registration, an online public comment form, and briefing book materials will be available two weeks prior to the meetings at: *https://safmc.net/safmc-meetings/scientific-and-statistical-committee-meetings.*

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: John Hadley, Fishery Management Plan Coordinator, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *john.hadley@safmc.net.*

SUPPLEMENTARY INFORMATION:

SSC Socio-Economic Panel

The SEP meeting agenda includes: Review and discussion of the Allocation Decision Tree, a tool that incorporates biological, economic, and social information into allocation decision making; review and discussion of a lexicon for best fishing practices outreach and social and economic analyses that could be considered when evaluating management techniques for reducing regulatory releases and release mortality; and presentations from NOAA Fisheries' Southeast Fishery Science Center (SEFSC) staff on alternative mechanisms for distributing fish to the recreational sector and on the South Atlantic golden tilefish fishery. SEP members will receive updates on recent Council amendments and the Council's Citizen Science Program. The SEP will provide recommendations for SSC and Council consideration as appropriate.

Scientific and Statistical Committee

The SSC meeting agenda includes: Review and discussion of a report from the SSC's workgroup for catch level projections; framework for the reduction of release mortality of snapper-grouper species; an interim analysis strategy presented by the SEFSC; overviews of the methods for estimating the abundance of red snapper in the South Atlantic and greater amberjack in the South Atlantic and Gulf of Mexico; updates from fishery-independent surveys conducted by NOAA and the South Carolina Department of Natural Resources; and recent updates to goliath grouper data and indices. The SSC will also review and provide comments on the Southeast Data Assessment and Review (SEDAR) terms of reference and scopes of work for several South Atlantic species, receive updates on South Atlantic fishery management plan amendments, and discuss other business as needed.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 4, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–07382 Filed 4–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB915]

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 Mid-Atlantic Fishery Management Council's (Council) Mackerel, Squid, and Butterfish Advisory Panel will hold a public webinar meeting.

DATES: The meeting will be held on Tuesday, April 26, 2022, from 2 p.m. to 5 p.m.

ADDRESSES: The meeting will be held via webinar. Connection information will be posted to *https://www.mafmc.org/council-events.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *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 Council's Mackerel, Squid, and Butterfish Advisory Panel will meet via webinar to discuss recent performance of the butterfish, longfin squid, and Atlantic chub mackerel fisheries and develop Fishery Performance Reports. These reports will be considered by the Scientific and Statistical Committee, the Monitoring Committee, and the Mid-Atlantic Fishery Management Council when reviewing or setting catch and landings limits and management measures for upcoming years.

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: April 4, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–07381 Filed 4–6–22; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2022–0020]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) is requesting to extend the Office of Management and Budget's (OMB's) approval for an existing information collection titled ''Interstate Land Sales Full Disclosure Act (Regulations J, K, and L).''

DATES: Written comments are encouraged and must be received on or before June 6, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2022–0020 in the subject line of the email.
- *Mail/Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552.

Please note that due to circumstances associated with the COVID–19 pandemic, the Bureau discourages the submission of comments by mail, hand delivery, or courier. Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to Anthony May, PRA Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Interstate Land Sales Full Disclosure Act (Regulations J, K, and L).

OMB Control Number: 3170–0012.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Businesses and other for-profit institutions.

Estimated Number of Respondents: 197.

Estimated Total Annual Burden Hours: 3,412.

Abstract: The Interstate Land Sales Full Disclosure Act (ILSA) requires land developers to register subdivisions of 100 or more non-exempt lots with the Bureau before selling or leasing the lots, and to provide each lot purchaser with a disclosure document designated as a property report, 15 U.S.C. 1703–1704. ILSA was enacted in response to a nationwide proliferation of developers of unimproved subdivisions who made elaborate, and often fraudulent, claims about their land to unsuspecting lot

purchasers. Information is submitted to the Bureau to assure compliance with ILSA and the implementing regulations. The Bureau also investigates developers who are not in compliance with the regulations.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the 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. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2022–07323 Filed 4–6–22; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2022–0021]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) is requesting to extend the Office of Management and Budget's (OMB's) approval for an existing information collection titled ''Consumer Leasing Act (Regulation M).''

DATES: Written comments are encouraged and must be received on or before June 6, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2022–0021 in the subject line of the email.
- *Mail/Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552.

Please note that due to circumstances associated with the COVID–19 pandemic, the Bureau discourages the submission of comments by mail, hand delivery, or courier. Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to Anthony May, PRA Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Consumer Leasing Act (Regulation M).

OMB Control Number: 3170–0006.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Businesses and other for-profit institutions.

Estimated Number of Respondents: 13,718.

Estimated Total Annual Burden Hours: 2,126.

Abstract: Consumers rely on the disclosures required by the Consumer Leasing Act, 15 U.S.C. 1667 *et seq.* (CLA) and Regulation M, 12 CFR 1013, for information to comparison shop among leases as well as to ascertain the true costs and terms of lease offers. Federal/State enforcement and private litigants use the records to ascertain whether accurate and complete disclosures of the cost of leases have been provided to consumers prior to consummation of the lease. This information provides the primary evidence of law violations in CLA enforcement actions brought by Federal agencies. The agency's ability to enforce the CLA would be significantly impaired without Regulation M's recordkeeping requirements.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the 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. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2022–07324 Filed 4–6–22; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2022–0022]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) is requesting to extend the Office of Management and Budget's (OMB's) approval for an existing information collection, titled ''Survey Screening Question List.''

DATES: Written comments are encouraged and must be received on or before June 6, 2022 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2022–0022 in the subject line of the email.
- *Mail/Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552. Please note that due to

circumstances associated with the COVID–19 pandemic, the Bureau discourages the submission of comments by mail, hand delivery, or courier. Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to Anthony May, PRA Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Survey Screening Question List.

OMB Control Number: 3170–00XX.

Type of Review: New information collection.

Affected Public: Individuals.

Estimated Number of Respondents: 50,000.

Estimated Total Annual Burden Hours: 12,500.

Abstract: The Bureau conducts a variety of research efforts to ascertain financial issues the American public may be experiencing. The Bureau developed a list of potential screener questions formulated to allow the Bureau's research efforts to focus on the appropriate consumers for each study and strengthen our ability to address financial needs and concerns of the public and to improve the Bureau's delivery of services and programs. Usage of questions included and approved within this list will reduce administrative burden on the Bureau and grant greater expediency in conducting research on emergent financial issues.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the 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. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2022–07325 Filed 4–6–22; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent To Grant an Exclusive License With a Joint Ownership Agreement

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant an exclusive license with a joint ownership agreement to The Research Foundation for The State University of New York, a non-profit entity having the primary function of managing inventions on behalf of The State University of New York and having a place of business at P.O. Box 9, Albany, NY 12201.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to Jason Sopko, AFRL/RYO, 2241 Avionics Cir., Wright-Patterson AFB, OH 45433; or Email: *jason.sopko.2@us.af.mil.* Include Docket No. ARY–220323A–JA in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Jason Sopko, AFRL/RYO, 2241 Avionics Cir., Wright-Patterson AFB, OH 45433; Telephone: 937–713–4494; or Email: *jason.sopko.2@us.af.mil.*

SUPPLEMENTARY INFORMATION: The Department of the Air Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Abstract of Patent Application(s)

There is set forth herein an integrated photonics structure having a waveguide disposed within a dielectric stack of the integrated photonics structure, wherein the integrated photonics structure further includes a field generating electrically conductive structure disposed within the dielectric stack; and a heterogeneous structure attached to the integrated photonics structure, the heterogeneous structure having field sensitive material that is sensitive to a field generated by the field generating electrically conductive structure. There is set forth herein a method including fabricating an integrated photonics structure, wherein the fabricating an integrated photonics structure includes fabricating a waveguide within a dielectric stack, wherein the fabricating an integrated photonics structure further includes fabricating a field generating electrically conductive structure within the dielectric stack; and attaching a heterogeneous structure to the integrated photonics structure, the heterogeneous structure having field sensitive material that is sensitive to a field generated by the field generating electrically conductive structure.

Intellectual Property

—COOLBAUGH et al., U.S. Patent No. 10,877,300, issued on 29 December 2020, and entitled ''*Heterogeneous Structure on an Integrated Photonics Platform.*''

—COOLBAUGH et al., U.S. Application Publication No. 2021/0072568, published on 11 March 2011, and entitled the same.

—COOLBAUGH et al., International Application Publication WO 2019/195441, published 10 March 2019, and entitled the same; and all national and regional stage applications claiming priority thereto.

Adriane Paris,

Air Force Federal Register Liaison Officer.

[FR Doc. 2022–07319 Filed 4–6–22; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF EDUCATION

Extension of the Application Deadline Date; Applications for New Awards; Competitive Grants for State Assessments Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: On February 16, 2022, the Department of Education (Department) published in the **Federal Register** a notice inviting applications for the fiscal year (FY) 2022 Competitive Grants for State Assessments Program (NIA), Assistance Listing Number (ALN) 84.368A. The NIA established a deadline date of April 18, 2022, for the transmittal of applications. This notice extends the deadline date for transmittal of applications until May 3, 2022, and extends the deadline for intergovernmental review until July 5, 2022.

DATES:

Deadline for Transmittal of Applications: May 3, 2022.

Deadline for Intergovernmental Review: July 5, 2022.

FOR FURTHER INFORMATION CONTACT: Donald Peasley, U.S. Department of Education, 400 Maryland Avenue SW, Room 3W106, Washington, DC 20202–6132. Telephone: (202) 453–7982. Email: *ESEA.Assessment@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

On February 16, 2022, we published the NIA in the **Federal Register** (87 FR 8821). The NIA established a deadline date of April 18, 2022, for the transmittal of applications. This notice extends the deadline date for transmittal of applications until May 3, 2022, as well as the deadline for intergovernmental review.

In March 2022, Congress passed, and the President signed, the Consolidated Appropriations Act, 2022, which provides a total of up to $20.9 million for competitive grants for State assessments for FY 2022, an amount significantly larger than what was estimated in the NIA. These FY 2022 funds are in addition to the $8,900,000 available from the FY 2021 appropriation. To give applicants more time to prepare and submit applications in light of the increased appropriation, we are extending the deadline data for transmittal of applications.

Applicants that have submitted applications on or before the original deadline date of April 18, 2022, may resubmit their applications on or before the new application deadline date of May 3, 2022, but are not required to do so. If a new application is not submitted, the Department will use the application that was submitted by the original deadline. If a new application is submitted, the Department will consider the application that was last successfully submitted and received by 11:59:59 p.m., Eastern Time, on May 3, 2022.

Note: All information in the NIA for this competition remains the same, except for the deadline for the transmittal of applications and the deadline for intergovernmental review.

Program Authority: Section 1203(b)(1) of the ESEA (20 U.S.C. 6363(b)(1)).

Accessible Format: Individuals with disabilities can obtain this document, the NIA, and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or 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.

Ruth E. Ryder,

Deputy Assistant Secretary for Policy and Programs, Office of Elementary and Secondary Education.

[FR Doc. 2022–07321 Filed 4–6–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM19–12–000]

Revisions to the Filing Process for Commission Forms; Notice of eFORMS Update

As provided for in the July 17, 2020 Order on Technical Conference, notice is hereby given of a technical update to the taxonomy code necessary for submitting Form No. 60.[1] This update is available at the eForms portal at *https://ecollection.ferc.gov/.* In particular, the Release 2.0 taxonomy code for Form No. 60 has been corrected to change the period type for DividendRate from instant to duration so that it is consistent with how the transaction is reported.

Dated: April 1, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–07400 Filed 4–6–22; 8:45 am]

BILLING CODE 6717–01–P

[1] *Revisions to the Filing Process for Comm'n Forms,* 172 FERC ¶ 61,059 (2020) (July 17, 2020 Order on Technical Conference).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1503–000]

Pisgah Mountain, 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 Pisgah Mountain, 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 April 21, 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: April 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–07435 Filed 4–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1927–140]

PacifiCorp; Notice of Reasonable Period of Time for Water Quality Certification Application

On March 31, 2022, PacifiCorp submitted to the Federal Energy Regulatory Commission (Commission) evidence of its application for a Clean Water Act section 401(a)(1) water quality certification filed with Oregon Department of Environmental Quality, in conjunction with the above captioned project. Pursuant to section 401 of the Clean Water Act [1] and section 4.34(b)(5) of the Commission's regulations,[2] a state certifying agency is deemed to have waived its certifying authority if it fails or refuses to act on a certification request within a reasonable period of time, which is one year after the date the certification request was received. Accordingly, we hereby notify the Oregon Department of Environmental Quality of the following:

Date that Oregon Department of Environmental Quality Received the Certification Request: February 25, 2022.

If Oregon Department of Environmental Quality fails or refuses to act on the water quality certification request on or before February 25, 2023, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: April 1, 2022.

Kimberly D. Bose,

Secretary.

[FR Doc. 2022–07405 Filed 4–6–22; 8:45 am]

BILLING CODE 6717–01–P

[1] 33 U.S.C. 1341(a)(1).

[2] 18 CFR 4.34(b)(5).

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 Instituting Proceedings

Docket Numbers: RP21–1188–000.
Applicants: Texas Eastern Transmission, LP.
Description: Motion Filing: TETLP Rate Case Motion Filing RP21–1188–000 to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5096.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–750–000.
Applicants: Colorado Interstate Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing (Conoco May 22) to be effective 5/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5074.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–752–000.
Applicants: Cheniere Creole Trail Pipeline, L.P.
Description: Compliance filing: CTPL 2021 Operation Transaction Report to be effective N/A.
Filed Date: 3/31/22.
Accession Number: 20220331–5079.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–753–000.
Applicants: Midship Pipeline Company, LLC.
Description: Compliance filing: MSPL 2021 Operation Transaction Report to be effective N/A.
Filed Date: 3/31/22.
Accession Number: 20220331–5080.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–754–000.
Applicants: Cheniere Corpus Christi Pipeline, LP.
Description: Compliance filing: CCPL 2021 Operation Transaction Report to be effective N/A.
Filed Date: 3/31/22.
Accession Number: 20220331–5085.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–755–000.
Applicants: East Tennessee Natural Gas, LLC.
Description: Compliance filing: 2020–2021 ETNG Cashout Report to be effective N/A.
Filed Date: 3/31/22.
Accession Number: 20220331–5092.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–757–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing (Targa) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5122.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–758–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20220331 Negotiated Rate to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5192.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–759–000.
Applicants: Kinder Morgan Louisiana Pipeline LLC.
Description: § 4(d) Rate Filing: Acadiana Out of Cycle Fuel filing to be effective 5/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5199.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–760–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: § 4(d) Rate Filing: TPC 2022–03–31 Negotiated Rate Agreements to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5200.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–761–000.
Applicants: Enable Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—April 1 2022 Ovintiv to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5210.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–762–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 4–1–2022 to be effective 4/1/2022.
Filed Date: 3/31/22.

Accession Number: 20220331–5217.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–763–000.
Applicants: Columbia Gas Transmission, LLC.
Description:§ 4(d) Rate Filing: OTRA Summer 2022 to be effective 5/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5219.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–764–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20220331 Housekeeping Filing to be effective 5/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5222.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–765–000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 4–1–22 to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5224.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–766–000.
Applicants: Eastern Gas Transmission and Storage, Inc.
Description: § 4(d) Rate Filing: EGTS—March 31, 2022 Negotiated Rate Agreement to be effective 5/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5247.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–767–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: REX 2022–03–31 Negotiated Rate Agreements and Amendments to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5282.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–768–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Neg Rate Agmt & Cap Rel (FPL 48381, FPL 48381 to Spire 54711) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5287.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–769–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (FPL 41618, 41619 releases eff 4–1–2022) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5291.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–770–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Pensacola 43993 to BP 55005) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5295.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–771–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Methanex 42805 to Tenaska 55076) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5299.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–772–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (CIMA) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5300.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–773–000.
Applicants: Bison Pipeline LLC.
Description: Compliance filing: Company Use Gas Annual Report 2022 to be effective N/A.
Filed Date: 3/31/22.
Accession Number: 20220331–5301.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–774–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (JERA 46434, 46435 to EDF 55083, 55084) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5302.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–775–000.
Applicants: Northern Border Pipeline Company.
Description: § 4(d) Rate Filing: Compressor Usage Surcharge 2022 to be effective 5/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5304.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–776–000.
Applicants: Great Lakes Gas Transmission Limited Partnership.
Description: § 4(d) Rate Filing: Neg. Rate Agreements—DTE—FT22073, Freepoint—FT22182, Citadel—FT22183 to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5307.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–777–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (SoCal April) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5309.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–778–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreements Filing (Direct Energy) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5315.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–779–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Osaka 46429 to Texla 55151) to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5343.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–780–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 4–1–22 to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5344.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–781–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 4–1–22 to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5355.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–782–000.
Applicants: LA Storage, LLC.
Description: § 4(d) Rate Filing: Filing of Negotiated Rate, Conforming IW Agreements 4.1.22 to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5381.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–783–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Jay-Bee 34447 to MacQuarrie 39624) to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5007.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–784–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement—3/31/2022 to be effective 3/31/2022.
Filed Date: 4/1/22.

Accession Number: 20220401–5008.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–785–000.
Applicants: Dominion Energy Overthrust Pipeline, LLC.
Description: § 4(d) Rate Filing: Company Name Change to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5011.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–788–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement—Roanoke 262643 to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5016.
Comment Date: 5 p.m. ET 4/13/22.

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.

Filings in Existing Proceedings

Docket Numbers: RP21–1188–003.
Applicants: Texas Eastern Transmission, LP.
Description: Compliance filing: TETLP Rate Case Compliance Filing RP21–1188–000 to be effective 4/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5102.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–417–003.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Tariff Amendment: TGP PCG Pooling Amendment No.3 to be effective 5/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5337.
Comment Date: 5 p.m. ET 4/12/22.

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.

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: April 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–07433 Filed 4–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings—2

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–789–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Constellation Energy to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5018.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–790–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Macquarie Energy 4/1/2022 to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5020.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–791–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Amendment to a Negotiated Rate Agreement Filing—Spire Marketing Inc. to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5021.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–792–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—4/1/2022 to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5023.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–793–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Sempra Gas 4/1/2022 to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5082.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–794–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Mercuria Energy 4/1/2022 to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5084.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–795–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: Update to NRA Footnote 4–1–22 to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5088.
Comment Date: 5 p.m. ET 4/13/22.

Docket Numbers: RP22–796–000.
Applicants: Panhandle Eastern Pipe Line Company, LP.
Description: § 4(d) Rate Filing: Update NRA Footnote 4–1–2022 to be effective 4/1/2022.
Filed Date: 4/1/22.
Accession Number: 20220401–5095.
Comment Date: 5 p.m. ET 4/13/22.

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.

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: April 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–07430 Filed 4–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1518–000]

Laurel Mountain BESS, LLC; Upplemental 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 Laurel

Mountain BESS, 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 April 21, 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: April 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–07432 Filed 4–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1505–000]

WEB Silver Maple Wind, 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 WEB Silver Maple Wind, 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 April 21, 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: April 1, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–07431 Filed 4–6–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0326; FRL–9658–01–OCSPP]

Pesticide Registration Review; Anthraquinone Draft Human Health and Ecological Risk Assessments and Final Work Plan; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's draft human health and ecological risk assessments for the registration review of anthraquinone for public comment. This notice also announces the availability of the anthraquinone Final Work Plan.

DATES: Comments must be received on or before June 6, 2022.

ADDRESSES: Submit your comments to the docket identification (ID) number for the specific pesticide of interest provided in the Table in Unit IV. using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For anthraquinone information contact:* Rachel Fletcher, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–566–2354; email address: *fletcher.rachel@epa.gov.*

For general questions on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0701; email address: *biscoe.melanie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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

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

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

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed comprehensive draft human health and ecological risk assessments for anthraquinone. After reviewing comments received during the public comment period, EPA may issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments and may request public input on risk mitigation before completing a proposed registration review decision for anthraquinone. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is initiating its reviews of the pesticide identified in this document pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's human health and ecological risk assessments for the pesticides shown in Table 1 and opens a 60-day public comment period on the risk assessments. This notice also announces the availability of the Final Work Plan.

TABLE 1—DRAFT RISK ASSESSMENTS BEING MADE AVAILABLE FOR PUBLIC COMMENT

Registration review case name and number	Docket ID No.	Chemical review manager and contact information
Anthraquinone (Case 6054)	EPA–HQ–OPP–2017–0326	Rachel Fletcher, *fletcher.rachel@epa.gov,* (202) 566–2354.

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's draft human health and ecological risk assessments for anthraquinone. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to a draft human health and/or ecological risk assessment. EPA may then issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments.

Information submission requirements: Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its

discretion, consider data or information submitted at a later date.

• The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English, and a written transcript must accompany any information submitted as an audio-graphic or video-graphic record. Written material may be submitted in paper or electronic form.

• Submitters must clearly identify the source of any submitted data or information.

• Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 31, 2022.

Mary Elissa Reaves,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2022–07443 Filed 4–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2017–0647; FRL–9243–01–OCSPP]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection and Request for Comment; PCBs, Consolidated Reporting and Recordkeeping Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on an Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB). The ICR, entitled: ''PCBs, Consolidated Reporting and Recordkeeping Requirements'' and identified by EPA ICR No. 1446.14 and OMB Control No. 2070–0112, represents the renewal of an existing ICR that is scheduled to expire on November 30, 2022. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the proposed information collection summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before June 6, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0647, using the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) is by appointment only. For the latest status information on EPA/DC and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Regulatory Support Branch (7101M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 420–0580; email address: *sleasman.katherine@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A), 44 U.S.C. 3506(c)(2)(A), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: PCBs, Consolidated Reporting and Recordkeeping Requirements.

ICR numbers: EPA ICR No. 1446.14; OMB control number: 2070–0112.

ICR status: The existing ICR is currently scheduled to expire on November 30, 2022. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 6(e)(1) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e), directs EPA to regulate the marking and disposal of PCBs. Section 6(e)(2) bans the manufacturing, processing, distribution in commerce, and use of PCBs in other than a totally enclosed manner. TSCA section 6(e)(3) establishes a process for obtaining exemptions from the prohibitions on the manufacture, processing, and distribution in commerce of PCBs. Since 1978, EPA has promulgated numerous rules addressing all aspects of the life cycle of PCBs as required by the statute. The regulations are intended to prevent the improper handling and disposal of PCBs and to minimize the exposure of human beings or the environment to PCBs. These regulations have been codified in the various subparts of 40 CFR 761. There are approximately 100 specific reporting, third-party reporting, and recordkeeping requirements covered by 40 CFR 761. To meet its

statutory obligations to regulate PCBs, EPA must obtain sufficient information to conclude that specified activities do not result in an unreasonable risk of injury to health or the environment. EPA uses the information collected under the 40 CFR 761 requirements to ensure that PCBs are managed in an environmentally safe manner and that activities are being conducted in compliance with the PCB regulations. The information collected by these requirements will update the Agency's knowledge of ongoing PCB activities, ensure that individuals using or disposing of PCBs are held accountable for their activities, and demonstrate compliance with the PCB regulations. Specific uses of the information collected include determining the efficacy of a disposal technology; evaluating exemption requests and exclusion notices; targeting compliance inspections; and ensuring adequate storage capacity for PCB waste. This collection addresses the several information reporting requirements found in the PCB regulations.

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is 7.28 hours. Burden is defined in 5 CFR 1320.3(b).

Respondents/affected entities: Entities potentially affected by this ICR are persons who currently possess PCB items, PCB-contaminated equipment, or other PCB waste.

Respondent's obligation to respond: Mandatory, per 40 CFR 761 and TSCA section 6(e).

Estimated total number of potential respondents: 76,258.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 678,043 hours.

Estimated total annual costs: $31,818,441, which includes an estimated burden cost of $31,815,826 and an estimated cost of $2,615 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

This ICR reflects a decrease of 3,364 hours (from 681,407 hours to 675,043 hours) in the total estimated respondent burden from that currently in the OMB inventory. This change is due to updates to the most current wage rate data and to revisions to the total number of respondents. The revisions to total number of respondents are the result of new data gathered for this ICR effort, updated Agency data regarding total numbers of regulated entities, and the overlapping coverage of the recently revised ICR for Universal Hazardous Waste Manifest, identified as EPA ICR No. 0801.25 and approved under OMB Control No. 2050–0039 through January 31, 2025.

In addition, OMB has requested that EPA move towards using the 18-question format for ICR Supporting Statements used by other federal agencies and departments and that is based on the submission instructions established by OMB in 1995, replacing the alternate format developed by EPA and OMB prior to 1995. The Agency does not expect this change in format to result in substantive changes to the information collection activities or related estimated burden and costs.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: April 1, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–07442 Filed 4–6–22; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 9:00 a.m., Thursday, April 14, 2022.

PLACE: You may observe the open portions of this meeting in person at 1501 Farm Credit Drive, McLean, Virginia 22102–5090, or virtually. If you would like to observe, at least 24 hours in advance, visit *FCA.gov*, select ''Newsroom,'' then select ''Events.'' From there, access the linked ''Instructions for board meeting visitors'' and complete the described registration process.

STATUS: Parts of this meeting will be open to the public. The rest of this meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The following matters will be considered:

PORTIONS OPEN TO THE PUBLIC:

- Approval of March 10, 2022, Minutes
- Quarterly Report on Economic Conditions and Farm Credit System Condition and Performance
- Implementation of Current Expected Credit Losses Methodology Final Rule

PORTIONS CLOSED TO THE PUBLIC:

- Office of Examination Quarterly Report on Supervisory and Oversight Activities [1]

CONTACT PERSON FOR MORE INFORMATION: If you need more information or assistance for accessibility reasons, or if you have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2022–07505 Filed 4–5–22; 11:15 am]

BILLING CODE 6705–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination of Receiverships

The Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for each of the following insured depository institutions, was charged with the duty of winding up the affairs of the former institutions and liquidating all related assets. The Receiver has fulfilled its obligations and made all dividend distributions required by law.

[1] Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

NOTICE OF TERMINATION OF RECEIVERSHIPS

Fund	Receivership name	City	State	Termination date
10430	Covenant Bank and Trust	Rock Spring	GA	04/01/2022
10444	Waccamaw Bank	Whiteville	NC	04/01/2022
10467	Community Bank of the Ozarks	Sunrise Beach	MO	04/01/2022

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary, including but not limited to releases, discharges, satisfactions, endorsements, assignments, and deeds. Effective on the termination dates listed above, the Receiverships have been terminated, the Receiver has been discharged, and the Receiverships have ceased to exist as legal entities.

(Authority: 12 U.S.C. 1819)

Dated at Washington, DC, on April 1, 2022.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–07331 Filed 4–6–22; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association.

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 whether the proposed transaction complies with the standards enumerated in the HOLA (12 U.S.C. 1467a(e)).

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 May 9, 2022.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204. Comments can also be sent electronically to *BOS.SRC.Applications.Comments@bos.frb.org:*

1. *Ion Financial, MHC, Naugatuck, Connecticut;* to merge with Lincoln Park Bancorp, and thereby indirectly acquire Lincoln 1st Bank, both of Pine Brook, New Jersey.

Board of Governors of the Federal Reserve System, April 4, 2022.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2022–07434 Filed 4–6–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The 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 the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than May 9, 2022.

A. Federal Reserve Bank of St. Louis (Holly A. Rieser, Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Alton Bancshares, Inc., Alton, Missouri;* to acquire Table Rock Community Bank, Kimberling City, Missouri.

B. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291. Comments can also be sent electronically to *MA@mpls.frb.org:*

1. *Lake Shore III Corporation, Glenwood City, Wisconsin;* to merge with Headwaters Bancorp, Inc., and thereby indirectly acquire Headwaters State Bank, both of Land O'Lakes, Wisconsin.

Board of Governors of the Federal Reserve System, April 4, 2022.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2022–07436 Filed 4–6–22; 8:45 am]

BILLING CODE P

GOVERNMENT ACCOUNTABILITY OFFICE

GAO Tribal Advisory Council

AGENCY: U.S. Government Accountability Office (GAO).

ACTION: Request for nominations for a GAO Tribal Advisory Council.

SUMMARY: This notice announces the U.S. Government Accountability Office's (GAO) intention to form its first

standing Tribal Advisory Council (TAC) expected to be composed of a diverse group of tribal leaders (elected or appointed by their Tribes); an elected or appointed leader of a state-recognized Tribe and/or Native Hawaiian organization; and advisors who are experts on tribal and indigenous issues. The TAC will advise GAO on vital and emerging issues affecting Tribes and Indigenous peoples for the purpose of informing GAO's strategic goals and priorities with respect to the agency's work evaluating federal programs serving Tribes and related topics. GAO is now accepting nominations for TAC appointments that will be effective in August 2022. Nominations should be sent to the email address listed below. Acknowledgement of submission will be provided within a week of submission.

DATES: Nominations should be submitted no later than May 20, 2022, to ensure adequate opportunity for review and consideration of nominees prior to appointment.

ADDRESSES: Submit nomination materials to *TAC@gao.gov* by May 20, 2022.

FOR FURTHER INFORMATION CONTACT: Paige Gilbreath at (214) 777–5724 or *gilbreathp@gao.gov* if you do not receive an acknowledgment or need additional information. For general information, contact GAO's Office of Public Affairs, (202) 512–4800.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Government Accountability Office (GAO) is establishing a Tribal Advisory Council (TAC) to advise GAO on vital and emerging issues affecting Tribes and Indigenous peoples and provide input into GAO's strategic goals and priorities with respect to the agency's related work. Among other things, this may include informing GAO of emerging topics of interest or concern, helping identify relevant stakeholders to ensure GAO work includes a diverse range of tribal and indigenous perspectives, and providing advice to GAO on its processes for working with Tribes.

The TAC is expected to be composed of up to 15 members including elected or appointed leaders from federally recognized Tribal entities, as identified in the **Federal Register** Notice published on January 28, 2022 (87 FR 4636); an elected or appointed leader of a state recognized Tribe and/or Native Hawaiian organization; and technical advisors who may be representatives of national or regional tribal or Native-serving organizations or subject-matter experts on topics relevant to Tribes and Indigenous peoples.

Individuals selected for appointment to the TAC will be invited to serve terms of two or three years. Subject to availability of federal funding, the TAC will meet at least annually, though GAO may periodically ask members to provide information or perspectives on selected issues between TAC meetings. Appointed TAC members will receive per diem and reimbursement for eligible travel expenses incurred for attending TAC meetings.

GAO will endeavor to ensure that the membership of the TAC is balanced in terms of points of view and the demographic, geographic, and other characteristics of Tribes and Native Hawaiian organizations represented. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Nomination Information

Nomination materials should be submitted to *TAC@gao.gov* by May 20, 2022. Required nomination materials vary based on the position the nominee is seeking to fill on the TAC. (1) Nominees who are elected or appointed leaders of federally or state recognized Tribes should obtain a tribal resolution certifying their nomination. This resolution, along with the name of the nominee, their Tribe, and their official role, should be provided to GAO in the nomination package. (2) Leaders of Native Hawaiian organizations should obtain a letter certifying their nomination from their Board of Directors. This letter, along with the name of the nominee and their official role, should be provided to GAO in the nomination package. (3) Technical advisors may be self-nominated or nominated by an individual or organization. Nomination materials should include the name of the nominee, the organization they represent (if applicable), qualifications, and/or a brief description of the nominee's interest in serving on the TAC.

About GAO

The U.S. Government Accountability Office (GAO) is an independent, non-partisan agency that works for Congress. GAO examines how taxpayer dollars are spent and provides Congress and federal agencies with objective, non-partisan, fact-based information to help the government save money and work more efficiently.

To do so, GAO conducts reviews of federal agencies and programs, including those that serve Tribes, their citizens, and descendants. (GAO generally does not audit Tribes' activities.) GAO reviews span a broad range of topics of concern to Tribes, including health care, education, economic development, environmental protection, justice, and infrastructure, among others. GAO's oversight of federal programs that serve Tribes and their citizens aims to help the Congress determine how best to meet the government's longstanding commitments to federally recognized Tribes.

Authority: 31 U.S.C. 711–712.

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2022–07423 Filed 4–6–22; 8:45 am]

BILLING CODE 1610–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Amended Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Agency Amended Order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), has amended its Order issued October 20, 2021, to align with revised CDC guidance published on January 4, 2022, related to isolation and quarantine after travel.

DATES: This Amended Order will be implemented at 12:01 a.m. EDT on April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Candice Swartwood, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, GA 30329; Telephone: 404–498–1600; Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: On October 25, 2021, the President issued a Proclamation pursuant to Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code (the Proclamation) titled, ''*Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*'' Pursuant to this Proclamation, the President has

implemented a global suspension and limitation on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19. The Proclamation directs the Secretary of HHS, through the CDC Director, to implement the Proclamation as it applies to public health in accordance with appropriate public health protocols and consistent with CDC's independent public health judgment. The Proclamation does not apply to crew members of airlines or other aircraft operators if they follow industry standard protocols for the prevention of COVID–19.

In this notice, CDC announces an Amended Order that revises some of the post-arrival requirements for certain people eligible for an exception to the vaccination requirement to travel to the United States. The Amended Order reduces the number of days for such persons to self-quarantine after international travel from seven days to five days. The number of days for isolation for those who are diagnosed with COVID–19 or have COVID–19 symptoms is also reduced from 10 days to five days. This Amended Order additionally clarifies language already on the Attestation Form that children under two years of age do not need to complete (or have a parent or guardian complete on their behalf) the attestation.

A copy of the Amended Order and Attestation Form is below. A copy of these documents can be found at: *https://www.cdc.gov/quarantine/order-safe-travel.html.*

Centers for Disease Control and Prevention (CDC)

Department of Health and Human Services (HHS)

Amended Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic

Summary

On October 25, 2021, the President issued a Proclamation pursuant to Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code, (the Proclamation), titled, ''*Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*'' Pursuant to this Proclamation, the President has implemented a global suspension and limitation on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19. The Proclamation directs the Secretary of Health and Human Services (HHS), through the Director of the Centers for Disease Control and Prevention (CDC), to implement the Proclamation as it applies to public health in accordance with appropriate public health protocols and consistent with CDC's independent public health judgment.

The Proclamation does not alter the obligation of persons, including persons whose entry is not covered by the Proclamation, to comply with the requirements of state, local, territorial, or Tribal authorities, or the applicable requirements of CDC Orders, including:

- *Requirement for Negative Pre-Departure COVID–19 Test Result or Documentation of Recovery from COVID–19 for All Airline or Other Aircraft Passengers Arriving in the United States from any Foreign Country* (published at 86 FR 7387, January 28, 2021; amended and republished at 86 FR 69256, December 7, 2021) (as may be further amended);
- *Requirement for Persons to Wear Masks While on Conveyances and at Transportation Hubs* (published at 86 FR 8025, February 3, 2021) (as may be further amended); and
- Other CDC Orders that may be published relating to preventing the introduction, transmission, and spread of COVID–19 into and throughout the United States.

This Amended Order further amends the previous Order signed by the CDC Director on October 30, 2021, to align with revised CDC guidance related to isolation and quarantine after travel that was published on January 4, 2022. The new guidance reduces the number of days recommended for a person to self-quarantine after travel from 7 days to 5 days. The new guidance also reduces the number of days recommended for isolation for people who are diagnosed with COVID–19 or have COVID–19 symptoms from 10 days to 5 days. This Amended Order also clarifies language already on the attestation form that children under 2 years of age do not need to complete (or have a parent or guardian complete on their behalf) the attestation. The Amended Order also revises what is required for some people eligible for an exception to the vaccination requirement and what public health actions, such as self-quarantine or testing, may be required for such eligible people after arriving in the United States. This Amended Order shall enter into effect at 12:01 a.m. EDT on April 14, 2022.

Definitions

For purposes of this Amended Order, the following definitions apply:

Accepted COVID–19 Vaccine means:

- A vaccine authorized for emergency use or approved by the U.S. Food and Drug Administration (FDA); [1] or
- A vaccine listed for emergency use (EUL) by the World Health Organization (WHO); [2] or
- A vaccine or combination of vaccines listed by CDC in the Technical Instructions.

Covered Individual means any passenger covered by the Proclamation and this Amended Order: A noncitizen [3] who is a nonimmigrant seeking to enter the United States by air travel. This term does not apply to crewmembers of airlines or other aircraft operators if such crewmembers and operators adhere to all industry standard protocols for the prevention of COVID–19, as set forth in relevant guidance for crewmember health issued by the CDC or by the Federal Aviation Administration in coordination with the CDC.

Covered Individual Attestation means the attestation in Attachment A,[4] in written or electronic form, that must be completed by each *Covered Individual* as a condition of their being able to enter the United States under the Proclamation and this Amended Order.

Excepted Covered Individual means a *Covered Individual* who is not fully vaccinated against COVID–19 and meets the criteria for an exception under the Proclamation and this Amended Order.

Foreign country means anywhere that is not a state, territory, or possession of the United States.

Foreign Country with Limited COVID–19 Vaccine Availability means a foreign country where less than 10 percent of

[1] For a list of vaccines approved or authorized in the United States to prevent COVID–19, see *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html.*

[2] For more information about WHO-listed COVID–19 vaccines, see *https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-(covid-19)-vaccines.*

[3] For purposes of this Amended Order, U.S. lawful permanent residents and U.S. nationals will be treated in the same manner as U.S. citizens. For more details regarding who is not a Covered Individual under the Order, see: *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html#immigrants.*

[4] CDC encourages airlines and aircraft operators to incorporate the attestation into paperless check-in processes. An airline or aircraft operator may use a third party (including a third-party application) to collect attestations, including to provide translations. However, an airline or aircraft operator will have sole legal responsibility to provide and collect attestations, to ensure the accuracy of any translation, and to comply with all other obligations under agency directives implementing the Proclamation. An airline or aircraft operator is responsible for any failure of a third party to comply with such directives. An airline or aircraft operator may not shift any legal responsibility to a third party.

the country's total population has been fully vaccinated with any available COVID–19 vaccine. These countries are listed by CDC in Technical Instructions.

Fully Vaccinated Against COVID–19 [5] means it has been:

- 2 weeks (14 days) or more since a person received one dose of an accepted single-dose-series COVID–19 vaccine; OR
- 2 weeks (14 days) or more since a person received a second dose in a 2-dose series of an accepted COVID–19 vaccine; OR
- 2 weeks (14 days) since a person received the full series of an accepted COVID–19 vaccine (not placebo) in a clinical trial; OR
- 2 weeks (14 days) since the person received 2 doses of any ''mix-and-match'' combination of accepted COVID–19 vaccines administered at least 17 days apart; [6] OR
- 2 weeks (14 days) or more since the person received a complete series of a vaccine or combination of vaccines listed by CDC in Technical Instructions.

Not Fully Vaccinated Against COVID–19 means a person does not meet the definition of *Fully Vaccinated Against COVID–19.*

Post-Arrival Viral Test means a viral test taken by an *Excepted Covered Individual,* obtained 3–5 days after arriving in the United States or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation.*[7]

Post-Arrival Vaccination means completion of the primary series of an *Accepted COVID–19 Vaccine* by an *Excepted Covered Individual* followed by a two-week period in order to become *Fully Vaccinated Against COVID–19* within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate, if the *Excepted Covered Individual* plans to be in the United States for longer than 60 days.

Proof of Being Fully Vaccinated Against COVID–19 means a paper or digital format of a vaccination record or a verifiable vaccination record, as listed by CDC in Technical Instructions, confirming that the person is *Fully Vaccinated Against COVID–19.*

Self-isolation/Self-isolate means actions taken by an *Excepted Covered Individual* who tests positive on a viral test for COVID–19 administered on a specimen collected 3–5 days (or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation*) after arriving in the United States or develops COVID–19 symptoms.[8] [9] These actions include separating from other individuals and staying in a home or other residence for at least 5 calendar days (or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation*) after symptom onset or the date of first positive test if asymptomatic.[10] The actions also include observing other public health precautions as set forth in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation,* such as properly wearing a well-fitting mask any time the *Excepted Covered Individual* must be around other people during the isolation period and for an additional 5 days after ending isolation.[11] [12]

Self-quarantine means actions taken by an *Excepted Covered Individual* to separate from other individuals after arriving in the United States, including staying in a home or other residence for a full 5 days, or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation,* and observing public health precautions as set forth in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation.*[13] [14]

Viral test means a viral detection test for current infection (*i.e.,* a nucleic acid amplification test [NAAT] or a viral antigen test) approved, cleared, or authorized by the FDA for the detection of SARS–CoV–2.

United States or *U.S.* has the same definition as ''United States'' in 42 CFR 71.1(b), meaning ''the 50 States, District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.''

Background

Since January 2020, the respiratory disease known as ''COVID–19,'' caused by a novel coronavirus (SARS–CoV–2), has spread globally, including cases reported in all 50 states within the United States, plus the District of Columbia and all U.S. territories. As of March 29, 2022, there have been almost 481,756,700 million cases of COVID–19 globally, resulting in almost 6,128,000 deaths.[15] More than 79,827,900 cases have been identified in the United States, with new cases reported daily, and over 975,500 deaths attributed to the disease.[16] Additionally, throughout the duration of this pandemic, cases have tended to surge in waves, especially after high-volume travel periods or when new variants have emerged.[17]

On November 24, 2021, the Republic of South Africa informed the World Health Organization (WHO) of a new variant of SARS–CoV–2, the virus that causes COVID–19, that was detected in that country. On November 26, 2021, WHO designated the variant B.1.1.529 as a variant of concern and named it Omicron.[18] This decision was based on the evidence presented to the Technical Advisory Group on SARS–CoV–2 Virus Evolution (TAG–VE) which is a group of independent experts charged with assessing the evolution of SARS–CoV–2 and examining if specific mutations and combinations of mutations may alter how the virus spreads and whether it may cause more severe illness. The evidence presented to the TAG–VE noted that Omicron has several mutations that may have an impact on

[5] While not a requirement of this Amended Order, CDC recommends that all travelers get a booster dose when eligible to stay up to date with their COVID–19 vaccines. See *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.*

[6] The recommended interval between the first and second doses of FDA-approved/authorized and WHO–EUL listed vaccines varies by vaccine type. However, for purposes of interpretation of vaccine records, the second dose in a two dose heterologous series must have been received no earlier than 17 days (21 days with a 4-day grace period) after the first dose.

[7] Requirement for Proof of COVID–19 Vaccination for Air Passengers, available at *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html.*

[8] *Ibid.*

[9] Symptoms of COVID–19, available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[10] Requirement for Proof of COVID–19 Vaccination for Air Passengers, available at *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html.*

[11] *Ibid.*

[12] Quarantine and Isolation, available at *https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html.*

[13] Requirement for Proof of COVID–19 Vaccination for Air Passengers, available at *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html.*

[14] Travel Guidance for Non-U.S. Citizens, Non-U.S. Immigrants, available at *https://www.cdc.gov/coronavirus/2019-ncov/travelers/noncitizens-US-air-travel.html.*

[15] *https://covid19.who.int/.*

[16] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[17] *Ibid.*

[18] *https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern.*

how easily it spreads or the severity of illness it causes.[19]

Even as COVID–19 rates fall in most of the United States, Omicron and sub-variants are still highly prevalent in other parts of the world. WHO and CDC continue to collaborate with researchers around the world to better understand Omicron and track potential future variants of SARS–CoV–2. Studies include assessments of transmissibility, severity of infection (including symptoms), and how well people who are fully vaccinated and boosted are protected against infection, hospitalization, and death. While data indicate that current vaccines are less effective at preventing infection from Omicron as compared to other variants, data also suggest that hospitalization and death rates are lower for individuals infected with Omicron who are vaccinated compared with other variants.[20] [21] With an estimated 100 percent increase in transmission for Omicron when compared to the original virus, vaccinations continue to play an important role in protecting the public from severe illness.[22] A booster dose of vaccine mitigates the reduction in vaccine effectiveness, and CDC has provided guidance advising that people stay up to date with their COVID–19 vaccines, including getting a booster dose if eligible.[23] [24]

The United States is taking a multi-layered approach to combatting COVID–19 by taking concurrent efforts to prevent and slow the continued introduction of cases and further spread of the virus within U.S. communities. Vaccines remain the best public health measure to protect people from severe illness or death from COVID–19, slow transmission, and reduce the likelihood of new variants emerging.

On October 25, 2021, the President issued a Proclamation under 3 U.S.C. 301 and 8 U.S.C. 1182(f), 1185(a)(1), titled, ''*Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*'' The Proclamation revoked prior, country-specific presidential proclamations issued under these authorities in response to the outbreak of COVID–19. In their place, the President implemented a global suspension and restriction on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID–19, with only limited exceptions. This Amended Order and associated Technical Instructions continue to implement the Proclamation. As further explained in this Amended Order, CDC continues to implement the Proclamation and require that *Covered Individuals* who are fully vaccinated show *Proof of Being Fully Vaccinated Against COVID–19* and complete a *Covered Individual Attestation* attesting that they are fully vaccinated. *Excepted Covered Individuals* who are unable to present *Proof of Being Fully Vaccinated Against COVID–19* must present a *Covered Individual Attestation* to the airline or aircraft operator prior to boarding the aircraft and attest that they have arranged to take specified public health actions after arrival in the United States.

Persons Whose Entry Is Not Covered by the Proclamation or Who Are Excepted Covered Individuals

The Proclamation applies only to non-U.S. citizens seeking entry as nonimmigrants. Individuals seeking admission to the United States as immigrants are subject to the medical examination and vaccination requirements of 8 U.S.C. 1182(a)(1)(A) and 42 CFR part 34. These requirements are further described in CDC's *COVID–19 Technical Instructions for Panel Physicians.*[25]

The Proclamation does not apply to crewmembers of airlines or other aircraft operators if they follow industry standard protocols for the prevention of COVID–19.[26] [27] Accordingly, per the terms of the Proclamation, these individuals are not *Covered Individuals* and are not required to present *Proof of Being Fully Vaccinated* nor required to present a completed *Covered Individual Attestation* to the airline or aircraft operator before boarding an aircraft destined to the United States.

The Proclamation permits *Excepted Covered Individuals* to enter the United States by air if they meet certain criteria as determined by the CDC. Except for children under the age of 2 years, *Excepted Covered Individuals* are required to present a *Covered Individual Attestation* to the airline or aircraft operator before boarding an aircraft destined to the United States attesting that they meet criteria outlined in the Technical Instructions for certain categories of exceptions.[28]

In the *Covered Individual Attestation, Excepted Covered Individuals* must also attest to arranging to take specified post-arrival public health actions that, depending on the exception, could include a *Post-arrival Viral Test, Self-quarantine,* or *Self-isolation* if they test positive; and a *Post-arrival Vaccination* if their exception requires it and they are staying in the country for more than 60 days. Information about the requirements for these actions is detailed in the definitions of this Amended Order, Technical Instructions, and in CDC guidance.[29] The exception categories include:

Diplomatic and Official Foreign Government Travel. The Proclamation excepts any noncitizen seeking entry into or transiting the United States for certain diplomatic or official foreign government activities. This includes:

• Noncitizens traveling pursuant to one of the following nonimmigrant visa classifications: A–1, A–2, C–2, C–3 (as a foreign government official or immediate family member of an official), E–1 (as an employee of TECRO or TECO or the employee's immediate family members), G–1, G–2, G–3, G–4, NATO–1 through NATO–4, or NATO–6 (or seeking to enter as a nonimmigrant in one of those NATO classifications); or

[19] *https://www.who.int/news/item/28-11-2021-update-on-omicron.*

[20] Johnson AG, Amin AB, Ali AR, et al. COVID–19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence—25 U.S. Jurisdictions, April 4–December 25, 2021. *MMWR* Morb Mortal Wkly Rep. ePub: 21 January 2022. DOI: *http://dx.doi.org/10.15585/mmwr.mm7104e2.*

[21] Thompson MG, Natarajan K, Irving SA, et al. Effectiveness of a Third Dose of mRNA Vaccines Against COVID–19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance—VISION Network, 10 States, August 2021–January 2022. *MMWR* Morb Mortal Wkly Rep. ePub: 21 January 2022. DOI: *http://dx.doi.org/10.15585/mmwr.mm7104e3.*

[22] *Ibid.*

[23] Accorsi EK, Britton A, Fleming-Dutra KE, Smith ZR, Shang N, Derado G, et al. Association Between 3 Doses of mRNA COVID–19 Vaccine and Symptomatic Infection Caused by the SARS–CoV–2 Omicron and Delta Variants. *JAMA* 2022. *https://jamanetwork.com/journals/jama/fullarticle/2788485.*

[24] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.*

[25] *https://www.cdc.gov/immigrantrefugeehealth/panel-physicians/covid-19-technical-instructions.html.*

[26] Crewmembers on official duty assigned by the airline or operator that involves operation of aircraft, or the positioning of crew not operating the aircraft (*i.e.,* on ''deadhead'' status), are exempt from the requirements of this Amended Order provided their assignment is under an air carrier's or operator's occupational health and safety program that follows applicable industry standard protocols for the prevention of COVID–19 as set forth in the most current relevant guidance issued by the CDC or the Federal Aviation Administration in coordination with the CDC (*e.g.,* SAFO 20009, COVID–19: Updated Interim Occupational Health and Safety Guidance for Air Carriers and Crews, available at *https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO20009.pdf.*).

[27] CDC Technical Instructions: *https://www.cdc.gov/quarantine/order-safe-travel/technical-instructions.html.*

[28] *Ibid.*

[29] Requirement for Proof of COVID–19 Vaccination for Air Passengers, available at *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html.*

• Any noncitizen whose travel falls within the scope of section 11 of the United Nations Headquarters Agreement or other travel pursuant to a United States legal obligation (as evidenced by a letter of invitation from the United Nations or other documentation showing the purpose of such travel).

These persons must provide proof of their visa classification or an official letter, such as a letter from the U.S. government or foreign government. If they have been invited by the United Nations, they will need to present a letter of invitation from the United Nations or other documentation showing the purpose of such travel. They will also be required to provide the *Covered Individual Attestation* to the airline or aircraft operator before boarding an aircraft destined to the United States. In the attestation, they must attest to having arranged to receive a *Post-arrival Viral Test* after arriving in the United States; to *Self-quarantine,* except during periods when their attendance is required to carry out the purposes of the diplomatic or official foreign government travel (*e.g.,* to attend official meetings or events); and *Self-isolate* if the result of the post-arrival viral test is positive or if they develop COVID–19 symptoms. Individuals who meet the Diplomatic and Official Foreign Government Travel exception will not be required to attest to arranging for a *Post-arrival Vaccination.*[30]

Children. The Proclamation excepts noncitizens who are nonimmigrants for whom, given their age, requiring vaccination would be inappropriate as determined by the CDC, taking into account global vaccine availability for individuals in that age group. In the United States, COVID–19 vaccinations are widely available for children and adolescents, with a vaccine approved or authorized for those 5 years and older.[31] However, the same availability does not exist globally.[32] Accordingly, considering the difficulty potentially posed to families traveling together when some members of the family can be vaccinated and others cannot, persons under the age of 18 years meet the age-based exception in the Proclamation.

Noncitizens who are nonimmigrants and who are children ages 2 through 17 and unable to present *Proof of Being Fully Vaccinated Against COVID–19* must present a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. CDC has determined that children under 2 years of age do not need to have an attestation completed because many are infants in arms, who are not required to have an airline ticket and for whom an attestation presents significant logistical burdens. Children ages 2 through 17 will be required to attest (or have a parent or guardian attest on their behalf) to arranging to get a *Post-arrival Viral Test* and *Self-isolate* if the test result is positive or if the child develops COVID–19 symptoms. However, children ages 2 through 17 will not be required to attest (or have a parent or guardian attest on their behalf) to having arranged to *Self-quarantine* in the United States after arrival. Based on the potential difficulty that self-quarantine may pose to children ages 2 through 17, especially when accompanied by a vaccinated parent or guardian who is not required to self-quarantine, CDC has determined that self-quarantine should not be required. As previously stated, children under 2 years of age are not required to attest (or have a parent or guardian attest on their behalf) to arranging to complete any post-arrival public health requirements. CDC believes that this approach fairly balances the interests of families traveling to the United States with protecting the public's health. CDC guidance strongly recommends vaccination for all adolescents and eligible children. However, given the still evolving circumstances of vaccination for children, attestation regarding post-arrival vaccination will not be required for children ages 2 through 17 at this time. This determination will be periodically reevaluated.

Clinical Trials. The Proclamation excepts noncitizens who are nonimmigrants and who have participated or are participating in certain clinical trials for COVID–19 vaccination, as determined by the CDC. Qualifying vaccine candidates that meet CDC criteria for the exception are specified in the Technical Instructions.[33] Because these clinical trial participants may have received a COVID–19 vaccine or series of COVID–19 vaccines that do not meet the definition of an *Accepted COVID–19 Vaccine,* these participants may not be able to present *Proof of Being Fully Vaccinated Against COVID–19.* Accordingly, noncitizens who are nonimmigrants and who have participated or are participating in certain COVID–19 vaccine trials and unable to present *Proof of Being Fully Vaccinated Against COVID–19* must present a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States.

To meet the clinical trial exception, *Covered Individuals* must provide official documentation of clinical trial participation outlined further in the Technical Instructions. Those who meet the clinical trial exception must attest (or have a parent or guardian attest on their behalf) to having arranged to receive a *Post-arrival Viral Test,* and *Self-isolate* if the test result is positive or if they develop COVID–19 symptoms. However, CDC has determined that these individuals should not be required to attest to arranging to self-quarantine or to be vaccinated after arriving in the United States. Requiring self-quarantine after arrival could potentially discourage clinical trial participation which would not serve the interests of public health and requiring vaccination could potentially invalidate the clinical trial study.

Medical Contraindications. The Proclamation excepts noncitizens who are nonimmigrants for whom receiving an accepted COVID–19 vaccine is medically contraindicated as determined by CDC.[34] Accordingly, CDC has determined that for an individual to meet this exception, a licensed physician must have determined that the individual has a medical contraindication to an accepted COVID–19 vaccine (*e.g.,* a demonstrated anaphylactic reaction to a prior dose of a COVID–19 vaccine or vaccine component). As further described in the Technical Instructions, such individuals are not required to present *Proof of Being Fully Vaccinated Against COVID–19.* COVID–19 vaccinations have been overwhelmingly proven to be safe and effective at preventing severe illness, hospitalizations, and deaths from COVID–19. However, as is the case with any vaccine, certain medical complications can occur, such as a severe allergic reaction. CDC intends for this exception to be applied in strict

[30] As noted in Frequently Asked Questions on CDC's website (see *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html*), this policy has been in place since December 2021 and was subsequently included in the *Covered Individual Attestation.* It is incorporated into the substance of this Amended Order, consistent with the need to expedite diplomatic and official foreign government travel and comity regarding how U.S. diplomats are treated abroad.

[31] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html.*

[32] *https://www.who.int/news/item/24-11-2021-interim-statement-on-covid-19-vaccination-for-children-and-adolescents.*

[33] *https://www.cdc.gov/quarantine/order-safe-travel/technical-instructions.html* (Table 3).

[34] Objections to vaccination based on religious or moral convictions do not qualify under this or any other exception listed in the Proclamation or this Amended Order.

accordance with scientific evidence and has provided additional details concerning exceptions for medical contraindications in the Technical Instructions. Persons who believe they meet the criteria for this exception must present a signed letter from a licensed physician documenting a medical contraindication to receiving a COVID–19 vaccine. In the *Covered Individual Attestation,* they must attest that they meet the exception, and must attest to having arranged to obtain a *Post-arrival Viral Test, Self-quarantine,* and *Self-isolate* if they test positive or if they develop COVID–19 symptoms.

Humanitarian and Emergency Exceptions. The Proclamation excepts any noncitizen nonimmigrant who has been granted an exception by the CDC for humanitarian or emergency reasons, as determined by the CDC. CDC applies this exception extremely narrowly, such as when an individual must travel to the United States to preserve health and safety (*e.g.,* emergency medical evacuations) and is unable to complete the vaccination requirement before travel. Individuals and organizations sponsoring individuals who meet the exception criteria should contact the U.S. embassy or consulate in or nearest the country from which they are departing for the United States. The embassy will then transmit this information to CDC for consideration. Any noncitizen who is a nonimmigrant granted an exception for humanitarian or emergency reasons must present an official U.S. government letter and a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. Such individual must attest to having arranged to obtain a *Post-arrival Viral Test, Self-quarantine,* and *Self-isolate* if they test positive or develop COVID–19 symptoms. They also must attest to having arranged to receive a *Post-arrival Vaccination* within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if they intend to stay in the United States for more than 60 days.

Limited Vaccine Availability. The Proclamation excepts any noncitizen who is a nonimmigrant with a nonimmigrant visa (excluding a B–1 or B–2 visa) and who is a citizen of a *Foreign Country with Limited COVID–19 Vaccine Availability,* which is defined pursuant to the Proclamation and this Amended Order as a foreign country where less than 10 percent of the country's total population has been fully vaccinated with any available COVID–19 vaccine or is otherwise determined by the Director of the CDC to qualify as a country where the availability of COVID–19 vaccination is limited.[35] The list of countries falling below the 10 percent threshold is maintained by CDC in the Technical Instructions and reviewed on a regular basis. In developing and maintaining this list, CDC relies on official source data as reported by foreign ministries of health but may also rely on other sources such as additional information provided by U.S. embassies and consulates.

Individuals entering the United States under this exception must show proof that they meet the exception through a passport issued by a foreign country with limited COVID–19 vaccine availability and a non-B–1 or B–2 nonimmigrant visa as well as a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. Additionally, these individuals must attest to having arranged to obtain a *Post-arrival Viral Test, Self-quarantine,* and *Self-isolate* if they test positive or develop COVID–19 symptoms. They also must attest to having arranged to receive a *Post-arrival Vaccination* within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if they intend to stay in the United States for more than 60 days.

Members of the U.S. Armed Forces. The Proclamation and this Amended Order except noncitizens who are members of the U.S. Armed Forces and the spouses and children under 18 years of age of members of the U.S. Armed Forces. CDC applies this exception in a similar manner as in the CDC Order, *Requirement for Proof of Negative COVID–19 Test or Recovery from COVID–19 for All Air Passengers Arriving in the United States.* Members of the U.S. Armed Forces and their family members observe U.S. Department of Defense (DoD) guidance to prevent the transmission of COVID–19 as set forth in *Force Protection Guidance (Supplement 20) Revision 1—Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic*[36] (January 10, 2022) or subsequent updated DoD guidance. Accordingly, members of the U.S. Armed Forces and their family members, if traveling with a U.S. military identification document or other proof of status as a member of the U.S. Armed Forces or as a spouse, or child ages 2 through 17 of a member of the U.S. Armed Forces, must attest (or have a parent or guardian attest on their behalf if a child ages 2 through 17) to their status on the *Covered Individual Attestation,* but are not required to attest to having arranged to complete any post-arrival public health requirements. As previously stated, children under 2 years of age are not required to attest or have a parent or guardian attest on their behalf, to having arranged to complete any post-arrival public health requirements.

Sea Crew Members. The Proclamation excepts any noncitizen seeking entry to or transiting through the United States as a sea crew member traveling pursuant to a C–1 and D nonimmigrant visa if such sea crew member adheres to all industry standard protocols for the prevention of COVID–19, as set forth in relevant guidance for sea crew member health by the CDC.[37] Any passenger granted an exception as a sea crew member must present documentation to the airline from their employer indicating that their entry to or transit through the United States is required for the purpose of operating a vessel or return travel after disembarking the vessel. Sea crew members entering the United States under this exception must present a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. Sea crew members traveling on this exception also must attest to having arranged to obtain a *Post-arrival Viral Test, Self-quarantine,* and *Self-isolate* if they test positive or develop COVID–19 symptoms. They also must attest to a *Post-arrival Vaccination* within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC if they intend to stay in the United States for more than 60 days. Given that sea crew members may need to board a ship soon after arrival in the United States, CDC has provided additional information about how *Excepted Covered Individuals* who are sea crew

[35] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[36] *https://media.defense.gov/2022/Jan/11/2002920095/-1/-1/1/FORCE-HEALTH-PROTECTION-GUIDANCE-SUPPLEMENT-20-REVISION-1-DEPARTMENT-OF-DEFENSE-GUIDANCE-FOR-PERSONNEL-TRAVELING-DURING-THE-CORONAVIRUS-DISEASE-2019-PANDEMIC.PDF.*

[37] See CDC's guidance: *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html* for additional information regarding post-arrival public health management of sea crew. Relevant CDC guidance pertaining to sea crew members serving on board cruise ships has been issued separately (available at *https://www.cdc.gov/quarantine/cruise/index.html*). Additional guidance applicable to crew serving onboard all vessels is available at *https://www.cdc.gov/quarantine/maritime/recommendations-for-ships.html.*

members can meet the requirements of the Amended Order and post-arrival requirements on CDC's website.[38]

National Interest Exception. The Proclamation excepts any noncitizen or group of noncitizens whose entry would be in the U.S. national interest, as determined by the Secretary of State, the Secretary of Transportation, or the Secretary of Homeland Security or their designees. Any *Excepted Covered Individual* granted an exception in the national interest must present an official U.S. government letter and a completed *Covered Individual Attestation* to the airline or aircraft operator prior to embarking an aircraft destined to the United States. Such an individual must also attest to having arranged to: Obtain a *Post-arrival Viral Test; Self-quarantine,* except during periods when attendance is required to carry out the purposes of the travel for the U.S. national interest (*e.g.,* to attend official meetings or events); and *Self-isolate* if they test positive or develop COVID–19 symptoms. They also must attest to having arranged to receive a *Post-arrival Vaccination* within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate, if they intend to stay in the United States for more than 60 days.

Requirement To Provide a Covered Individual Attestation

The Proclamation directs the HHS Secretary, acting through the CDC Director, to implement the Proclamation as it applies to public health through such procedures as may be established, and consistent with CDC's independent public health judgment. In accordance with the President's direction, this Amended Order requires that *Covered Individuals* seeking to enter the United States by air travel who are fully vaccinated may embark an aircraft destined for the United States only if they show *Proof of Being Fully Vaccinated Against COVID–19* and complete a *Covered Individual Attestation* attesting that they are fully vaccinated.

Additionally, *Covered Individuals* seeking to enter the United States by air travel and who are not *Fully Vaccinated Against COVID–19* may embark an aircraft destined for the United States only if they qualify as *Excepted Covered Individuals* pursuant to the Proclamation. Under the Proclamation and this Amended Order, such individuals must agree, depending on their category of exception, that they will comply with applicable public health precautions established by CDC to protect against the public health risk posed by these travelers entering into the United States. These include:

- Providing proof in the form of an attestation of pre-departure testing for COVID–19 or documentation of recovery from COVID–19, as determined by the CDC;
- taking precautions during air travel to protect against the further introduction, transmission, and spread of COVID–19, including by complying with the requirement to wear a face mask, as determined by the CDC;
- providing proof in the form of an attestation of having arranged for post-arrival testing for COVID–19, as determined by the CDC; and
- providing proof in the form of an attestation of having arranged to self-quarantine or self-isolate after arriving in the United States, as determined by the CDC.

Some categories of *Excepted Covered Individuals* (subject to certain exceptions) must also attest to having arranged to become fully vaccinated against COVID–19 within 60 days[39] of arriving in the United States if the individual intends to stay in the United States for more than 60 days, or as soon thereafter as is medically appropriate as determined by the CDC, and must provide proof in the form of an attestation of having arranged to become fully vaccinated against COVID–19 after arriving in the United States.

The *Covered Individual Attestation* must be completed, in written or electronic form, by the *Covered Individual* and is subject to 18 U.S.C. 1001. As further explained in the attached Attestation form (Attachment A), persons who knowingly submit false information may be subject to fines, imprisonment, and other penalties. Airlines or other aircraft operators, as directed by the Transportation Security Administration (TSA), including through the Security Directive issued, and consistent with this Amended Order, are required to retain a copy of the *Covered Individual Attestation* for 2 years; however, individuals are not required to retain a copy of the attestation in their possession upon arriving in the United States.

Future CDC Orders implementing the Proclamation may require other public health measures consistent with the Proclamation to protect against the further introduction, transmission, and spread of COVID–19 into the United States by *Covered Individuals*.

Statement of Good Cause Under the Administrative Procedure Act

This Amended Order is not a legislative rule within the meaning of the Administrative Procedure Act (APA), but rather an Order implementing the Proclamation, which itself is not subject to the APA. Because this Amended Order qualifies as a legislative rule under the APA, notice and comment and a delay in the effective date are not required because there is good cause to dispense with prior public notice and comment and for a delay in the effective date. *See* 5 U.S.C. 553(b)(B), (d)(3). Considering the rapid and unpredictable developments in the public health emergency caused by COVID–19, it would be impracticable and contrary to the public's health, and by extension the public's interest, to delay the issuance and effective date of this Amended Order implementing the Proclamation. In light of the rapid spread of Omicron and its impact on travel, any delay in issuing these amendments would adversely affect travelers and the air travel industry by depriving these persons and entities of the ability to rely on the most up-to-date findings and scientific determinations relating to the ongoing COVID–19 pandemic. In addition, the APA does not require a delay in the effective date because this Amended Order relieves certain restrictions. *See* 5 U.S.C. 553(d)(1).

This Amended Order is being issued to align with revised CDC guidance related to isolation and quarantine after travel that was published on January 4, 2022 and make other changes based on CDC's public health expertise. Revised CDC guidance reduces the number of days recommended for a person to self-quarantine after travel from 7 to 5 days.[40] [41] Additionally, the new guidance reduces the number of days recommended for isolation for people who are diagnosed with COVID–19 or have COVID–19 symptoms from 10 days to 5 days. Further delay to these updates

[38] *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html#faq-exceptions.*

[39] CDC considers 60 days an appropriate time frame for requiring that persons arriving in the United States be fully vaccinated against COVID–19. The mRNA COVID–19 vaccines (Pfizer-BioNTech and Moderna) available in the United States are administered 3–4 weeks apart (see *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html*). It takes 14 days after the second dose to be considered fully vaccinated. Therefore, it is reasonable to conclude that individuals should be able to complete the vaccination series and the 14-day period within 60 days of arriving in the United States.

[40] Quarantine and Isolation, available at *https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html.*

[41] Travel Guidance for Non-U.S. Citizens, Non-U.S. Immigrants, available at *https://www.cdc.gov/coronavirus/2019-ncov/travelers/noncitizens-US-air-travel.html.*

may result in travelers quarantining or isolating longer than needed after travel. This Amended Order also allows for these time periods to be adjusted if further updates are made to CDC's guidance. Updates will be reflected in the attestation and on CDC's website.[42]

This Amended Order also provides that children under 2 years of age do not need to complete (or have a parent or guardian complete on their behalf) an attestation, revises what is required for *Excepted Covered Individuals* to meet the criteria for an exception, and provides more clarity on what public health actions (*e.g., Self-quarantine, Post-arrival Viral Test*) may be required after arriving in the United States. It is imperative that these amendments be issued without further delay so that affected individuals have the necessary clarity when arranging their travel and post-travel plans in accordance with the requirements of this Amended Order. Overall, these updates reduce the burden to the air passenger, such as by reducing the time period they would be required to attest to arranging after arrival in the United States and being more explicit about which activities are not required for certain exceptions.

This Amended Order is an economically significant regulatory action under Executive Order 12866 and has therefore been reviewed by the Office of Information and Regulatory Affairs of the Office of Management and Budget. Similarly, the Office of Information and Regulatory Affairs has determined that if this Amended Order were a rule, it would be a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act), 5 U.S.C. 804(2), but there would not be a delay in its effective date as the agency has determined that there would be good cause to make the requirements herein effective immediately under the APA, 5 U.S.C. 808(2).

If any provision of this Amended Order continuing to implement the Proclamation, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

Pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated above, I hereby conclude that notice-and-comment rulemaking would defeat the purpose of this Amended Order implementing the Proclamation and endanger the public health, and is, therefore, impracticable and contrary to the public interest. For the same reasons, I have determined, consistent with 5 U.S.C. 553(d)(3), that there is good cause to make this Amended Order implementing the Proclamation effective without a 30-day delay in effective date. In addition, consistent with 5 U.S.C. 553(d)(1), this Amended Order implementing the Proclamation does not require a 30-day delay in effective date because it relieves certain restrictions.

Action

Accordingly, for the reasons set forth in the Proclamation and in this Amended Order:

1. Directions to Airlines and Other Aircraft Operators

As directed by TSA, including through its Security Directive or Emergency Amendment issued after consultation with CDC, and consistent with this Amended Order, any airline or other aircraft operator transporting by air into the United States individuals who are *Covered Individuals* from any foreign country, as determined and confirmed by the airline or other aircraft operator, is required to:

A. Confirm that every *Covered Individual,* unless excepted, prior to boarding the aircraft, has presented paper or digital documentation of *Proof of Being Fully Vaccinated Against COVID–19* that includes personal identifiers (*e.g.,* name and date of birth) that match the personal identifiers on the passenger's passport or other travel documents, and provides a *Covered Individual Attestation.*

B. Confirm that every *Covered Individual* who has not presented *Proof of Being Fully Vaccinated Against COVID–19* prior to boarding the aircraft has presented documentation proving that they are an *Excepted Covered Individual* under the Proclamation and this Amended Order as further explained by CDC in the Technical Instructions.

C. Confirm that every *Excepted Covered Individual*[43] who has not presented *Proof of Being Fully Vaccinated Against COVID–19* prior to boarding the aircraft provides a *Covered Individual Attestation,* and as further explained in the Technical Instructions, attests to the following (as applicable):

a. Being excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* for one of the reasons set forth in the Proclamation and this Amended Order;

b. having arranged to be tested with a COVID–19 viral test 3–5 days after arriving in the United States, or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation,* unless the *Excepted Covered Individual* has documentation of having recovered from COVID–19 in the past 90 days, or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation*;

c. having arranged to self-quarantine, even if the test result to the post-arrival viral test is negative, unless the *Excepted Covered Individual* has documentation of having recovered from COVID–19 in the past 90 days or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation*; and

d. having arranged to self-isolate if the result of the post-arrival viral test is positive or if they develop COVID–19 symptoms.

D. Confirm that every *Excepted Covered Individual* who does not present *Proof of Being Fully Vaccinated Against COVID–19,* provides a *Covered Individual Attestation,* as applicable and as further explained in the Technical Instructions, attesting to the following:

a. Having arranged to become fully vaccinated against COVID–19 within 60 days after arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if such person intends to stay in the United States for more than 60 days, unless the individual is excepted from this requirement.

E. Not board any *Covered Individual* without confirming the applicable documentation as set forth in A, B, C, or D of this section.

The attestation is attached to this Amended Order as Attachment A.[44]

[42] Requirement for Proof of COVID–19 Vaccination for Air Passengers, available at *https://www.cdc.gov/coronavirus/2019-ncov/travelers/proof-of-vaccination.html.*

[43] Parents or guardians of children under 2 years of age do not need to attest on behalf of these children, but they must present proof of the child's age to the airline or aircraft operator before boarding.

[44] CDC has provided a combined passenger disclosure and attestation that fulfills the requirements of CDC Orders: *Requirement for Proof of Negative COVID–19 Test Result or Recovery from COVID–19 for All Airline Passengers Arriving into the United States* and *Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*

2. Requirements for Aircraft Passengers

In addition, I order that any aircraft passenger[45] who is a *Covered Individual* under the Proclamation, prior to boarding an aircraft traveling from a foreign country to the United States, shall:

A. Present to the airline or other aircraft operator paper or digital documentation reflecting *Proof of Being Fully Vaccinated Against COVID–19* and provide a *Covered Individual Attestation*;

OR

B. If not presenting *Proof of Being Fully Vaccinated Against COVID–19,* present to the airline or aircraft operator documentation confirming that they are an *Excepted Covered Individual* under the Proclamation and this Amended Order, as applicable and as further explained by CDC in the Technical Instructions.

C. If an *Excepted Covered Individual,*[46] accurately complete and provide the airline or aircraft operator with a *Covered Individual Attestation,* as further explained by CDC in the Technical Instructions, attesting that the *Excepted Covered Individual* (as applicable):

a. Is excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* for one of the reasons set forth in the Proclamation and this Amended Order;

b. has arranged to be tested with a COVID–19 viral test 3–5 days after arriving in the United States, or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation,* unless the *Excepted Covered Individual* has documentation of having recovered from COVID–19 in the past 90 days, or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation*;

c. has arranged to self-quarantine, even if the test result to the post-arrival viral test is negative, unless the *Excepted Covered Individual* has documentation of having recovered from COVID–19 in the past 90 days, or other period as specified in the most current CDC guidance in effect at the time the *Excepted Covered Individual* completes the *Covered Individual Attestation*; and

d. has arranged to self-isolate if the result of the post-arrival viral test is positive or if they develop COVID–19 symptoms.

D. If an *Excepted Covered Individual,* provide the airline or aircraft operator with a *Covered Individual Attestation,* as applicable and as further explained by CDC in the Technical Instructions, additionally attesting that the *Excepted Covered Individual*:

(1) has arranged to become fully vaccinated against COVID–19 within 60 days after arriving in the United States, or as soon thereafter as is medically appropriate as determined by CDC, if intending to stay in the United States for more than 60 days, unless the individual is excepted from this requirement.

E. Retain a copy of the applicable documentation listed in parts A, B, C, and D of this section and produce such documentation upon request, or as required by, any U.S. government official or a cooperating state, local, territorial, or Tribal public health authority after arrival in the United States.

Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia,* 18 U.S.C. 1001.

This Amended Order shall be enforced through the relevant provisions of law, in coordination with other federal departments and agencies, including the U.S. Department of Justice, U.S. Department of Homeland Security, U.S. Department of State, and U.S. Department of Transportation.

Effective Date

This Amended Order shall enter into effect at 12:01 a.m. EDT on April 14, 2022.

ATTACHMENT A: COMBINED PASSENGER DISCLOSURE AND ATTESTATION TO THE UNITED STATES OF AMERICA

This combined passenger disclosure and attestation fulfills the requirements of U.S. Centers for Disease Control and Prevention (CDC) Amended Orders: *Requirements for Negative Pre-Departure COVID–19 Test Result or Documentation of Recovery from COVID–19 for All Airline or Other Aircraft Passengers Arriving into the United States from Any Foreign Country* and *Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic.*[47] As directed by the CDC and the Transportation Security Administration (TSA), through Security Directive 1544–21–03 and Emergency Amendment 1546–21–02, and consistent with CDC's Order implementing the Proclamation, all airline or other aircraft operators must provide the following disclosures to all passengers prior to their boarding a flight from a foreign country to the United States.

Airline and Aircraft Operator Disclosure Requirements

As required by United States federal law, all airlines or other aircraft operators must collect the passenger attestation on behalf of the U.S. Government.[48]

Required Proof of Negative COVID–19 Test Result or Recovery From COVID–19

All airlines and other aircraft operators must additionally confirm one of the following for each passenger ages 2 years or older prior to their boarding a flight to the United States from a foreign country:

1. A negative result for a *Qualifying Test*; or

2. *Documentation of Recovery* from COVID–19 in the form of a positive COVID–19 viral test on a sample taken no more than 90 days prior to departure and a letter from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel.

Required Proof of COVID–19 Vaccination for Non-U.S. Citizen, Nonimmigrant Air Passengers

As directed by the TSA, including through a security directive or emergency amendment, all airlines and other aircraft operators must additionally confirm one of the following for each noncitizen who is a nonimmigrant passenger prior to their boarding a flight to the United States from a foreign country:

[45] A parent or other authorized individual may present the required documentation on behalf of a passenger ages 2 through 17. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (*e.g.,* by reason of age, or physical or mental impairment). There are no documentation requirements for passengers under the age of 2 years of age.

[46] Parents or guardians of children under 2 years of age do not need to attest on behalf of these children, but they must present proof of the child's age to the airline or aircraft operator before boarding.

[47] These requirements (*e.g.,* proof of negative COVID–19 test result or recovery and proof of being fully vaccinated against COVID–19) do not apply to crewmembers of airlines or other aircraft operators if they are traveling for the purpose of operating the aircraft or repositioning (*i.e.,* on ''deadhead'' status), provided their assignment is under an air carrier's or operator's occupational health and safety program that follows applicable industry standard protocols for the prevention of COVID–19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).

[48] Section 1 and Section 2 of this attestation do not need to be completed by or on behalf of children under 2 years of age. The airline or other aircraft operator may permit them to board an aircraft without an attestation.

1. Proof of being *Fully Vaccinated Against COVID–19*; or
2. Proof of being excepted from the requirement to be *Fully Vaccinated Against COVID–19*.

OMB Control No.: 0920–1318

Expiration Date: 05/31/2022

PASSENGER DISCLOSURE AND ATTESTATION TO THE UNITED STATES OF AMERICA

The information provided below must be accurate and complete to the best of the individual's knowledge. Under United States federal law, the applicable portion of the attestation must be completed for each passenger ages 2 years or older and the attestation must be provided to the airline or aircraft operator prior to boarding a flight to the United States from a foreign country. Failure to complete and present the applicable portion of the attestation, or submitting false or misleading information, could result in delay of travel, denial of boarding, or denial of boarding on future travel, or put the passenger or other individuals at risk of harm, including serious bodily injury or death. Any passenger who fails to comply with these requirements may be subject to criminal penalties. Willfully providing false or misleading information may lead to criminal fines and imprisonment under, among other provisions, 18 U.S.C. 1001. Providing this information can help protect you, your friends and family, your communities, and the United States. CDC appreciates your cooperation.

One attestation form must be filled out for each passenger ages 2 years or older. The attestation may be filled out by the air passenger or on behalf of the air passenger by a legal representative, such as a parent or guardian.

—*Section 1:* All air passengers ages 2 years or older flying to the United States must complete Section 1.
—*Section 2:* Any passenger age 2 years or older who is not a U.S. citizen, U.S. national, lawful permanent resident, or an immigrant (''*Covered Individual*'') who is seeking to enter the United States by air travel must also complete Section 2 of this attestation and comply with applicable after travel requirements in Section 2.[49]

I, _____ am attesting on (Select one):

PRINT FIRST AND LAST NAME

☐ My own behalf ☐ Behalf of:

_____

PRINT FIRST AND LAST NAME

SECTION 1: Requirement for Proof of Negative COVID–19 Test Result or Recovery From COVID–19 *(check one box)*

A. NEGATIVE PRE-DEPARTURE TEST RESULT

☐ I attest that I have (or the person I am attesting on behalf of has) received a negative pre-departure test result for COVID–19. The test was a viral test that was conducted on a specimen collected no more than 1 calendar day before the flight's departure.

B. DOCUMENTATION OF RECOVERY FROM COVID–19

☐ I attest that I have (or the person I am attesting on behalf of has) tested positive for COVID–19 and been cleared for travel by a licensed healthcare provider or public health official. The test was a viral test that was conducted on a specimen collected no more than 90 days before the flight's departure.

C. HUMANITARIAN EXEMPTION

☐ I attest that I have (or the person I am attesting on behalf of has) received a humanitarian exemption to the testing requirement, as determined by CDC and documented by an official U.S. Government letter.

SECTION 2: Requirement for Proof of COVID–19 Vaccination for *Covered Individuals* (Not a U.S. Citizen, U.S. National, Lawful Permanent Resident, or an Immigrant)

A. FULLY VACCINATED (If you check box A, skip to signature page and sign the form to complete Attestation.)

☐ I attest that I am (or the person I am attesting on behalf of is) fully vaccinated against COVID–19.

B. NOT FULLY VACCINATED

☐ I am not fully vaccinated and attest that I am (or the person I am attesting on behalf of is) excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* based on one of the following (*check only one box, as applicable*):

☐ Diplomatic and Official Foreign Government Travel *(complete C only, then sign the form to complete Attestation).*
☐ Child ages 2 through 17 years *(complete D only, then sign the form to complete Attestation).*
☐ Participant in certain COVID–19 vaccine trials, as determined by CDC *(complete D only, then sign the form to complete Attestation).*
☐ Medical contraindication to an accepted COVID–19 vaccine, as determined by CDC *(complete E only, then sign the form to complete Attestation).*
☐ Humanitarian or emergency exception, as determined by CDC and documented by an official U.S. Government letter (*complete F only, then sign the form to complete Attestation).*
☐ Valid nonimmigrant visa holder (excluding B–1 or B–2 visas) and citizen of a *Foreign Country with Limited COVID–19 Vaccine Availability,* as determined by CDC (*complete F only, then sign the form to complete Attestation).*
☐ Member of the U.S. Armed Forces or spouse or child (ages 2 through 17 years) of a member of the U.S. Armed Forces (*proceed to signature line only, then sign the form to complete Attestation*).
☐ Sea crewmember traveling pursuant to a C–1 and D nonimmigrant visa (*complete F only, then sign the form to complete Attestation*).
☐ Person whose entry is in the U.S. national interest as determined by the Secretary of State, the Secretary of Transportation, the Secretary of Homeland Security, or their designees *(complete G only, then sign the form to complete*

[49] Any passenger who is not a U.S. citizen, U.S. national, lawful permanent resident, or an immigrant is referred to as a *Covered Individual* because they are covered by the Presidential Proclamation and CDC's Amended Order: Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID–19 Pandemic. This term does not apply to crewmembers of airlines or other aircraft operators if such crewmembers and operators adhere to all industry standard protocols for the prevention of COVID–19, as set forth in relevant guidance for crewmember health issued by the CDC or by the FAA in coordination with the CDC.

Public reporting burden of this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be submitted to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D–74, Atlanta, Georgia 30333; ATTN: PRA 0920–1318.

Attestation).

C. EXCEPTION: Diplomat and Official Foreign Government Travel

☐ I attest that I am (or the person I am attesting on behalf of is) excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* and made the following arrangements (*must check all boxes in C and then sign Attestation*).

☐ To be tested with a COVID–19 viral test 3–5 days after arriving in the United States, unless I have (or this person has) documentation of having recovered from COVID–19 in the past 90 days;

☐ To self-quarantine for a full 5 calendar days following arrival, even if the result of my (or this person's) post-arrival viral test is negative, except during periods when my (or this person's) attendance is required to carry out the purposes of the diplomatic or official foreign government travel (*e.g.,* to attend official meetings or events), unless I have (or this person has) documentation of having recovered from COVID–19 in the past 90 days; and

☐ To self-isolate for a full 5 calendar days and properly wear a well-fitting mask any time I am (or this person is) around others during my (or this person's) isolation period and for an additional 5 days after ending isolation,

- if the result of the post-arrival viral test is positive; or
- if I develop (or this person develops) COVID–19 symptoms.

D. EXCEPTIONS

- *Child ages 2 through 17 years*
- *Participant in certain COVID–19 vaccine trials as determined by CDC*

☐ I attest that I am (or the person I am attesting on behalf of is) excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* and made the following arrangements (*must check all boxes in D and then sign Attestation*).

☐ To be tested with a COVID–19 viral test 3–5 days after arriving in the United States, unless I have (or the person has) documentation of having recovered from COVID–19 in the past 90 days;

☐ To self-isolate for a full 5 calendar days and properly wear a well-fitting mask any time I am (or this person is) around others during my (or this person's) isolation period and for an additional 5 days after ending isolation,

- if the result of the post-arrival viral test is positive, or
- if I develop (or this person develops) COVID–19 symptoms.

E. EXCEPTION: Medical Contraindication to an Accepted COVID–19 Vaccine as Determined by CDC

☐ I attest that I am (or the person I am attesting on behalf of is) excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* and made the following arrangements (*must check all boxes in E and then sign Attestation).*

☐ To be tested with a COVID–19 viral test 3–5 days after arriving in the United States, unless I have (or this person has) documentation of having recovered from COVID–19 in the past 90 days;

☐ To self-quarantine for a full 5 calendar days, even if the result of my (or this person's) post-arrival viral test is negative, unless I have (or this person has) documentation of having recovered from COVID–19 in the past 90 days; and

☐ To self-isolate for a full 5 calendar days and properly wear a well-fitting mask any time I am (or this person is) around others during my (or this person's) isolation period and for an additional 5 days after ending isolation,

- if the result of the post-arrival viral test is positive, or
- if I develop (or this person develops) COVID–19 symptoms.

F. EXCEPTIONS

- *Humanitarian or emergency exception as determined by CDC*;
- *Valid nonimmigrant visa holder (excluding B–1 or B–2 visas) and citizen of a Foreign Country with Limited COVID–19 Vaccine Availability as determined by CDC*; or
- *Sea crewmember traveling pursuant to a C–1 and D nonimmigrant visa*

☐ I attest that I am (or the person I am attesting on behalf of is) excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* and made the following arrangements (*must check all boxes in F and then sign Attestation*).

☐ To be tested with a COVID–19 viral test 3–5 days after arriving in the United States, unless I have (or this person has) documentation of having recovered from COVID–19 in the past 90 days;

☐ To self-quarantine for a full 5 calendar days, even if the result of my (or this person's) post-arrival viral test is negative, unless I have (or this person has) documentation of having recovered from COVID–19 in the past 90 days;

☐ To self-isolate for a full 5 calendar days and properly wear a well-fitting mask any time I am (or this person is) around others during my (or this person's) isolation period and for an additional 5 days after ending isolation,

- if the result of the post-arrival viral test is positive; or
- if I develop (or this person develops) COVID–19 symptoms; and

☐ To become fully vaccinated against COVID–19 within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate, if intending to stay in the United States for more than 60 days.

G. EXCEPTION: Person Whose Entry Is in the U.S. National Interest

☐ I am (or the person I am attesting on behalf of is) excepted from the requirement to present *Proof of Being Fully Vaccinated Against COVID–19* and made the following arrangements (*must check all boxes in G and then proceed to sign Attestation*).

☐ To be tested with a COVID–19 viral test 3–5 days after arriving in the United States, unless I have (or this person has) documentation of having recovered from COVID–19 in the past 90 days;

☐ To self-quarantine for a full 5 calendar days, even if the result of my (or this person's) post-arrival viral test is negative, except during periods when my (or this person's) attendance is required to carry out the purposes of the travel for the U.S. national interest (*e.g.,* to attend official meetings or events), unless I have (or this person has) documentation of having recovered from COVID–19 in the past 90 days.

☐ To self-isolate for a full 5 calendar days and properly wear a well-fitting mask any time I am (or this person is) around others during my (or this person's) isolation period and for an additional 5 days after ending isolation

- if the result of the post-arrival viral test is positive, or
- if I develop (or this person develops) COVID–19 symptoms; and

☐ To become fully vaccinated against COVID–19 within 60 days of arriving in the United States, or as soon thereafter as is medically appropriate, if intending to stay in

the United States for more than 60 days.

_____Print Name
_____Signature
_____Date

Privacy Act Statement for Travelers Relating to the Requirement To Provide Proof of a Negative COVID–19 Test Result

The U.S. Centers for Disease Control and Prevention (CDC) requires airlines and other aircraft operators to collect this information pursuant to 42 CFR 71.20 and 71.31(b), as authorized by 42 U.S.C. 264. Providing this information is mandatory for all passengers arriving by aircraft into the United States. Failure to provide this information may prevent you from boarding the plane. Additionally, passengers will be required to attest to providing complete and accurate information, and failure to do so may lead to other consequences, including criminal penalties. CDC will use this information to help prevent the introduction, transmission, and spread of communicable diseases by performing contact tracing investigations and notifying exposed individuals and public health authorities; and for health education, treatment, prophylaxis, or other appropriate public health interventions, including the implementation of travel restrictions.

The Privacy Act of 1974, 5 U.S.C. 552a, governs the collection and use of this information. The information maintained by CDC will be covered by CDC's System of Records No. 09–20–0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR parts 70 and 71. See 72 FR 70867 (Dec. 13, 2007), as amended by 76 FR 4485 (Jan. 25, 2011) and 83 FR 6591 (Feb. 14, 2018). CDC will only disclose information from the system outside the CDC and the U.S. Department of Health and Human Services as the Privacy Act permits, including in accordance with the routine uses published for this system in the **Federal Register**, and as authorized by law. Such lawful purposes may include, but are not limited to, sharing identifiable information with state and local public health departments, and other cooperating authorities. CDC and cooperating authorities will retain, use, delete, or otherwise destroy the designated information in accordance with federal law and the System of Records Notice (SORN) set forth above. You may contact the system manager at *dgmqpolicyoffice@cdc.gov* or by mailing Policy Office, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329, if you have questions about CDC's use of your data.

Authority

The authority for the Presidential Proclamation is Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code. CDC's Order is issued pursuant to the Presidential Proclamation.

Sherri Berger,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2022–07450 Filed 4–4–22; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–224–14 and CMS–10305]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 6, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–224–14 Federally Qualified Health Center Cost Report Form

CMS–10305 Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j))

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this

requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Federally Qualified Health Center Cost Report Form; *Use:* The Form CMS–224–14 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and to calculate the FQHC settlement amount. These providers, paid under the FQHC prospective payment system (PPS), may receive reimbursement outside of the PPS for Medicare reimbursable bad debts, pneumococcal, influenza, and COVID–19 vaccines, and monoclonal antibody products. CMS uses the Form CMS–224–14 for rate setting; payment refinement activities, including developing a FQHC market basket; Medicare Trust Fund projections; and to support program operations. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the FQHC Medicare cost report data to calculate Medicare margins; to formulate recommendations to Congress regarding the FQHC PPS; and to conduct additional analysis of the FQHC PPS. *Form Number:* CMS–224–14 (OMB control number: 0938–1298); *Frequency:* Yearly; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 2,890; *Total Annual Responses:* 2,890; *Total Annual Hours:* 167,620. (For policy questions regarding this collection contact LuAnn Piccione at 410–786–5423.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j)); *Use:* Sections 1857(e) and 1860D–12 of the Social Security Act (''the Act'') authorize CMS to establish information collection requirements with respect to MAOs and Part D sponsors. Section 1857(e)(1) of the Act requires MAOs to provide the Secretary of the Department of Health and Human Services (DHHS) with such information as the Secretary may find necessary and appropriate. Section 1857(e)(1) of the Act applies to Prescription Drug Plans (PDPs) as indicated in section1860D–12. Pursuant to statutory authority, CMS codified these information collection requirements in regulation at §§ 422.516(g) Validation of Part C Reporting Requirements, and 423.514(j) Validation of Part D Reporting Requirements respectively.

Data collected via Medicare Part C and Part D reporting requirements are an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of Medicare benefits to beneficiaries. CMS uses the findings collected through the data validation process to substantiate the data reported via Medicare Part C and Part D reporting requirements. Data validation provides CMS with assurance that plan-reported data are credible and consistently collected and reported by Part C and D SOs. CMS uses validated data to respond to inquiries from Congress, oversight agencies, and the public about Part C and D SOs. The validated data also allows CMS to effectively monitor and compare the performance of SOs over time. Validated plan-reported data may be used for Star Ratings, Display measures and other performance measures. Additionally, SOs can take advantage of the DV process to effectively assess their own performance and make improvements to their internal operations and reporting processes. *Form Number:* CMS–10305 (OMB control number: 0938–1115); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 793; *Total Annual Responses:* 793; *Total Annual Hours:* 21,535. (For policy questions regarding this collection contact Chanelle Jones at 410–786–8008.)

Dated: April 4, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–07426 Filed 4–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; ORR–1, Cash and Medical Assistance Program Estimates

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is requesting a 3-year extension of the form ORR–1, Cash and Medical Assistance Program Estimates (OMB #0970–0030, expiration 5/21/2022). There are no changes requested to the form or instructions.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ORR–1, Cash and Medical Assistance Program Estimates, is the application for grants under the Cash and Medical Assistance (CMA) program. The application is required by ORR program regulations at 45 CFR 400.11(b). The regulation specifies that states must submit, as their application for this program, estimates of the projected costs they anticipate incurring in providing cash and medical assistance for eligible recipients and the costs of administering the program. Under the CMA program, states are reimbursed for the costs of providing these services and benefits for 8 months after an eligible recipient arrives in this country. The eligible recipients for these services and benefits are refugees, Amerasians, Cuban and Haitian Entrants, asylees, Afghans and Iraqi with Special Immigrant Visas, and victims of a severe form of trafficking. States that provide services for unaccompanied refugee minors also provide an estimate for the cost of these services for the year for which they are applying for grants.

Respondents: State Agencies, the District of Columbia, and Replacement Designees under 45 CFR 400.301(c) administering or supervising the administration of programs under Title IV of the Act.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ORR–1, Cash and Medical Assistance Program Estimates	57	1	0.6	34

Estimated Total Annual Burden Hours: 34.

Authority: 8 U.S.C. 412(a)(4).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–07369 Filed 4–6–22; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1302]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. The general function of the subcommittee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on May 11, 2022, from 10 a.m. to 3:30 p.m. and May 12, 2022, from 10 a.m. to 3:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–1302. The docket will close on May 10, 2022. Submit either electronic or written comments on this public meeting by May 10, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 10, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 10, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before April 27, 2022, will be provided to the subcommittee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–1302 for ''Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.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: Joyce Yu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–837–7126, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On May 11, 2022, the subcommittee will discuss the development of a conceptual framework that will inform the decision making of FDA on sponsor plans and requests for waivers of early pediatric investigations of molecularly targeted cancer drugs and biologics when multiple same-in-class products are approved and/or in development, recognizing that the rarity of pediatric cancers may preclude the feasibility of investigations of multiple products. Investigation of more than one product may be appropriate when specific product characteristics predict an improved benefit-risk assessment that warrants clinical investigation.

On May 12, 2022, the subcommittee will consider and discuss the potential utility and steps to validation of an intermediate clinical endpoint, response to induction therapy, in the development of new drugs for the first-line treatment of patients with high-risk neuroblastoma. The European Medicines Agency has also been invited to present on both days.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before April 27, 2022, will be provided to the subcommittee. Oral presentations from the public will be scheduled between approximately 1:45 p.m. to 2:15 p.m. Eastern Time on May 11, 2022. Oral presentations from the public will also be scheduled between approximately 2 p.m. to 2:30 p.m. Eastern Time on May 12, 2022. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 19, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 20, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Joyce Yu (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07378 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–P–1097 and FDA–2021–P–1111]

Determination That PEPCID (Famotidine) for Oral Suspension, 40 Milligrams/5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that PEPCID (famotidine) for oral suspension, 40 milligrams (mg)/5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for PEPCID (famotidine) for oral suspension, 40 mg/5 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions

of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PEPCID (famotidine) for oral suspension, 40 mg/5 mL, is the subject of NDA 019527, held by Bausch Health US, LLC, and initially approved on February 2, 1987. PEPCID is indicated in adults for the treatment of active duodenal ulcer (DU); active gastric ulcer; symptomatic nonerosive gastroesophageal reflux disease (GERD); erosive esophagitis due to GERD, diagnosed by biopsy; treatment of pathological hypersecretory conditions (*e.g.,* Zollinger-Ellison syndrome, multiple endocrine neoplasias); and reduction of the risk of DU recurrence. PEPCID is indicated in pediatric patients 1 year of age and older for the treatment of peptic ulcer, and GERD with or without esophagitis and ulcerations. PEPCID is indicated in pediatric patients from birth to less than 1 year of age for the treatment of GERD.

In a letter received on January 11, 2019, the applicant notified FDA that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Ajanta Pharma USA Inc., submitted a citizen petition dated October 11, 2021 (Docket No. FDA–2021–P–1097), and Lachman Consultant Services, Inc., submitted a citizen petition dated October 13, 2021 (Docket No. FDA–2021–P–1111), both under 21 CFR 10.30, requesting that the Agency determine whether PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PEPCID (famotidine) for oral suspension, 40 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PEPCID (famotidine) for oral suspension, 40 mg/5 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PEPCID (famotidine) for oral suspension, 40 mg/5 mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07391 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0242]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on collection of information under FDA's current good manufacturing practice (CGMP) regulations for positron emission tomography (PET) drugs. PET is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug product.

DATES: Submit either electronic or written comments on the collection of information by June 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include Docket No. FDA–2013–N–0242 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m. Eastern Time, 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Current Good Manufacturing Practices for Positron Emission Tomography Drugs—21 CFR Part 212

OMB Control Number 0910–0667—Revision

FDA CGMP regulations in part 212 (21 CFR part 212) are intended to ensure that PET drug products meet the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding safety, identity, strength, quality, and purity and are issued under the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115). These CGMP requirements are designed according to the unique characteristics of PET drugs, including their short half-lives and because most PET drugs are produced at locations close to the patients to whom the drugs are administered.

I. Investigational and Research PET Drugs

Section 212.5(b) (21 CFR 212.5(b)) provides that for investigational PET drugs produced under an investigational new drug application (IND) and research PET drugs produced with approval of a Radioactive Drug Research Committee (RDRC), PET producers must meet the requirement (FD&C Act) to follow CGMP by complying with the regulations under part 212 or complying with United States Pharmacopeia (USP) 32 Chapter 823. We believe that PET production facilities producing drugs under INDs and RDRCs are already substantially complying with the recordkeeping requirements of USP 32 Chapter 823 (see section 121(b) of FDAMA). Some IND and RDRC PET facilities also produce PET drugs approved under abbreviated new drug applications (ANDAs) or new drug applications (NDAs), and our estimates include these facilities. The facilities described above are included under academia or small firms. The corporate sites that also produce IND PET drugs are included in the estimated 91 individual corporate sites.

To estimate the amount of time that respondents have spent complying with

CGMP requirements, we relied on the following:

- Informal communications with PET producers.
- FDA staff visits to PET production facilities.
- Our experience with PET drug applications, including amendment and supplement submissions.
- Our general knowledge of pharmaceutical manufacturing practices.
- Various CGMP compliance reports FDA received from 2019 to 2021.

II. Recordkeeping Burden

A. One-Time Recordkeeping Burden for Corporate Firms

We estimate that corporate firms will have to employ one-time and annual recordkeeping. We estimate that, for some major PET manufacturing corporations, most of the quality, manufacturing, and testing procedures are developed at the corporate level and issued to the individual production and testing sites located in various States across the country. It is estimated that a total of 91 of these individual corporate sites are controlled among 4 major corporations. Thus, we have calculated the burden for 4 recordkeeping activities as a one-time effort for creating standard operating procedures (SOPs) and master batch records (MBRs) instead of 91 recordkeeping activities for individual corporate sites.

Each corporate firm is estimated to expend approximately 8 hours to create 1 MBR per PET drug. We estimate that 4 corporate firms will each create and maintain 10 MBRs associated with production and quality control (QC) testing procedures (a total of 40 records), which results in a total recordkeeping burden of approximately 320 hours.

Sections 212.20(c), 212.30(b), 212.50(d), and 212.60(f) (21 CFR 212.20(c), 212.30(b), 212.50(d), and 212.60(f) contain written SOP provisions for equipment operation, maintenance, and cleaning, including maintenance of physical facilities. We estimate that 4 corporate firms will expend approximately 5 hours each to establish and maintain 13 procedures for equipment and facility maintenance (a total of 52 procedures), which results in a total recordkeeping burden of approximately 260 hours.

Sections 212.20(b) and 212.40(a) and (b) contain requirements on SOPs regarding receiving, testing, and accepting components. We estimate that 4 corporate firms will expend approximately 8 hours each to create 1 procedure for acceptance of raw materials and components (a total of 4 procedures), which results in a total recordkeeping burden of approximately 32 hours.

We estimate that approximately 4 corporate firms will expend 2 hours each to create 25 specification data sheets for components (a total of 100 specification data sheets), which results in a total recordkeeping burden of approximately 200 hours.

Section 212.71(a) and (b) requires that PET drug firms establish procedures for rejecting PET drug batches that do not conform to established specifications and requires that PET drug firms establish procedures for investigating deviations and out-of-specifications (OOS) failures of products during manufacturing and testing. Section 212.50(a) also requires that firms establish written production and process control procedures to ensure and document that all key process parameters are controlled and that any deviations from the procedures are justified. We estimate that 4 corporate firms will expend approximately 8 hours each to establish 1 procedure (a total of 4 procedures), which results in a total recordkeeping burden of approximately 32 hours.

Section 212.90(a) requires the establishment and maintenance of written procedures for the distribution of PET drug products. We estimate that 4 corporate firms will each expend approximately 8 hours to establish and maintain 1 written procedure regarding the distribution of PET drugs (a total of 4 records), which results in a total recordkeeping burden of approximately 32 hours.

Sections 212.20(e) and 212.100(a), (b), and (c) require that PET drug firms establish and maintain written procedures for handling complaints and establish and maintain procedures for field alert reports (FARs). We estimate that 4 corporate firms will each establish 3 written procedures (a total of 12 procedures) and that each corporate firm will expend approximately 8 hours for each procedure. Establishing and maintaining written procedures results in a total recordkeeping burden of approximately 96 hours.

B. One-Time Recordkeeping Burden for Academia, Small Firms, and High-Risk Component Manufacturers

A total of 63 combined sites represent academia and small commercial firms, including some IND and RDRC sites manufacturing ANDA-approved and NDA-approved PET drugs, and high-risk component manufacturers. Of the 63 combined sites (herein and the other sections of this document referred to as ''entities''), 14 producers of starting materials, precursors, generators, and sterile component material manufacturing for kits are also required to comply with selected regulations in part 212, according to the *PET drug* definition in section 121(a) of FDAMA and codified in section 201(ii)(1)(A) of the FD&C Act (21 U.S.C. 321(ii)(1)(A)). We refer to such producers as high-risk component manufacturers in tables 2 and 5.

The 63 entities will expend approximately 8 hours each to create MBRs and manufacturing and quality procedures. We estimate that the entities will each maintain 8 records (a total of approximately 504 records), which results in a total recordkeeping burden of 4,032 hours.

Each of the entities will expend approximately 8 hours to create equipment-related and facility-related procedures (consistent with corporate firms discussed in section II.A above). A total of 63 entities will each maintain an estimated 12 records (a total of 756 records), which results in a total recordkeeping burden of approximately 6,048 hours.

The estimated burden for the 63 entities to each create and maintain 12 procedures for acceptance of raw materials and components (a total of 126 procedures) is approximately 8 hours per procedure. The creation and maintenance of these procedures results in a total recordkeeping burden of approximately 1,008 hours.

We estimate that the 63 entities will each expend approximately 30 minutes to create and maintain 21 specification data sheets (a total of 1,323). The creation and maintenance of specification data sheets results in a total recordkeeping burden of approximately 662 hours.

We estimate that approximately 63 entities will each create 1 procedure relating to deviations and OOS investigations and 1 procedure relating to the distribution of finished products (2 procedures for a total of 126). Each of these entities will expend 8 hours per procedure, which results in a total recordkeeping burden of 1,008 hours—504 hours for each procedure.

We estimate that each of the 63 entities will create approximately 3 procedures relating to customer complaints, returned products, and FAR (a total of 189 records). Each of these entities will expend 8 hours per record, which results in a total recordkeeping burden of 1,512 hours.

C. Annual Recordkeeping Burden for Corporate Firms

As discussed in section II.A, we estimate that there are a total of 91 individual corporate sites controlled under 4 major corporations. The information collection discussed in this section relates to individual PET drugs manufactured at each of the sites located across the country.

We estimate that the 91 corporate sites will each expend approximately 30 minutes to fill 240 batches (approximately 20 batches each month and a total of 21,840 batches for all 91 sites), which results in a total recordkeeping burden of 10,920 hours. We further estimate that, annually, corporate firms may have to create some new batch records or quality records for newly introduced or existing drugs.

We estimate that the 4 major corporations will each expend approximately 8 hours to create 9 new quality procedure and MBRs (a total of 36 records), which results in a total recordkeeping burden of 288 hours.

We estimate that approximately 91 individual corporate sites will each expend approximately 15 minutes to create 480 records for equipment maintenance, cleaning, calibration, and facilities maintenance (a total of 43,680 records), which results in a total recordkeeping burden of 10,920 hours.

Sections 212.20(b) and (c) and 212.40(a) and (b) set forth requirements for acceptance of raw materials and component shipments received at the centrally controlled, corporate quality assurance (QA) facilities annually. We estimate that the 4 corporate QA sites, internally located within corporate administrative sites, will create 48 records for incoming raw material acceptance (a total of 192 records) for approximately 4 bulk shipments per month (12×4) on behalf of the individual corporate sites. Corporate QA sites will expend approximately 2 hours to create records, which results in a total recordkeeping burden of 384 hours.

Sections 212.60(g), 212.61(b), and 212.70(d)(2) and (d)(3) set forth requirements for documenting laboratory testing results obtained from each PET drug manufactured and referred to in laboratory testing, including final release testing. Each of the 91 individual corporate firms must maintain records of different tests for each of their products. We estimate that approximately 91 individual corporate sites will each expend 30 minutes to document 240 records of cumulative QC test results (1 record that includes 5 to 6 tests and a total of 21,840 records), which results in a total recordkeeping burden of approximately 10,920 hours.

We estimate approximately 2 hours for each of the 91 individual corporate sites to record OOS events and perform investigations for each incident. We also estimate that the individual corporate sites will each conduct an average of 2 OOS investigations per site (a total of 182 records for OOS investigations), which results in a total recordkeeping burden of 364 hours. This estimate includes reprocessing or conditional release events, which are very rare.

Section 212.100(b) and (c) requires that PET drug firms document how they handle each complaint that they receive. We estimate that each of the 4 corporate QA sites will expend approximately 2 hours to document and investigate 1 complaint. Because complaints are usually investigated at the corporate firm level, we estimate that each corporate QA site will receive and handle 5 complaints annually (a total of 20 complaints for documentation), which results in a total recordkeeping burden of 40 hours.

Our estimate for PET drug firms-performing QA and release of manufactured PET drugs from the 91 individual corporate sites is approximately 5,460 hours from 21,840 released batches (15 minutes per batch for each of the 240 released batches).

Section 212.90(b) requires that corporate firms maintain distribution records. We estimate that each of the 91 corporate firms will expend approximately 5,460 hours to release 21,840 batches (15 minutes per batch for each of the 240 released batches).

D. Annual Recordkeeping Burden for Academia and Small Firms

We assume that each academia and small firm will expend the same amount of time to perform the same information collection activities as corporate firms (discussed in section II.A above).

Approximately 49 academia and small firms will each expend approximately 30 minutes to fill 96 batch and production records (a total of 4,704 records), which results in a total recordkeeping burden of 2,352 hours.

For the 49 academia and small firms to create new MBRs or quality records, we estimate they will expend 8 hours per record (147 total records (3 per site)), which results in a total recordkeeping burden of 1,176 hours.

We estimate that approximately 49 academia and small firms will maintain 23,520 calibration and cleaning records (480 records per site), such as logbooks for each piece of equipment and documentation of calibration records in each PET production firm. The calibration efforts for academia and small firms is twice per year per equipment (10 pieces of equipment per site). In addition, we estimate that academic and small firms will each expend 30 minutes to maintain records, which results in a total recordkeeping burden of 11,760 hours.

Under §§ 212.20(b) and (c) and 212.40(a) and (b), academia and firms will maintain a total of approximately 588 raw material and component acceptance records (12 shipments per year). We estimate that they will expend 30 minutes to create records, which results in a total recordkeeping burden of 294 hours.

We estimate that approximately 49 academia and small firms will each expend 30 minutes to document a total of 4,704 laboratory QC test records (96 records per site), which results in a total recordkeeping burden of approximately 2,352 hours.

We estimate that approximately 49 academic and small firms will each maintain records of OOS and customer-complaint events and perform investigations and that they will expend approximately 2 hours annually for these activities. We also estimate an average of 2 OOS events and 2 customer complaints and investigations per firm, with a total of 392 hours for each category (196 for each site). This estimate includes any reprocessing or special batch release events, which have been rarely observed.

We estimate that approximately 49 academia and small firms will each perform QA and release of manufactured PET drugs and that they will expend 15 minutes per batch (96 batches per site), which results in a total recordkeeping burden of 1,176 hours for 4,704 batches.

Section 212.90(b) requires that academia and small firms maintain distribution records. We estimate that it will take approximately 15 minutes per batch (96 batches per site) to create a distribution record for each batch of PET drug product, with a total recordkeeping burden of approximately 1,176 hours for 4,704 batches per site.

E. Annual Recordkeeping Burden for High-Risk Component Manufacturers (Producers of Starting Materials, Precursors, Generators, and Sterile Raw Materials)

According to section 121(a) of FDAMA, the *PET drug* definition includes any non-radioactive or radioactive reagents, kits, nuclidic generators, target materials, synthesizers, or other apparatus or computer program to be used in preparation of PET drug. FDA performs

risk assessments of each manufacturer and inspects such manufacturers. Producers of sterile kit components, precursors, and generators are included in this category, including producers of sterile raw materials. We have estimated that 14 such facilities be included in this category based on inspections and have included them in this section. These manufacturers must comply with selected sections of part 212 since they are not producing the final PET drug products to be administered to patients. As stated in section II.B, we refer to such producers as high-risk component manufacturers in tables 2 and 5.

We estimate that approximately 14 high-risk component manufacturers will expend 30 minutes to complete each manufacturing batch record (24 batches per site) and that there will be a total of 336 records, which results in a total recordkeeping burden of approximately 168 hours.

We also estimate that the 14 high-risk component manufacturers will each expend approximately 30 minutes to create and file equipment calibration and cleaning and facility maintenance-related records (130 records each and a total of 1,820), which results in a total recordkeeping burden of 910 hours.

We estimate that the 14 such manufacturers will each expend 30 minutes to document 24 records for components, containers, and closures for incoming acceptance tests (a total of 336 batches), which results in a total recordkeeping burden of approximately 168 hours from all sites.

We estimate that the 14 such manufacturers will expend 30 minutes to document 24 laboratory testing records for 336 batches, which results in a total burden of approximately 168 hours. These manufacturers will also document OOS investigations for any laboratory test failures (1 record for each site), which results in a total recordkeeping burden of 14 hours.

We also estimate that such manufacturers will perform QA and release manufactured PET drugs for a total of 336 batches (24 each) released annually. In addition, we estimate that such manufacturers will expend approximately 15 minutes per batch, which results in a total recordkeeping burden of 84 hours.

We estimate that such manufacturers will each expend approximately 15 minutes to create and maintain distribution records that will result in 336 records (24 each). The total recordkeeping burden hours will result in 84 hours.

F. One-Time and Annual Recordkeeping for External Control Testing Laboratories

We have included a new category of facilities—external control testing laboratories—in this information collection. These testing laboratories perform chemical, microbiological, or sterility testing functions to support manufacturing and release of final PET drug products. Assignment and inspection of control testing laboratories may be determined through risk-based assessments. We have estimated that 23 such facilities be included in this category, based on inspections and NDA and ANDA applications that FDA has received. These testing laboratories must comply with selected sections of part 212 (and compliance with 21 CFR part 211 is acceptable) since they are not producing the final PET drugs to be administered to patients. In this section, we refer to these testing laboratories as external testing facilities in general; however, in table 6, we refer to them as external control testing laboratories.

We estimate that approximately 23 external testing facilities will each expend 9 hours to complete testing SOP and validation of test methods and assays (6 records each and a total of 138), which results in a total recordkeeping burden of approximately 1,242 hours.

We estimate that 23 external testing facilities will expend approximately 30 minutes each to perform incoming acceptance test for testing materials and to create test result records, which results in a total recordkeeping burden of 368 hours. For incoming acceptance tests, sites will expend 276 hours (24 records for a total of 552), and for testing records, sites will expend 92 hours (8 records for a total of 184).

We estimate that 23 external testing facilities will each document 2,254 equipment cleaning and calibration records, 184 QA release records, and 23 OOS investigation records, which results in a total recordkeeping burden of approximately 564, 23, and 46 hours, respectively (see table 6).

III. Process Verification

Section 212.50(f)(2) requires the recordkeeping of any process verification activities and results. PET drug producers usually perform process verification as a one-time activity before a product is approved or if any major manufacturing process or equipment changes are made. We have estimated that PET drug producers will conduct process verification under one-time batch creation for existing products; annual new creation of MBRs; and manufacturing and quality procedures for ongoing activities, including media fills (see tables 1 and 2).

IV. Conditional Final Releases

Section 212.70(f) requires that PET drug producers document any conditional final releases of a product. We believe that conditional final releases will be uncommon, and we have included them in the burden estimates under annual OOS investigations and final QA release efforts for each manufactured batch in tables 3 and 4.

V. Reprocessing Procedures

Sections 212.20(c) and 212.71(d) require that PET drug producers establish and document procedures for reprocessing PET drugs. We have rarely received reprocessing options for application of such drugs and, if reprocessing occurs, we have included such rare events in the burden estimates under annual QA release efforts in tables 3 and 4.

VI. Third-Party Disclosure Burden for Sterility Test Failure Notices

Section 212.70(e) requires that PET drug producers notify all receiving facilities if a batch fails sterility tests. FDA receives FARs based on confirmed sterility failures of released PET drugs. Based on the last 3 years' sterility failure reports, we estimate that all 140 sites (91 individual corporate sites and 49 academia and small firms) will send notifications to the affected clinical or receiving facilities of approximately 7 failures. Therefore, we estimate that 7 PET drug producers will submit 2 reports to FDA and send 1 notification (a total of 3 reports) to FDA and the affected clinical or receiving site per year. PET drug producers would submit the notice to the receiving site by email or Fax and submit the FAR notice to FDA electronically and would expend 2.5 hours per incident, which results in a total burden of 53 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME RECORDKEEPING BURDEN FOR CORPORATE FIRMS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Master Batch Production and Quality Control Procedures (§§ 212.20(c) and (e) and 212.50(a) and (b))	4	10	40	8	320
Subparts C, D, F, and G; §§ 212.20 to 212.60					
Equipment and Facilities Records (SOP) (§§ 212.20(c), 212.30(b), 212.50(d), and 212.60(f))	4	13	52	5	260
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures (SOP) (§§ 212.20(b) and 212.40(a) and (b))	4	1	4	8	32
Records of Components, Containers, and Closures (specification data sheets) (§§ 212.20(b) and (c) and 212.40(a) and (b))	4	25	100	2	200
Subpart H; § 212.71					
. OOS Investigations (SOP) (§ 212.71(a) and (b))	4	1	4	8	32
Subpart J; § 212.90					
Distribution Records (SOP) (§ 212.90(a))	4	1	4	8	32
Subparts C and K; §§ 212.20 to 212.100					
Complaints and Returned Product (§§ 212.20(e) and 212.100(a), (b), and (c))	4	3	12	8	96
Total			216		972

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN FOR ACADEMIA, SMALL FIRMS, AND HIGH-RISK COMPONENT MANUFACTURERS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Batch Production and Control Records (§§ 212.20(c) and 212.50(a) and (b))	63	8	504	8	4,032
Subparts C, D, F, and G; §§ 212.20 to 212.60					
Equipment and Facilities Records (SOP) (§§ 212.20(c), 212.30(b), 212.50(d), and 212.60(f))	63	12	756	8	6,048
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures (SOP) (§§ 212.20(b) and 212.40(a) and (b))	63	2	126	8	1,008
Records of Components, Containers, and Closures (specification data sheets) (§§ 212.20(b) and (c) and 212.40(a) and (b))	63	21	1,323	0.5	662
Subparts C and H; §§ 212.20 to 212.71					
OOS Investigations (SOP) (§§ 212.20(c) and 212.71(a) and (b))	63	1	63	8	504

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN FOR ACADEMIA, SMALL FIRMS, AND HIGH-RISK COMPONENT MANUFACTURERS [1]—Continued

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subpart J; § 212.90					
Distribution Records (SOP) (§ 212.90(a))	63	1	63	8	504
Subparts C and K; §§ 212.20 to 212.100					
Complaints and Returned Product (§§ 212.20(e) and 212.100(a), (b), and (c))	63	3	189	8	1,512
Total			3,024		14,270

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR CORPORATE FIRMS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Batch Production Records (create batch-related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	91	240	21,840	0.5	10,920
Creating Any New Batch Records and Quality Records for New or Existing Drugs (§§ 212.20(c) and (e) and 212.50(a) and (b))	4	9	36	8	288
Subparts D, F, and G; §§ 212.30 to 212.60					
Equipment and Facilities Records (calibration and cleaning records systems) (§§ 212.30(b), 212.50(d), and 212.60(f))	91	480	43,680	0.25	10,920
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures for incoming inspection (§§ 212.20(b) and (c) and 212.40(a) and (b))	4	48	192	2	384
Subparts G and H; §§ 212.60 to 212.70					
Laboratory Testing Records (record laboratory test results) §§ 212.60(g), 212.61(b), and 212.70(d)(2) and (d)(3)	91	240	21,840	0.5	10,920
Subpart H; § 212.71					
Out-of-Specification Investigations (record events and investigations) (§ 212.71(b))	91	2	182	2	364
Subparts H and K; §§ 212.70 to 212.100					
Complaints (§ 212.100(b) and (c))	4	5	20	2	40
QA and Release of Batches (§ 212.70)	91	240	21,840	0.25	5,460
Subpart J; § 212.90					
Distribution Records (§ 212.90(b))	91	240	21,840	0.25	5,460
Total			131,470		44,756

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR ACADEMIA AND SMALL FIRMS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Batch Production Records (filling batch-related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	49	96	4,704	0.5	2,352
Creating Any New Batch Records and Procedures for New Drugs (§§ 212.20(c) and (e) and 212.50(a) and (b))	49	3	147	8	1,176
Subparts D, F, and G; §§ 212.30 to 212.60					
Equipment and Facilities Records (calibration and cleaning records) (§§ 212.30(b), 212.50(d), and 212.60(f))	49	480	23,520	0.5	11,760
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures (incoming acceptance tests) (§§ 212.20(b) and (c) and 212.40(a) and (b))	49	12	588	0.5	294
Subparts G and H; §§ 212.60 to 212.70					
Laboratory Testing Records (QC test results) §§ 212.60(g), 212.61(b), and 212.70(d)(2) and (d)(3)	49	96	4,704	0.5	2,352
Subpart H; § 212.71					
Out-of-Specification Investigations (record events and investigations) (§ 212.71(b))	49	2	98	2	196
Subparts H and K; §§ 212.70 to 212.100					
Complaints (Record events and investigations) (§ 212.100(b) and (c))	49	2	98	2	196
QA and Release of Batches (§ 212.70)	49	96	4,704	0.25	1,176
Subpart J; § 212.90					
Distribution Records (§ 212.90(b))	49	96	4,704	0.25	1,176
Total			43,267		20,678

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HIGH-RISK COMPONENT MANUFACTURERS [1]

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts C and F; §§ 212.20 to 212.50					
Batch Production (creating manufacturing records and batch-related records per year) (§§ 212.20(c) and (e) and 212.50(a) and (b))	14	24	336	0.5	168
Subparts D, F, and G; §§ 212.30 to 212.60 and 212.90					
Equipment and Facilities Records (calibration and cleaning records systems) (§§ 212.30(b), 212.50(d), and 212.60(f))	14	130	1,820	0.5	910
Subparts C and E; §§ 212.20 to 212.40					
Records of Components, Containers, and Closures (incoming acceptance test) (§§ 212.20(c) and 212.40(a) and (b))	14	24	336	0.5	168

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HIGH-RISK COMPONENT MANUFACTURERS [1]—Continued

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
Subparts G and H; §§ 212.60 to 212.70					
Laboratory Testing Records (record QC test results) §§ 212.60(g), 212.61(b), and 212.70(d)(2) and (d)(3)	14	24	336	0.5	168
Subpart H; § 212.71					
OOS Investigations (record events and investigations) (§ 212.71(b))	14	1	14	1	14
QA and Release of Batches (§ 212.70)	14	24	336	0.25	84
Subpart J; §§ 212.90 to 212.50					
Distribution Records (§ 212.90(b))	14	24	336	0.25	84
Total			3,514		1,596

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

TABLE 6—ESTIMATED ONE-TIME AND ANNUAL RECORDKEEPING BURDEN FOR EXTERNAL CONTROL TESTING LABORATORIES [1]

Information collection activity; 21 CFR citation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours [2]
One-Time Recordkeeping Assay Validation (creating SOP and performing validation)	23	6	138	9	1,242
Subparts C, E, and F; §§ 212.20, 212.40, and 212.50					
Annual Recordkeeping Incoming Acceptance Tests Records (§§ 212.20(c), 212.40(a) and (b))	23	24	552	0.5	276
Annual Recordkeeping Batch Testing (creating testing records for sterility, periodic quality indicator test, or any test) (§§ 212.20(c) and (e) and 212.50(a) and (b))	23	8	184	0.5	92
Subparts D, F, and G; §§ 212.30, 212.50, and 212.60					
Annual Recordkeeping Equipment and Facilities Records (calibration, cleaning, and maintenance records) (§§ 212.30(b), 212.50(d), and 212.60(f))	23	98	2,254	0.25	564
Subpart H; § 212.71					
Annual OOS Investigations (recording events and investigations) (§ 212.71(b))	23	1	23	1	23
Annual QA and Release of Test Results	23	8	184	0.25	46
Total			3,335		2,243

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

TABLE 7—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR PET DRUG PRODUCERS [1]

Information collection activity; 21 CFR section	Number of sterility failure incidents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours [2]
Subpart H; § 212.70					
Sterility Test Failure Notices [3] (§ 212.70(e))	7	3	21	2.5	53

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.
[3] Two reports are sent to FDA per incident, and 1 notification is sent to the receiving site.

Our estimated burden for the information collection reflects an overall increase of 25,425 hours and a corresponding increase of 84,703 records. We attribute this increase to the inclusion of external control testing laboratories that perform only specialized chemical, microbiological, or sterility testing functions to support manufacturing and release of final PET drug products.

Dated: March 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07392 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4951]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for humanitarian use devices (HUDs).

DATES: Submit either electronic or written comments on the collection of information by June 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–4951 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices.'' 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 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB

for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Humanitarian Use Devices—21 CFR Part 814

OMB Control Number 0910–0332—Revision

This collection of information implements the humanitarian use devices (HUDs) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)) and part 814, subpart H (21 CFR part 814, subpart H). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is designed to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States; (2) would not be available to a person with a disease or condition unless an exemption is granted and there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose such disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Respondents may submit a humanitarian device exemption (HDE) application seeking exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2) of the FD&C Act. The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (*i.e.,* for profit), except in narrow circumstances. Under section 520(m)(6)(A)(i) of the FD&C Act, a HUD approved under an HDE is eligible to be sold for profit if the device meets the following criteria: The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or the device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients, or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Section 520(m)(6)(A)(ii) of the FD&C Act, provides that the Secretary of Health and Human Services will determine the annual distribution number (ADN) for devices that meet the eligibility criteria to be permitted to be sold for profit. The Cures Act amended the FD&C Act definition of the ADN as the number of devices reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States.

Section 520(m)(6)(A)(iii) of the FD&C Act provides that an HDE holder immediately notify the Agency if the number of such devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) of the FD&C Act provides that an HDE holder may petition to modify the ADN if additional information arises.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section or FD&C act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for HUD designation—814.102	20	1	20	40	800
HDE Application—814.104	4	1	4	328	1,312
HDE Amendments and resubmitted HDEs—814.106	20	5	100	50	5,000
HDE Supplements—814.108	116	1	116	80	9,280
Notification of withdrawal of an HDE—814.116(e)(3)	2	1	2	1	2
Notification of withdrawal of institutional review board approval—814.124(b)	1	1	1	2	2
Periodic reports—814.126(b)(1)	50	1	50	120	6,000
Pediatric Subpopulation and Patient Information—515A(a)(2) of the FD&C Act (21 U.S.C. 360e–1(a)(2))	1	1	1	100	100
Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act	1	1	1	50	50
Request for Determination of Eligibility Criteria—613(b) of the Food and Drug Administration Safety and Innovation Act	1	1	1	10	10
ADN Notification—520(m)(6)(A)(iii) of the FD&C Act	1	1	1	100	100
ADN Modification—520(m)(6)(C) of the FD&C Act	1	1	1	100	100
Total					22,756

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2)	62	1	62	2	124

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification of emergency use—814.124(a)	22	1	22	1	22

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an increase of 360 total burden hours and a corresponding increase of five total annual responses. For efficiency of Agency operations, we are consolidating the related information activity and account for burden associated with HDE regulations currently approved in OMB control number 0910–0661. As a result, there is an increase in the total number of burden hours for this information collection.

Dated: March 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07376 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3903]

Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment; 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 final guidance for industry entitled ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs and biologics for the treatment of chronic hepatitis B virus (HBV) infection from the initial investigational new drug application (IND) through the new drug application (NDA)/biologics license application (BLA) and postmarketing phases. This guidance finalizes the draft guidance of the same title issued on November 2, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on April 7, 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–2018–D–3903 for ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' 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 the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Poonam Mishra, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6100, Silver Spring, MD 20993, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' The purpose of this guidance is to provide general recommendations on the clinical development of drugs and biologics for the treatment of chronic HBV infection from the initial IND through the NDA/BLA and postmarketing phases. The guidance includes general considerations for nonclinical toxicology and virology studies, early phase clinical development, clinical pharmacology assessments, and phase 3 safety and efficacy trials. The guidance discusses phase 3 trial design considerations and efficacy endpoints for the development of finite duration therapies for the treatment of chronic HBV infection. Drug development considerations for specific subpopulations such as patients co-infected with hepatitis D virus or human immunodeficiency virus and for pediatric patients with chronic HBV infection are also included.

This guidance finalizes the draft guidance of the same name issued on November 2, 2018 (83 FR 55187). FDA provided clarifying edits to the final guidance and included additional information after considering comments received on the draft guidance. Changes from the draft to the final guidance include the following: Considerations and recommendations for studies evaluating oligonucleotide-based investigational drugs, considerations for drugs developed to modulate innate and adaptive immune responses, updates to trial design considerations, updates to recommendations for safety monitoring (including monitoring for hepatitis flares after treatment discontinuation), and updates to efficacy extrapolation from adult to pediatric patients.

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 ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' 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 for review of investigational new drug regulations in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collections of information for review of new drug applications and biologic license applications in 21 CFR parts 314 and 601, have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. The collection of information regarding accelerated approval of serious conditions for drugs and biologics is approved under OMB control number 0910–0765. The collection of information regarding labeling of prescription drug and biologic products is approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07397 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–1529, FDA–2014–D–0609, FDA–2012–N–0961, FDA–2021–N–1022, FDA–2018–N–4130, and FDA–2018–N–3037]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Reclassification Petitions for Medical Devices	0910–0138	2/28/2025
Pharmaceutical Distribution Supply Chain	0910–0806	2/28/2025
Environmental Impact Considerations	0910–0322	3/31/2025
Reporting Associated with Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declaration of Color Additives on Animal Food Labels	0910–0546	3/31/2025
Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water	0910–0658	3/31/2025
Generic Clearance for Quantitative Testing for the Development of FDA Communications (CFSAN)	0910–0865	3/31/2025

Dated: March 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07394 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2778]

Agency Information Collection Activities; Proposed Collection; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for data needed to evaluate requests for Threshold of Regulation Exemptions for Substances Used in Food-Contact Articles.

DATES: Submit either electronic or written comments on the collection of information by June 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–2778 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles.'' 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 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39

OMB Control Number 0910–0298—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the FD&C Act; (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6) of the FD&C Act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) of the FD&C Act or an effective notification in accordance with section 409(a)(3)(B) of the FD&C Act.

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The Agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion. The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

To determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use. We use this information to determine whether the food-contact substance meets the threshold criteria.

Description of Respondents: Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (*i.e.,* food packaging and food processing equipment) or of the articles themselves.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 170.39	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Threshold of regulation for substances used in food-contact articles	7	1	7	48	336

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of FD&C Act (OMB control number 0910–0495) in that the use of a substance exempted by FDA is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (*e.g.,* use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both Agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and we would not have to review, similar submissions for identical components of food-contact articles used under identical conditions.

Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Dockets Management Staff and on the internet at *https://www.fda.gov/food/packaging-food-contact-substances-fcs/threshold-regulation-exemptions-substances-used-food-contact-articles*. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or

a notification for the same type of food-contact application of a substance for which the Agency has previously granted an exemption from the food additive listing regulation requirement.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07389 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0055]

M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes; 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 ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes; International Council for Harmonisation; Draft Guidance for Industry.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance adds monographs for seven new compounds to the M7 Guideline which outlines considerations for assessment and control of DNA reactive (mutagenic) impurities to limit potential carcinogenic risk. The compounds are: Acetaldehyde, dibromoethane, epichlorohydrin, ethyl bromide, formaldehyde, styrene, and vinyl acetate. The addendum is intended to update the M7 Guideline in line with the ICH process for its maintenance and includes other revisions.

DATES: Submit either electronic or written comments on the draft guidance by May 9, 2022 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–0055 for ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes.'' 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 guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Aisar Atrakchi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4118, Silver Spring, MD 20993–0002, 301–796–1036; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes; International Council for Harmonisation; Draft Guidance for Industry.'' 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 the 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 2021, the ICH Assembly endorsed the draft guideline entitled ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance adds monographs for seven new compounds to the M7 Guideline which outlines considerations for assessment and control of DNA reactive (mutagenic) impurities to limit potential carcinogenic risk. The compounds are: Acetaldehyde, dibromoethane, epichlorohydrin, ethyl bromide, formaldehyde, styrene, and vinyl acetate. The addendum is intended to update the M7 Guideline in line with the ICH process for its maintenance and includes other revisions.

This draft guidance has been left in the original ICH format. It contains only a list of revisions to the M7(R1) Guideline as well as the monographs for seven new compounds submitted for public consultation. The final guidance will include a complete, integrated M7(R2) Guideline and Addendum and 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 ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk'' and its Addendum. 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 draft 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, and the collection of information under 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: April 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07395 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0907]

Medical Device User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a virtual public meeting entitled ''Medical Device User Fee Amendments.'' The purpose of the meeting is to discuss proposed recommendations for the

reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years (FYs) 2023 through 2027. MDUFA authorizes FDA to collect fees and use them for the process for the review of device applications. The current legislative authority for MDUFA expires September 30, 2022. At that time, new legislation will be required for FDA to continue collecting device user fees in future fiscal years. Following discussions with the device industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register**, provide for a period of 30 days for the public to provide written comments on such recommendations, and hold a meeting at which the public may present its views on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

DATES: The public meeting will be held virtually on April 19, 2022, from 12 p.m. to 4:30 p.m. Eastern Time. Submit electronic or written comments to the public docket by April 21, 2022.

ADDRESSES: Registration to attend this virtual public meeting and other information can be found at *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.*

You may submit written comments on the recommendations as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 21, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 21, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–0907 for ''Medical Device User Fee Amendments; Public Meeting.'' FDA published the commitment letter on March 22, 2022. The commitment letter can be found in the docket and on this website at *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.* The docket will close on April 21, 2022. 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 available 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.

FOR FURTHER INFORMATION CONTACT: Mimi Nguyen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5547, Silver Spring, MD 20993, 301–796–4125, *MDUFAVReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of proposed recommendations for the reauthorization of MDUFA, which authorizes FDA to collect user fees and use them for the process for the review of device applications. We are also announcing a virtual public meeting to discuss such recommendations. The current authorization of the MDUFA program continues until September 30, 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to provide funds for the process for the review of device applications.

Section 738A(b)(4) of the FD&C Act (21 U.S.C. 379j–1(b)(4)) requires that, after holding negotiations with regulated industry, we take the following actions: (1) Present the recommendations to the Committee on Energy and Commerce of the U.S. House of Representatives and the Committee on Health, Education, Labor, and

Pensions of the U.S. Senate; (2) publish the recommendations in the **Federal Register**; (3) provide a period of 30 days for the public to submit written comments on the recommendations; (4) hold a meeting at which the public may present its views on the recommendations; and (5) after consideration of public views and comments, revise the recommendations as necessary. This notice, the 30-day comment period, and the public meeting will satisfy parts of these requirements. After the public meeting, we will revise the recommendations as necessary. In addition, the Agency will present the recommendations to the Congressional committees.

The purpose of the meeting is for the public to present its views on the proposed recommendations for the reauthorized program (MDUFA V). The meeting format will include presentations by FDA and different stakeholder interest groups (such as industry, patient and consumer advocates, healthcare professionals, and scientific and academic experts). The Agency will also provide an opportunity for other interested individuals to make presentations at the meeting.

The following information is provided to help potential meeting participants better understand the history and evolution of the medical device user fee program and the current status of the proposed MDUFA V recommendations.

II. What is MDUFA and what does it do?

MDUFA is the law that authorizes FDA to collect fees from device companies that register their establishments, submit applications to market devices, and make other types of device submissions. In the years preceding enactment of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), FDA's medical device program suffered a long-term, significant loss of resources that undermined the program's capacity and performance. MDUFMA was enacted ''in order to provide FDA with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier point in time, and to ensure that reprocessed medical devices are as safe and effective as original devices.'' H.R. Rep. 107–728 at p. 21 (October 7, 2002). MDUFMA was authorized for 5 years and contained two important features that relate to reauthorization:

- User fees for the review of medical device premarket applications, reports, supplements, and premarket notification submissions provided additional resources to make FDA reviews more timely, predictable, and transparent to applicants. User fees and other appropriations for the medical device program helped FDA expand available expertise, modernize its information management systems, provide new review options, and provide more guidance to prospective submitters. The ultimate goal was for FDA to clear or approve safe and effective medical devices more rapidly and predictably, benefiting applicants, the healthcare community, and most importantly, patients.
- Negotiated performance goals for many types of premarket reviews provided FDA with benchmarks for measuring review improvements. These quantifiable goals became more demanding each year and included FDA decision goals and cycle goals (cycle goals refer to FDA actions prior to a final action on a submission). Under MDUFMA, FDA also agreed to several other commitments that did not have specific timeframes or direct measures of performance, such as expanding the use of meetings with industry, maintenance of current performance in review areas where specific performance goals had not been identified, and publication of additional guidance documents.

Medical device user fees and increased appropriations were viewed by FDA, Congress, and industry stakeholders as essential to support high-quality, timely medical device reviews, and other activities critical to the device review program.

MDUFMA provided for—and reauthorizations have maintained—fee discounts and waivers for qualifying small businesses. Small businesses make up a large proportion of the medical device industry, and these discounts and waivers helped reduce the financial impact of user fees on this sector of the device industry, which plays an important role in fostering innovation.

Since MDUFMA was first enacted in 2002, it has been reauthorized three times through the Medical Device User Fee Amendments of 2007 (MDUFA II), the Medical Device User Fee Amendments of 2012 (MDUFA III), and the Medical Device User Fee Amendments of 2017 (MDUFA IV). MDUFA IV has been in effect since 2017 and will expire on September 30, 2022 (*https://www.fda.gov/media/100848/download).* The MDUFA IV agreement enabled FDA to continue making progress on reducing review times and bringing devices to patients more quickly, while also enabling FDA to move forward in critical areas, including:

- Building a sustainable infrastructure for efficient, consistent, transparent, and high-quality regulation of devices throughout the total product lifecycle;
- Accessing and using real-world evidence in the regulatory decision-making process;
- Advancing patient engagement and the regulatory science of patient input;
- Advancing the smart oversight of digital health technologies in ways that support innovation, balance innovation and safety, and show promise as a potential blueprint for future regulatory approaches to emerging technologies.

In terms of review goals, FDA's performance was strong during the initial years of MDUFA IV (FY 2018 and FY2019), continuing to meet and exceed performance goals and working to reduce the time for patients to have access to safe, new, innovative devices. During this time, FDA achieved all of our submission review goals, met 21 of 24 performance enhancement goals, and FDA and industry met three of four shared outcome goals. Starting in FY 2020, the strain from the pandemic, as well as a workload that exceeded assumptions underlying the MDUFA IV agreement, resulted in failure to meet certain MDUFA IV goals.

Preliminary performance data through September 30, 2021, including completed and pending reviews, indicate that FDA has met (or has the potential to meet) 13 of the 16 FY 2020 review goals and 9 of the 13 FY 2021 review goals for which FDA had a sufficient MDUFA cohort to calculate performance. FDA also completed, on time, all eight performance enhancement goals due in FY 2021. However, FDA's response to the unprecedented COVID–19 public health emergency has impacted FDA's MDUFA performance, resulting in three missed FY 2020 review goals and four missed FY 2021 review goals. Information about FDA's performance is available in the yearly and quarterly MDUFA performance reports, which are online at: *https://www.fda.gov/about-fda/user-fee-performance-reports/mdufa-performance-reports and https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-reports.*

III. Proposed MDUFA V Recommendations

In preparing the proposed recommendations to Congress for MDUFA reauthorization, FDA conducted discussions with the device

industry and consulted with stakeholders, as required by the FD&C Act. The Agency began the MDUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input on the reauthorization and announcing a public meeting that was held on October 27, 2020. The meeting included presentations by FDA (which complemented videos released ahead of the public meeting highlighting FDA's efforts and accomplishments under the MDUFA IV agreement) and a series of panels with representatives of different stakeholder groups, including patient and consumer advocacy groups, regulated industry, and healthcare professionals. The materials from the meeting, including a transcript and webcast recording, can be found at *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-10272020.*

From February 2021 through March 2022, FDA conducted negotiations with representatives of the device industry: The Advanced Medical Technology Association; the Medical Device Manufacturers Association; the Medical Imaging and Technology Alliance; and the American Clinical Laboratory Association. During its negotiations with industry, FDA also held monthly consultations with representatives of patient and consumer advocacy groups and other public stakeholders. Meeting minutes are posted on FDA's website at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.*

The proposed recommendations for MDUFA V address many priorities identified by industry and other stakeholders. While some of the proposed recommendations are new, many either build on successful enhancements or refine elements from the existing program. FDA posted the full text of the proposed MDUFA V commitment letter at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.* Each significant new or modified recommendation is briefly described below with reference to the applicable section of the proposed commitment letter.

A. Shared Outcome Goals

FDA and representatives of the device industry believe that the process improvements outlined in the proposed commitment letter, when implemented by all parties as intended, should reduce the average Total Time to Decision for premarket approval applications (PMAs), and premarket notification (510(k)) submissions, provided that the total funding of the device review program adheres to the assumptions underlying the MDUFA V agreement. Reducing average Total Time to Decision, as defined in the commitment letter, is an important aspect of the user fee program, so that safe and effective devices reach patients and healthcare professionals more quickly. FDA proposes, for PMA and 510(k) submissions, with the performance improvement adjustments described below, that the Total Time to Decision will reach 270 calendar days for original PMA and panel-track supplement submissions and 108 calendar days for 510(k)s by FY 2027.

Additional details regarding the shared outcome goals can be found in Sections I and III of the proposed commitment letter.

B. Pre-Submissions

MDUFA V provides additional resources for FDA to address the increasing volume of Pre-Submissions requests and to improve the Pre-submission performance goal. FDA proposes to ramp up to a performance goal of providing written feedback on at least 90 percent of Pre-Submissions within 70 days or 5 calendar days prior to the scheduled meeting, whichever comes sooner, by FY 2025. With the performance improvement adjustments described below, FDA may continue to improve this performance goal in FY 2026–2027. FDA will also update guidance to include additional information to assist applicants and review staff in identifying the circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission. Additional details regarding Pre-Submissions can be found in Sections II.A and III.C of the proposed commitment letter.

C. De Novo Requests

FDA will have an opportunity, with the performance improvement adjustments described below, to ramp up to a De Novo decision goal of 90 percent of De Novo request submissions within 150 days in FY 2027. Additional details regarding De Novo requests can be found in Sections II.E and III.B of the proposed commitment letter.

D. Opportunity for Performance Improvements

FDA proposes adding a new performance improvement adjustment for MDUFA V that would allow FDA to collect fees in addition to annual total revenue in FY 2025, FY 2026, and/or FY 2027, if certain review performance and/or shared outcome goals are met for FY 2023, 2024, and/or 2025. If applicable, these fee increases will apply solely to establishment registration fees and support improvements to the 510(k) and PMA Shared Outcome Total Time to Decision goals, the Pre-Submission Written Feedback goal, and the De Novo decision goal. The following examples describe adjustments if goals are met for FY 2023:

- If FDA's 510(k) decision goal, the FDA/Industry 510(k) Shared Outcome Total Time to Decision goal, FDA's PMA decision goal, and the FDA/Industry PMA Shared Outcome Total Time to Decision goal are met for FY 2023, and fee revenue above the annual total revenue amount is provided in FYs 2026 and 2027, then the 510(k) Shared Outcome Total Time to Decision goal and the PMA Shared Outcome Total Time to Decision goal will be adjusted. Specifically, the 510(k) Shared Outcome Total Time to Decision goal will be improved to 108 days for FYs 2026 and 2027, and the PMA Shared Outcome Total Time to Decision goal will be improved to 275 days for FYs 2026 and 2027.
- If the Pre-Submission Written Feedback goal is met for FY 2023, and fee revenue above the annual total revenue amount is provided to support performance improvements in FYs 2025, 2026, and 2027, the maximum number of Pre-Submissions subject to the goal will improve to 4,700 Pre-Submissions in FYs 2025, 2026, and 2027.
- If the De Novo decision goal is met for FY 2023, and fee revenue above the annual total revenue amount is provided in FYs 2026 and 2027 to support performance improvements, the goal will improve to 80 percent of De Novo requests receiving a MDUFA decision within 150 FDA days for FYs 2026 and 2027.

Additional details regarding the opportunity for performance improvements can be found in Section III of the proposed commitment letter. Under the new performance improvement adjustment, FDA may receive additional funding up to the following maximum amounts (which would be adjusted for inflation):

- $15,396,600 for FY 2025
- $44,135,700 for FY 2026
- $56,244,000 for FY 2027

E. Deficiency Letters

To support improved communication in FDA letters requesting additional

information, FDA will clarify what constitutes a statement of the basis for the deficiency in updated guidance, train staff and managers on the updated guidance, and establish a performance goal for providing a statement of the basis for the deficiency that ramps up to 95 percent by FY 2027.

F. Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot

FDA will launch a voluntary pilot program to provide more frequent and timely interactions for industry and other stakeholders earlier in the device development process with a focus on Breakthrough (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program*) and Safer Technologies Program devices (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices*). Through the TAP Pilot, FDA will provide strategic engagement for innovative devices of public health importance by facilitating improved strategic decision making during product development, including earlier identification, assessment, and mitigation of product-development risk. The TAP Pilot will also support engagement to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process. Additional details regarding the TAP Pilot can be found in Section V.J of the proposed commitment letter.

G. Patient Science and Engagement

FDA proposes to continue building the Patient Science and Engagement program, which engages patients and supports incorporating their perspectives in the regulatory process. In particular, FDA proposes to expand the program through the following activities: Facilitate patient engagement through patient-friendly educational content; explore ways to advance health equity; continue to expand patient science review expertise and capacity; improve the regulatory predictability and impact of patient science, including shared examples; hold a public meeting on patient-generated health data for collecting clinical outcome assessment (COA) data and for remote clinical trials; and issue draft guidance on incorporating COA into premarket studies and update patient preference information guidance. Additional details regarding patient science and engagement can be found in Section V.E of the proposed commitment letter.

H. Enhanced Use of Consensus Standards

During MDUFA IV, FDA initiated the voluntary Accreditation Scheme for Conformity Assessment (ASCA) pilot to enhance product reviewers' and device manufacturers' confidence in medical device testing when manufacturers rely on testing completed by ASCA-accredited testing laboratories. FDA proposes to use lessons learned from implementation of the ASCA pilot in MDUFA IV to transition to a sustainable and expanded program in MDUFA V. Additional details regarding the enhanced use of consensus standards can be found in Section V.C of the proposed commitment letter.

I. International Harmonization

FDA will enhance international harmonization activities by expanding engagement in international harmonization and convergence efforts to promote alignment with international best practices and internationally developed policies. Additional details regarding international harmonization can be found in Section V.I of the proposed commitment letter.

J. Third Party Premarket Review Program

FDA proposes to maintain the Accredited Persons (Third Party Review) program in MDUFA V. Additional details regarding the Third Party Review program can be found in Section V.D of the proposed commitment letter.

K. Real World Evidence (RWE)

FDA proposes to continue to advance the development of Real-World Data (RWD) and RWE methods and policies to advance regulatory acceptance for premarket submissions. Additional details regarding RWE can be found in Section V.F of the proposed commitment letter.

L. Digital Health

FDA proposes to continue building its digital health expertise, working to streamline and align FDA review processes with software lifecycles for digital health products, engaging in international harmonization efforts related to software review, and conducting other activities related to digital health. Additional details regarding digital health can be found in Section V.G of the proposed commitment letter.

M. Information Technology (IT)

FDA proposes to continue to enhance IT infrastructure to support the process for the review of device applications, including improving a submission progress tracking system and developing electronic submission templates for more submission types. Additional details regarding IT can be found in Section IV.C of the proposed commitment letter.

N. Financial Transparency and Hiring

FDA proposes to take several new steps to provide additional transparency and accountability measures with respect to MDUFA V finances and hiring. The Agency proposes to publish a MDUFA 5-year financial plan that will be updated annually. In addition, new statutory language for an operating reserve adjustment is proposed to reflect FDA and industry-agreed measures for managing the amount of operating reserves in the MDUFA carryover balance. Under this new provision, FDA would decrease registration fees if the amount of operating reserves exceeds the designated amount. The designated amount for a fiscal year is equal to 13 weeks of operating reserves plus the 1 month of operating reserves required by statute. Further, the amount of carryover user fees intended to support the Third Party Review program and TAP Pilot during MDUFA V would be excluded for the period of FY 2023 through FY 2026 when calculating the amount of operating reserves to determine if registration fees will be decreased. User fee funds in the carryover balance that are considered unappropriated or unearned are not included in the operating reserves.

To help ensure that FDA accomplishes hiring in accordance with the assumptions underlying the MDUFA V agreement, FDA proposes to set annual hiring goals for MDUFA V positions. Proposed statutory language would provide for the reduction of establishment registration fees for FYs 2025, 2026, and 2027, if the Agency does not meet those goals for FYs 2023, 2024, and 2025, respectively, by a certain threshold. The amount of the hiring adjustment fee decrease would be the product of the number of hires by which the hiring goal was missed and one-quarter of the inflation-adjusted cost per full time equivalent. Additional details regarding financial transparency and hiring can be found in Section IV.B of the proposed commitment letter.

O. Independent Assessments

FDA and industry propose to participate in a targeted assessment of the management of the process for the review of device applications. FDA also proposes to retain an independent contractor with expertise in assessing public sector workforce data analysis

and reporting to conduct an assessment of current methodologies and data/metrics available to represent the MDUFA workforce. Additional details regarding the independent assessments can be found in Section VI of the proposed commitment letter.

P. Performance Reports

FDA proposes to continue to report quarterly and annually on performance against commitments. Additionally, FDA proposes to report quarterly on progress toward hiring goals and funding intended for RWE activities. FDA will report annually on the primary cost drivers for changes to personnel compensation and benefits costs. Additional details regarding performance reporting can be found in Section VII of the proposed commitment letter.

Q. User Fee Revenue and Fee Allocations

As part of MDUFA V, FDA and industry propose updating the base fee amounts for PMAs and annual establishment registrations, as well as the annual total revenue amounts, to reflect negotiated fee levels. The statutory total revenue amounts, base fee amounts, and amounts for potential performance improvement adjustments are proposed in FY 2021 dollars, such that annual inflation adjustments will be used to inflate FY 2021 dollars to the appropriate amounts for each fiscal year in MDUFA V. FDA and industry also propose to change the fee for a PMA Panel-Track supplement from 75 percent to 80 percent of the fee for an original PMA and to change the fee for a 510(k) submission from 3.4 percent to 4.5 percent of the fee for a PMA. Finally, a minor change is proposed to the statutory provisions regarding fee waivers and reductions for small businesses to clarify that an applicant seeking a waiver or reduction is not required to submit a certification from the national taxing authority of the foreign country in which the applicant, or its affiliate, is located, if the country has no national taxing authority.

FDA will post the agenda approximately 5 days before the meeting at: *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.*

IV. Participating in the Public Meeting

Registration: To register for the public meeting, please visit *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.* Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Registrants will receive confirmation after they have been accepted.

Registration is free. Persons interested in attending by webcast the MDUFA virtual public meeting must register online by 4 p.m. Eastern Time, April 18, 2022. Early registration is recommended.

If you need special accommodations because of a disability, please contact Susan Monahan at 240–205–2260 or *Susan.Monahan@fda.hhs.gov* no later than April 11, 2022.

Requests for Oral Presentations: This meeting includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during the public comment session or a specific session, and which topic(s) you wish to address. All requests to make oral presentations virtually by webcast must be received by April 11, 2022, at 4 p.m. Eastern Time. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify speakers by April 12, 2022. If selected for presentation, any presentation materials must be emailed to Mimi Nguyen (see **FOR FURTHER INFORMATION CONTACT**) no later than April 13, 2022, at 4 p.m.. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

FDA is holding this meeting to provide information on the proposed recommendations for the reauthorization of MDUFA for FYs 2023 through 2027. To permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the meeting topics. The docket was opened on March 22, 2022. The proposed commitment letter was posted in the docket and on this website at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.* The docket will close on April 21, 2022, 30 days after the proposed commitment letter was posted.

Streaming Webcast of the Public Meeting: The webcast link will be available on the registration web page after April 11, 2022. Organizations are requested to register all participants.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *in the docket at https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available approximately 45 days after the public workshop on the internet at: *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.*

Dated: April 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07451 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; COVID–19 Provider Relief Fund (PRF) and American Rescue Plan (ARP) Rural Payment Reporting Activities, OMB No. 0906–0068—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 6, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft

instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Acting Information Collection Clearance Officer at (240) 276–7189.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: COVID–19 Provider Relief Fund (PRF) Reporting Activities OMB No. 0906–0068—Revision.

Abstract: HRSA disburses the PRF and ARP Rural payments to eligible health care providers to support health care-related expenses or lost revenues attributable to the COVID–19 pandemic. Providers who have attested to the Terms & Conditions (T&Cs) regarding their PRF and ARP Rural payment(s), including the requirement that the provider ''shall submit reports as the Secretary determines are needed to ensure compliance with conditions that are imposed on this Payment, and such reports shall be in such form, with such content, as specified by the Secretary in future program instructions directed to all recipients,'' will be using the PRF Reporting Portal to submit information about their use of PRF and ARP Rural payments. In anticipation of the approved OMB form (control number 0906–0068) expiring on January 31, 2023, HRSA is undergoing the revision of the ICR approval to include the ARP Rural reporting requirements and to allow for data collection beyond the January 31, 2023, expiration.

Need and Proposed Use of the Information: Recipients of a PRF and ARP Rural payment agreed to a set of T&Cs, which, among other requirements, mandate compliance with certain reporting requirements that will facilitate appropriate oversight of recipients' use of funds.

Information collected will allow for (1) assessing whether recipients have met statutory and programmatic requirements, (2) conducting audits, (3) gathering data required to report on findings with respect to the disbursements of PRF and ARP Rural payments, and (4) program evaluation. HRSA staff will also use information collected to identify and report on trends in health care metrics and expenditures before and during the allowable period for expending PRF and ARP Rural payments.

Likely Respondents: PRF and ARP Rural payment recipients who have received more than $10,000 in aggregate PRF and ARP Rural payments during one of the Payment Received Periods outlined below and that agreed to the associated T&Cs are required to submit a report in the PRF Reporting Portal during the applicable Reporting Time Period.

Reporting period	Payment received period (payments exceeding $10,000 in aggregate received)	Reporting time period
Period 1	April 10, 2020, to June 30, 2020	July 1, 2021, to September 30, 2021.
Period 2	July 1, 2020, to December 31, 2020	January 1, 2022, to March 31, 2022.
Period 3	January 1, 2021, to June 30, 2021	July 1, 2022, to September 30, 2022.
Period 4	July 1, 2021, to December 31, 2021	January 1, 2023, to March 31, 2023.
Period 5	January 1, 2022, to June 30, 2022	July 1, 2023, to September 30, 2023.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. 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. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
PRF Reporting Portal, Reporting Period 1 (Providers who received payments April 10, 2020, to June 30, 2020)	126,831	1	126,831	5.6	710,254
PRF Reporting Portal, Reporting Period 2 (Providers who received payments July 1, 2020, to December 31, 2020)	120,536	1	120,536	4.2	506,251
PRF Reporting Portal, Reporting Period 3 (Providers who received payments, January 1, 2021, to June 30, 2021)	20,493	1	20,493	6.1	125,565
PRF and ARP Rural Reporting Portal, Reporting Period 4 (Providers who received payments July 1, 2021, to December 31, 2021)	51,622	1	51,622	5.6	287,514
PRF and ARP Rural Reporting Portal, Reporting Period 5 (Providers who received payments January 1, 2022, to June 30, 2022)	4,256	1	4,256	5.5	23,288
Total	323,738		323,738		1,652,872

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–07408 Filed 4–6–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Zero Suicide Initiative Coordinating Center

Announcement Type: New.

Funding Announcement Number: HHS–2022–IHS–ZSICC–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.654.

Key Dates

Application Deadline Date: July 6, 2022.

Earliest Anticipated Start Date: August 22, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a cooperative agreement for the IHS Zero Suicide Initiative (ZSI) Coordinating Center. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1665a. This program is described in the Assistance Listings located at *https://sam.gov/content/home* (formerly known as the CFDA) under 93.654.

Background

Since 1999, suicide rates within the United States have been steadily increasing.[1] On March 2, 2018, the Centers for Disease Control and Prevention's Morbidity and Mortality Weekly report released a data report, ''Suicides Among American Indian/Alaska Natives National Violent Death Reporting System, 18 States, 2003 to 2014,'' which highlights American Indian/Alaska Native (AI/AN) people having the highest rates of suicide of any racial/ethnic group in the United States. Suicide rates for AI/AN adolescents and young adult ages 15 to 34 (19.1/100,000) were 1.3 times that of the national average for that age group (14/100,000).[2] In June 2019, the National Center for Health Statistics, Health E-Stat reported in ''Suicide Rates for Females and Males by Race and Ethnicity: United States, 1999 and 2017,'' that suicide rates increased for all race and ethnicity groups but the largest increase occurred for AI/AN females (139% from 4.6 to 11.0 per 100,000). Suicide is the 8th leading cause of death among all AI/AN people across all ages and may be underestimated.

The Zero Suicide Initiative (ZSI) is a key concept of the National Strategy for Suicide Prevention and is a priority of the National Action Alliance for Suicide Prevention (*https://theactionalliance.org/*). Under a separate funding opportunity announcement, the IHS intends to fund a new ZSI Cohort of eight to ten projects that will support the implementation of the Zero Suicide model within Tribal and Urban Indian health care facilities and systems that provide direct care services to AI/AN patients in order to raise awareness of suicide, establish an integrated system of care, and improve outcomes for such individuals in fiscal year (FY) 2022–FY 2026. Applicants are encouraged to visit *https://www.hhs.gov/surgeongeneral/reports-and-publications/suicide-prevention/index.html* to access a copy of the 2012 National Strategy.

Purpose

The purpose of this cooperative agreement is to build capacity of ZSI projects to improve the system of care for those at risk for suicide by implementing a comprehensive, culturally informed, multi-setting approach to suicide prevention in Indian health systems. The ZSI Coordinating Center will provide technical assistance in the areas of data collection, reporting, training, resources, and implementation of the Zero Suicide approach in Indian Country. The ZSI Coordinating Center technical assistance will be framed to promote the core Seven Elements of the Zero Suicide model that was developed by the Suicide Prevention Resource Center (SPRC) at *https://zerosuicide.edc.org/toolkit/zero-suicide-toolkit.*

1. Lead—Create and sustain a leadership-driven, safety-oriented culture committed to dramatically reducing suicide among people under care. Include survivors of suicide attempts and suicide loss in leadership and planning roles.
2. Train—Develop a competent, confident, and caring workforce.
3. Identify—Systematically identify and assess suicide risk among people receiving care.
4. Engage—Ensure every individual has a pathway to care that is both timely and adequate to meet his or her needs. Include collaborative safety planning and restriction of lethal means.
5. Treat—Use effective, evidence-based treatments that directly target suicidal thoughts and behaviors.
6. Transition—Provide continuous contact and support, especially after acute care.
7. Improve—Apply a data-driven quality improvement approach to inform system changes that will lead to improved patient outcomes and better care for those at risk.

Required Activities

The ZSI Coordinating Center award funds must be used primarily to support activities to improve performance of a new cohort of ZSI projects in implementing the ZSI model and support recipients in meeting data collection and reporting requirements. The awardee will be required to:

1. Identify or develop key training, educational resources, and products to promote and implement the Zero Suicide model that is a multi-setting approach and culturally informed in the prevention of suicide in Indian health systems.
2. Build and maintain collaborative relationships with key stakeholders including: ZSI projects; state, territorial, Tribal, and local governments; local health departments; health care systems; tribal epidemiology centers, provider associations; national suicide prevention and behavioral health organizations; academic institutions; professional, recovery community, and racial/ethnic-specific or LGBT organizations; survivors; and others.
3. Ensure the technical assistance strategies provided include information related to specific target populations at risk for suicide, such as older adults, veterans, the LGBT community, individuals with serious mental illness, and AI/AN people.
4. Convene Recipient Training (Biannually)—Execute in person and/or virtual training events that help ZSI projects learn the foundational principles for the Zero Suicide model while helping the teams develop detailed action plans to be implemented.
5. Develop a virtual Learning Collaborative—that will provide culturally specific suicide prevention tools, resources, and consultation to implement the project.
6. Provide tailored Technical Assistance—Site-specific consultations and face-to-face or virtual site visits for ZSI projects that may experience complex challenges while implementing the Zero Suicide model.
7. Provide consultation with ZSI projects in the collection, analysis, and reporting of data.
8. Produce and provide the IHS a quarterly summary of the Center's technical assistance activities to include

[1] Curtin SC, Hedegaard H. Suicide rates for females and males by race and ethnicity: United States, 1999 and 2017. NCHS Health E-Stat. 2019.

[2] Leavitt RA, Ertle AE, Sheats K, Petrosky E, Ivey-Stephenson A, Fowler KA (2018) Suicides Among American Indian/Alaska Natives—National Violent Death Reporting System, 18 States, 2003 to 2014. MMWR Morb Mortal Wkly Rep 2018;67: 37–240.

any publications, audiovisuals, and other materials produced (drafts and final products).

9. Complete all activities proposed in the required activities section of this announcement.

10. Participate and plan face-to-face and/or virtual meetings and conference calls with the ZSI projects and IHS during the period of the cooperative agreement.

11. Develop a National Evaluation Plan for the ZSI within 60 days of receiving funding:

i. Coordinate a cross-site evaluation with the new cohort of ZSI funded projects;

ii. Export and organize a quantitative and qualitative data set for ZSI into one database for each project at the end of each project year and within 60 days of receiving the data to include the data points outlined in the Data Collection and Reporting section of this announcement;

iii. Complete an Evaluation Report within 30 days of the end of each project year; and,

iv. Create standard tables, slides, and talking points from the Evaluation Report within 30 days of the end of each project year.

Pre-Conference Award Requirements

The awardee is required to comply with the ''HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications,'' dated January 23, 2015 (Policy), as applicable to conferences funded by grants and cooperative agreements. The Policy is available at *https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html?language=es.*

The awardee is required to: Provide a separate detailed budget justification and narrative for each conference anticipated. The cost categories to be addressed are as follows: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration website, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, and (8) Other (explain in detail and cost breakdown). For additional questions please contact Monique Richards at (240) 252–9625 or email her at *Monique.Richards@ihs.gov.*

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for FY 2022 is approximately $500,000. The award amount for the first budget year is anticipated to be up to $500,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately one award will be issued under this program announcement.

Period of Performance

The period of performance is for 5 years.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as grants. However, the funding agency, IHS, is anticipated to have substantial programmatic involvement in the project during the entire period of performance. Below is a detailed description of the level of involvement required of the IHS.

Substantial Agency Involvement Description for Cooperative Agreement

1. Liaise with ZSI projects to ensure the ZSI Coordinating Center is able to provide timely and appropriate technical assistance.

2. Facilitate linkages to other IHS/Federal government resources and promote collaboration with other IHS and Federal health and behavioral health initiatives, including the Substance Abuse Mental Health Services Administration, the National Action Alliance for Suicide Prevention, the National Suicide Prevention Lifeline, the Suicide Prevention Resource Center (SPRC), and the Zero Suicide Institute.

3. Provide input and monitor the technical assistance being administered by the ZSI Coordinating Center. Ensure that the ZSI Coordinating Center receives ZSI project data according to IHS polices.

4. Provide suggested revisions or comments for quarterly and annual reports.

III. Eligibility Information

1. Eligibility

To be eligible for this new funding opportunity, an applicant must be one of the following as defined under 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term ''Indian Tribe'' means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.
- A Tribal organization as defined by 25 U.S.C. 1603(26). The term ''Tribal organization'' has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l)): ''Tribal organization'' means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.
- An Urban Indian organization as defined by 25 U.S.C. 1603(29). The term ''Urban Indian organization'' means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of nonprofit status with the application, *e.g.,* 501(c)(3).

In addition, Applicant must also have demonstrated expertise as follows:

- Representing Tribal governments and providing a variety of services to Tribes, area health boards, Tribal organizations, Federal agencies, and playing a major role in focusing attention on Indian health care needs resulting in improved health outcomes for Tribes.
- Promoting and supporting health education for AI/AN people and coordinating efforts to inform AI/AN people of Federal decisions that affect

Tribal government interests, including the improvement of Indian health care.

• Administering national health policy and health programs.

• Maintaining a national AI/AN constituency and clearly supporting critical services and activities.

• Supporting improved health care in Indian Country.

The program office will notify any applicants deemed ineligible.

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as proof of nonprofit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

Proof of Nonprofit Status Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at *https://www.Grants.gov.*

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

• Abstract (one page) summarizing the project.

• Application forms:

1. SF–424, Application for Federal Assistance.

2. SF–424A, Budget Information—Non-Construction Programs.

3. SF–424B, Assurances—Non-Construction Programs.

• Project Narrative (not to exceed 12 pages). See Section IV.2.A, Project Narrative for instructions.

1. Background information on the organization.

2. Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.

• Budget Justification and Narrative (not to exceed five pages). See Section IV.2.B, Budget Narrative for instructions.

• One-page Work Plan.

• Logic Model.

• Letters of Support from organization's Board of Directors (if applicable).

• 501(c)(3) Certificate (if applicable).

• Biographical sketches for all Key Personnel.

• Contractor/Consultant resumes or qualifications and scope of work.

• Disclosure of Lobbying Activities (SF–LLL), if applicant conducts reportable lobbying.

• Certification Regarding Lobbying (GG-Lobbying Form).

• Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).

• Organizational Chart.

• Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

2. Face sheets from audit reports. Applicants can find these on the FAC website at *https://harvester.census.gov/facdissem/Main.aspx.*

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See *https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html.*

Requirements for Project and Budget Narratives

A. *Project Narrative:* This narrative should be a separate document that is no more than 12 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger (tables may be done in 10 point font); (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and will not be reviewed. The 12-page limit for the narrative does not include the work plan, standard forms, budget, budget justifications, narratives, and/or other items.

There are three parts to the narrative: Part 1—Program Information; Part 2—Program Planning and Evaluation; and Part 3—Program Report. See below for additional details about what must be included in the narrative.

The page limits below are for each narrative and budget submitted.

Part 1: Program Information (Limit—5 Pages)

Section 1: Introduction and need for assistance

Must include the applicant's background information, a description of epidemiological service, epidemiologic capacity, suicide prevention, Zero Suicide model expertise, and history of support for such activities. Applicants need to include current public health activities, what program services they currently provide, and interactions with other public health authorities in the region (state, local, or Tribal).

Section 2: Organizational capabilities

The applicant must describe staff capabilities or hiring plans for the key personnel with appropriate expertise in suicide prevention, Zero Suicide model, epidemiology, health sciences, and program management. The applicant must also demonstrate access to specialized expertise, such as a Masters level epidemiologist and/or a biostatistician. Applicants must include an organizational chart and provide position descriptions and biographical sketches of key personnel including consultants or contractors. The position description should clearly describe each position and its duties. Resume should indicate that proposed staff is qualified to carry out the project activities.

Part 2: Program Planning and Evaluation (Limit—5 Pages)

Section 1: Program Plans

Applicant must include a work plan that describes program goals, objectives, activities, timeline, and responsible person for carrying out the objectives/activities.

The work plan should only include the first year of the project period showing dates, key activities, and responsible staff for key requirements.

Describe the proposed technical assistance recipients and the methods you will use to engage them. In your response, describe your expertise and experience in providing suicide

prevention technical assistance to federally recognized Indian Tribes, Tribal organizations, Urban Indian organizations, domestic public/private entities, community organizations, or faith-based organizations.

Discuss the service gaps, barriers, and other problems related to the need for technical assistance in the area of suicide prevention in Indian Country.

Section 2: Program Evaluation

Applicant must define the criteria they will use to evaluate activities listed in the work plan under the Required Activities section. They must explain the methodology they will use to determine if the needs identified for the objectives are being met and if the outcomes identified are being achieved, and describe how evaluation findings will be disseminated to the IHS, co-funders, and the population served. The evaluation plan must include a logic model (not counted in the page limit) with at least one measurable outcome per required activity.

Provide specific information about how you will collect the required data for this program and how you will use such data to manage, monitor, and enhance the program.

Part 3: Program Report (Limit—2 Pages)

Section 1: Describe major accomplishments over the last 24 months providing technical assistance, training, and in the area of suicide prevention.

B. *Budget Narrative* (limit—5 pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF–424A (Budget Information for Non-Construction Programs). The budget narrative can include a more detailed spreadsheet than is provided by the SF–424A. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the ''Other'' category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the narrative should highlight the changes from the first year or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at *https://www.Grants.gov*). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), Acting Director, DGM, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least 10 days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.
- The available funds are inclusive of direct and indirect costs.
- Only one cooperative agreement may be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov.* Please use the *https://www.Grants.gov* website to submit an application. Find the application by selecting the ''Search Grants'' link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov,* a waiver must be requested. Prior approval must be requested and obtained from Mr. Paul Gettys, Acting Director, DGM. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Paul.Gettys@ihs.gov.* The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method; and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in *https://www.Grants.gov* by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at *https://www.Grants.gov*).
- Upon contacting *Grants.gov,* obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and recipient organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no

charge. To obtain a DUNS number, please access the request service through *https://fedgov.dnb.com/webform,* or call (866) 705–5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS recipients must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime recipient organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page at *https://sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at *https://sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics web page at *https://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities; information for multi-year projects should be included as a separate document. See ''Multi-year Project Requirements'' at the end of this section for more information. The project narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application.

A. Program Information (20 Points)

Describe the applicant's current public health activities, including Technical Assistance services currently provided, interactions with other public health authorities in the regions (Federal, state, local, or Tribal) and how long it has been operating. Specifically, describe current epidemiologic capacity and history of support for such activities.

Describe staff capabilities or hiring plans for the key personnel with appropriate expertise in suicide prevention, Zero Suicide model, epidemiology, health sciences, and program management.

B. Project Objectives, Work Plan, and Approach (45 Points)

a. Describe the goals and measure objectives of your proposed project and align them with the Statement of Need.

b. Describe how you will implement the Required Activities. Also describe how you will assess your activities, identify resources, and reassess recipient needs.

c. Provide a work plan depicting a realistic timeline for the first year of the project period showing dates, key activities, and responsible staff. These key activities should include the requirements.

C. Program Evaluation (15 Points)

Applicants need to clearly demonstrate the ability to collect and report on required data associated with this project and lead all aspects of the cross-site program evaluation. Provide specific information on the development of the annual data report for this program and how such data will be used to manage, monitor, and enhance the program.

a. Define the criteria to be used to evaluate activities listed in the work plan under the Required Activities.

b. Explain the methodology that will be used to determine if the needs identified for the objectives are being met and if the outcomes identified are being achieved. Be explicit about how the logic model relates to the objectives and activities.

c. Explain how the applicant will lead the cross-recipient site organization evaluation activities.

D. Organizational Capabilities, Key Personnel, and Qualifications (15 Points)

a. Explain both the management and administrative structure of the organization, including documentation of current certified financial management systems from the Bureau of Indian Affairs, IHS, or a Certified Public Accountant, and an updated organizational chart.

b. Describe the ability of the organization to manage a program of the proposed scope.

c. Provide position descriptions and biographical sketches of key personnel, including those of consultants or contractors. Position descriptions should very clearly describe each position and its duties, indicating desired qualification and experience requirements related to the project. Resumes should indicate that the proposed staff is qualified to carry out the project activities. Applicants must include an organizational chart.

d. The applicant must also demonstrate access to specialized expertise, such as a Masters level epidemiologist and/or a biostatistician. Applicants with expertise in epidemiology will receive priority.

E. Categorical Budget and Budget Justification (5 Points)

a. Provide a justification by line item in the budget including sufficient cost and other details to facilitate the determination of cost allowance and relevance of these costs to the proposed project. The funds requested should be appropriate and necessary for the scope of the project.

b. If use of consultants or contractors is proposed or anticipated, provide a detailed budget and scope of work that clearly defines the activities' outcomes anticipated.

Multi-Year Project Requirements

Applications must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov.* These can include:

- Work plan for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Rate Agreement.

- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS Office of Clinical and Preventive Services within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The Notice of Award (NoA) is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence, other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization, is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at *https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf.*
- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at *https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.*

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' at 45 CFR part 75 subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of IDC in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, ''any non-Federal entity (NFE) [*i.e.,* applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.''

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS recipients are negotiated with the Division of Cost Allocation at *https://rates.psc.gov/* or the Department of the Interior (Interior Business Center) at *https://ibc.doi.gov/ICS/tribal.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

3. Reporting Requirements

The recipient must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions,

and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the awardee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in Section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the period of performance.

B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at *https://pms.psc.gov.* Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the period of performance.

Recipients are responsible and accountable for reporting accurate information on all required reports: The Progress Reports, the Federal Cash Transaction Report, and the Federal Financial Report.

C. Data Collection and Reporting

The IHS will provide ZSI project data and any aggregate program statistics including associated community-level GPRA health care facility data available in the National Data Warehouse as needed.

Recipient will receive ZSI project site data reports and will be required to compile a cross-site evaluation that will include both qualitative and qualitative analysis. The project site data reports will include the following data points:

Treat

- Number of patient visits.
- Number of patients screened for suicide risk.
- Number of patients placed on suicide care pathway or registry.
- Number of patients hospitalized for suicide risk.
- Number of patients with safety plan.
- Number of patients counseled on access to lethal means.
- Number of approved ZSI Policies for Screening, Assessment, Safety-Planning, Means Restriction, Transfer, and Follow-up.
- Number of Protocol Guide of culturally informed practices and activities to be used with Evidence Based Practices (EBP).
- Number of Integrated Electronic Health Records (EHR).

Train

- Number of staff trained in EBP for Screening.
- Number of staff trained in EBP for Assessment.
- Number of staff trained in EBP for Treatment.
- Number of staff trained, number of trainings, type of trainings, and number of staff trained in each health care profession in evidence-based treatment of suicide risk.
- Number of staff that report feeling competent to deliver suicide care.
- Number of staff that report feeling confident to deliver suicide care.
- Number of patients who received a suicide screening during the reporting period.
- Number of staff using EBP to provide treatment of suicide risk.
- Number of staff incorporating culturally informed practices and activities with EBP.
- Number of culturally informed practices and activities used.
- Number of patients with a Safety Plan that receive follow-up within 8 hours of missed appointment.
- Number of patients who receive follow-up within 24 hours of inpatient emergency department visit.

Improve

- Existence of multidisciplinary ZSI Leadership Succession Team.
- Existence of Approved ZSI Policies for screening, assessment, safety-planning, means restriction, prescription, and follow-up.
- Protocol Guide of culturally informed practices and activities to be used with EBP.
- Existence of Integrated EHR.
- Existence of data collection and surveillance processes in place.
- Results from Organizational Self-Study.
- Results from the Workforce Survey (WFS).
- Existence of trained, competent staff as evidenced by results of WFS.
- Existence of approved Implementation Work Plan.

D. Post Conference Grant Reporting

The following requirements were enacted in Section 3003 of the Consolidated Continuing Appropriations Act, 2013, Public Law 113–6, 127 Stat. 198, 435 (2013), and; *Office of Management and Budget Memorandum M–17–08, Amending OMB Memorandum M–12–12:* All HHS/IHS awards containing grants funds allocated for conferences will be required to complete a mandatory post award report for all conferences. Specifically: The total amount of funds provided in this award/cooperative agreement that were spent for ''Conference X'' must be reported in final detailed actual costs within 15 calendar days of the completion of the conference. Cost categories to address should be: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration website, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, and (8) Other.

E. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at *https://www.ihs.gov/dgm/policytopics/.*

F. Non-Discrimination Legal Requirements of Federal Financial Assistance

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see *https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html* and *https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.*

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see *https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html* and *https://www.lep.gov.*
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see *https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.*
- HHS funded health and education programs must be administered in an environment free of sexual harassment. See *https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.*
- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see *https://www.hhs.gov/conscience/conscience-protections/index.html* and *https://www.hhs.gov/conscience/religious-freedom/index.html.*

G. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at *https://www.fapiis.gov* before making any award in excess of the simplified acquisition threshold (currently $250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants, as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. All applicants and recipients must disclose in writing, in a timely manner, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Paul Gettys, Acting Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857. (Include ''Mandatory Grant Disclosures'' in subject line), Office: (301) 443–5204, Fax: (301) 594–0899, Email: *Paul.Gettys@ihs.gov*

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: *https://oig.hhs.gov/fraud/report-fraud/.* (Include ''Mandatory Grant Disclosures'' in subject line), Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or, Email: *MandatoryGranteeDisclosures@oig.hhs.gov.*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: LCDR Monique Richards, MSW, LICSW, Public Health Advisor, Indian Health Service, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 08N70C, Rockville, MD 20857, Telephone: (240) 252–9625, Fax: (301) 443–5610, Email: *Monique.Richards@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Sheila Miller, Grants Management Specialist, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (240) 535–9308, Email: *Sheila.Miller@ihs.gov.*

3. Questions on systems matters may be directed to: Paul Gettys, Acting Director, Division of Grants Management, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, E-Mail: *Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

[FR Doc. 2022–07333 Filed 4–6–22; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Initial Review Group; Career Development for Clinicians/Health Professionals Study Section Career development for clinicians/health care professionals.

Date: June 6–7, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda, Gateway Building, 72001 Wisconsin Avenue, Bethesda, MD 20814 (Virtual Meeting).

Contact Person: Maurizio Grimaldi, Ph.D., MD, Scientific Review Officer, Scientific Review Branch, NIA (National Institute on Aging), GWY BG RM 2W200, 7201 Wisconsin Ave., Bethesda, MD 20892, 301–496–9374, *maurizio.grimaldi@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07386 Filed 4–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA DK21–017: NIDDK HIRN–HPAC.

Date: July 7, 2022.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07379 Filed 4–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Alzheimer's Disease Drug Development.

Date: May 26, 2022.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07384 Filed 4–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA DK21–029: NIDDK Diabetes Research Center (P30 Clinical Trial Optional).

Date: June 27–28, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology

and Hematology Research, National Institutes of Health, HHS)

Dated: April 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07377 Filed 4–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Muscular Dystrophy Coordinating Committee (MDCC).

The meeting will be open to the public. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Muscular Dystrophy Coordinating Committee.

Date: May 9, 2022.

Time: 1:00 p.m. to 5:00 p.m. EST.

Agenda: The purpose of this meeting is to bring together committee members, representing government agencies, patient advocacy groups, other voluntary health organizations, and patients and their families to update one another on progress relevant to the Action Plan for the Muscular Dystrophies and to coordinate activities and discuss gaps and opportunities leading to better understanding of the muscular dystrophies, advances in treatments, and improvements in patients' and their families' lives. The agenda for this meeting is available on the MDCC website: *https://www.mdcc.nih.gov/.*

Registration: To register, please go to: *https://roseliassociates.zoomgov.com/webinar/register/WN_-4KzEwSKRniqdjFz12Zh0A.*

Webcast Live: https://videocast.nih.gov/.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Glen Nuckolls, Ph.D., Program Director, National Institute of Neurological Disorders and Stroke (NINDS), NIH, 6001 Executive Blvd., Rm 2203, Bethesda, MD 20892, 301–496–5876, *MDCC@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

More information can be found on the Muscular Dystrophy Coordinating Committee home page: *https://mdcc.nih.gov/.*

Dated: April 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07380 Filed 4–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; High Priority HIV and Substance Use Research (R01 Clinical Trial Optional).

Date: May 3, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Trinh T. Tran, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5843, *trinh.tran@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Respiratory Safety Evaluations of Potential Medications for Opioid Overdose (8958).

Date: May 4, 2022.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–5702, *sindhu.kizhakkemadathil@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 1, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07388 Filed 4–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Drug Repositioning and Combination Therapy for AD.

Date: May 6, 2022.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer National, Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07385 Filed 4–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Biologics Contract Review.

Date: May 3, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Boulevard, Room 3205, MSC 9529, Bethesda, MD 20892, 301–496–9223, *joel.saydoff@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 1, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07387 Filed 4–6–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Cybersecurity Measures for Surface Modes

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0074, abstracted below, to OMB for an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. Specifically, the collection involves the submission of data concerning the designation of a Cybersecurity Coordinator; the reporting of cybersecurity incidents to the Cybersecurity and Infrastructure Security Agency (CISA); the development of a cybersecurity contingency/recovery plan to address cybersecurity gaps; and the completion of a cybersecurity assessment.

DATES: Send your comments by May 9, 2022. A comment to OMB is most effective if OMB receives it within 30 days of publication.

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 Review—Open for Public Comments'' and by using the find function.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology, TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on December 23, 2021, 86 FR 72988.

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

Title: Cybersecurity Measures for Surface Modes.

Type of Request: Extension.

OMB Control Number: 1652–0074.

Form(s): TSA Optional Forms. TSA Surface Cybersecurity Vulnerability Assessment Form.

Affected Public: Owner/Operators with operations that identified in 49 CFR part 1580 (Freight Rail), 49 CFR part 1582 (Mass Transit and Passenger Rail), and 49 CFR part 1584 (Over-the-Road Bus).

Abstract: Under the authorities of 49 U.S.C. 114, TSA may take immediate action to impose measures to protect transportation security without providing notice or an opportunity for comment.[1] On November 30, 2021, OMB approved TSA's request for emergency approval of the collections of information within Security Directive (SD) 1580–21–01, SD 1582–21–02, and an ''information circular'' (IC) all issued on December 2, 2021. The OMB approval allowed for the institution of mandatory reporting requirements under the SDs and collection of information voluntarily submitted under the IC. As OMB emergency approval is only valid for six months, TSA is now seeking renewal of this information collection for the maximum three-year approval period.

The cybersecurity threats to surface transportation infrastructure that necessitate these collections are consistent with TSA's mission, as well as TSA's responsibility and authority for ''security in all modes of transportation

[1] TSA issues security directives (SDs) for surface transportation operators under the statutory authority of 49 U.S.C. 114(l)(2)(A). This provision, from section 101 of the Aviation and Transportation Security Act (ATSA), Public Law 107–71 (115 Stat. 597; Nov. 19, 2001), states: ''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.''

. . . including security responsibilities . . . over modes of transportation that are exercised by the Department of Transportation.'' *See* 49 U.S.C. 114(d). The SDs require, and the IC recommends, the following security measures:

1. Designate a Cybersecurity Coordinator and alternate Cybersecurity Coordinator and provide contact information to TSA; these individuals are to be available to TSA 24/7 to coordinate cybersecurity practices, address any incidents that arise, and serve as a principal point of contact with TSA and CISA for cybersecurity-related matters;

2. Report cybersecurity incidents to CISA;

3. Develop a cybersecurity incident response plan to reduce the risk of operational disruption should an owner/operator's Information and/or Operational Technology systems be affected by a cybersecurity incident; and

4. Complete a cybersecurity vulnerability assessment to address cybersecurity gaps using the form provided by TSA and submit the form to TSA.

Number of Respondents: 781.

Estimated Annual Burden Hours: An estimated 96,163 hours annually.

Dated: April 4, 2022.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2022–07370 Filed 4–6–22; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2022–N015; FXES11130300000–201–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before May 9, 2022.

ADDRESSES: *Document availability and comment submission:* Submit requests for copies of the applications and related documents, as well as any comments, by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TEXXXXXX; see table in **SUPPLEMENTARY INFORMATION**):

- *Email: permitsR3ES@fws.gov.* Please refer to the respective application number (*e.g.,* Application No. TEXXXXXX) in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Nathan Rathbun, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Nathan Rathbun, 612–713–5343 (phone); *permitsR3ES@fws.gov* (email). 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.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications:

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
PER0036813	Adam Benshoff, Kent, OH	Roanoke logperch (*Percina rex*); 27 freshwater mussel species.	AL, AR, CT, DC, GA, IA, KS, KY, IL, IN, LA, MA, MD, MI, MN, MO, MS, NC, NE, NH, NJ, NY, OH, OK, PA, SC, TN, VA, VT, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release, and relocate due to stranding.	New.
ES28570D	Midwest Natural Resources, Inc., St. Paul, MN.	Add rusty patched bumble bee (*Bombus affinis*) to existing authorized species; Dakota skipper (*Hesperia dacotae*).	MN, WI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, and release	Amend.
TE60999A	Ohio Department of Natural Resources (Levi Miller), Logan, OH.	Indiana bat (*Myotis sodalis*) and northern long-eared bat (*M. septentrionalis*).	OH	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist nets and harp traps, handle, identify, radio-tag, band, collect non-intrusive measurements, release, enter hibernacula, and bio-sample.	Renew.
PER0037601	Jeremiah Van Deventer, Moneta, VA.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*M. septentrionalis*), and gray bat (*M. grisescens*).	AL, AR, CT, DE, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, NE, NH, NJ, NY, OH, OK, PA, RI, SC, TN, TX, VA, VT, WI, WV, WY.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist nets and harp traps, handle, identify, radio-tag, band, collect non-intrusive measurements, and release.	New.
PER0037956	Cory Murphy, Granger, IN	Indiana bat (*Myotis sodalis*), gray bat (*M. grisescens*), northern long-eared bat (*M. septentrionalis*), Virginia big-eared bat (*Corynorhinus townsendii virginianus*), and Ozark big-eared bat (*C. townsendii ingens*).	AL, AR, CO, CT, DE, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NY, OH, PA, RI, SD, SC, TN,UT, VA, VT, WI, WV, WY.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist nets and harp traps, enter hibernacula, handle, identify, radio-tag, band, collect non-intrusive measurements, and release.	New.
TE38842A	Sanders Environmental, Inc., Bellefonte, PA.	Indiana bat (*Myotis sodalis*) and northern long-eared bat (*M. septentrionalis*); Add gray bat (*M. grisescens*), Virginia big-eared bat (*Corynorhinus townsendii virginianus*), and Ozark big-eared bat (*C. townsendii ingens*).	AL, AR, CO, FL, GA, IA, IL, IN, KS, KY, LA, MI, MN, MO, MS, MT, NC, ND, NE, OK, OH, SC, SD, TN, UT, WI, WY.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist nets and harp traps, capture with hand nets, handle, identify, radio-tag, light-tag, band, collect non-intrusive measurements, mark, collect bio-samples, and release.	Amend.
TE38821A	Stantec Consulting Services, Inc. Louisville, KY.	Indiana bat (*Myotis sodalis*), gray bat (*M. grisescens*), northern long-eared bat (*M. septentrionalis*), Virginia big-eared bat (*Corynorhinus townsendii virginianus*), and Ozark big-eared bat (*C. townsendii ingens*); copperbelly water snake (*Nerodia erythrogaster neglecta*); Big Sandy crayfish (*Cambarus callainus*); relict darter (*Etheostoma chienense*), duskytail darter (*E. percnurum*), Kentucky arrow darter (*E. spilotum*), palezone shiner (*Notropis albizonatus*), blackside dace (*Phoxinus cumberlandensis*), pallid sturgeon (*Scaphirhynchus albus*); 41 freshwater mussel species.	AL, AR, CO, CT, DE, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, NE, ND, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, TX, VA, VT, WI, WV, WY.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist nets and harp traps, enter hibernacula, handle, identify, radio-tag, band, collect non-intrusive measurements, collect intrusive samples, relocation, electrofish, and release.	Renew and Amend.
PER0037865	Mark Hove, Saint Paul, MN.	Higgins eye pearlymussel (*Lampsilis higginsii*), winged mapleleaf (*Quadrula fragosa*).	MN, WI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, transport, relocate due to stranding, and release.	New.
PER0037923	Thomas Estrem, Valparaiso, IN.	Clubshell (*Pleurobema clava*), snuffbox mussel (*Epioblasma triquetra*).	IL, IN, MI, MN, OH, WI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, relocate, and release.	New.

Public Availability of Comments

All comments we receive become part of the administrative record associated with this action. Requests for copies of comments will be handled in accordance with the Freedom of Information Act, National Environmental Policy Act, and Service and Department of the Interior policies and procedures. 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 to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services.

[FR Doc. 2022–07424 Filed 4–6–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2022–N226; FXES11130100000–223–FF01E00000]

Endangered Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation and survival of endangered species under the Endangered Species Act of 1973, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before May 9, 2022.

ADDRESSES:

Document availability and comment submission: Submit a request for a copy of the application and related documents and submit any comments by one of the following methods. All requests and comments should specify the applicant name and application number (*e.g.,* Dana Ross, ESPER0001705):

- *Email: permitsR1ES@fws.gov.*
- *U.S. Mail:* Marilet Zablan, Regional Program Manager, Restoration and Endangered Species Classification, Ecological Services, U.S. Fish and Wildlife Service, Portland Regional Office, 911 NE 11th Avenue, Portland, OR 97232–4181.

FOR FURTHER INFORMATION CONTACT: Colleen Henson, Regional Recovery Permit Coordinator, Ecological Services, (503) 231–6131 (phone); *permitsR1ES@fws.gov* (email). 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.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting, in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations (CFR) at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
ES146777	Arleone Dibben-Young, Kaunakakai, HI.	Hawaiian coot (*Fulica americana alai*), Hawaiian duck (*Anas wyvilliana*), Hawaiian stilt (*Himantopus mexicanus knudseni*).	Hawaii	Harass by capture, handle, band, mark, biosample, release, and salvage.	Renew.
PER0029891	Greenbelt Land Trust, Corvallis, OR.	Fender's blue butterfly (*Icaricia icarioides fenderi*).	Oregon	Harass by survey, capture, handle, release.	New.
PER0036534	Oregon Coast Aquarium, Newport, OR.	Hawksbill sea turtle (*Eretmochelys imbricata*), Leatherback sea turtle (*Dermochelys coriacea*), Loggerhead sea turtle (*Caretta caretta*).	Oregon	Harass through rehabilitation and transfer of stranded sea turtles.	New.

Application No.	Applicant, city, state	Species	Location	Take activity	Permit action
PER0008917	Institute for Applied Ecology, Corvallis, OR.	*Sidalcea oregana* var. *calva* (Wenatchee Mountains checkermallow).	Washington ..	Remove/reduce to possession—handle, collect seed, capture and release pollinators, and monitor.	Amend.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue a permit to an applicant listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Marilet A. Zablan,

Regional Program Manager for Restoration and Endangered Species Classification, Pacific Region.

[FR Doc. 2022–07366 Filed 4–6–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS01000 L5105.0000.EA0000 LVRCF220 22X MO#4500160529]

Notice of Temporary Closures of Public Lands for the 2022 Laughlin Off-Highway Vehicle Races, Clark County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closures.

SUMMARY: The Las Vegas Field Office announces the temporary closures of certain public lands under its administration. The off-highway vehicle (OHV) race area in Laughlin, Nevada, is used by OHV recreationists, and the temporary closures are needed to limit access to the race area and to minimize the risk of potential collisions with spectators and racers during two events: The 2022 Laughlin Desert Classic and the 2022 Southern Nevada Off Road Enthusiasts (SNORE) Laughlin Race.

DATES: The temporary closure for the 2022 Laughlin Desert Classic will take effect at 12:01 a.m. on October 22, 2022, and will remain in effect until 11:59 p.m. on October 23, 2022. The temporary closure for the 2022 SNORE Laughlin Race will take effect at 12:01 a.m. on December 10, 2022, and will remain in effect until 11:59 p.m. on December 11, 2022.

ADDRESSES: The temporary closure order, communications plan, and map of the temporary closure area for each event will be posted at the BLM Las Vegas Field Office, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130, and on the BLM website: *www.blm.gov.* These materials will also be posted at the access point of the Laughlin race area and surrounding areas.

FOR FURTHER INFORMATION CONTACT: Jenna Giddens, Outdoor Recreation Planner, (702) 515–5156, or *jgiddens@blm.gov.* 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.

SUPPLEMENTARY INFORMATION: This action is being taken to help ensure public safety during the official permitted running of the 2022 Laughlin Desert Classic and 2022 SNORE Laughlin Off-Highway Vehicle Races. The public lands affected by this closure are described as follows:

Mount Diablo Meridian, Nevada

T. 32 S., R. 66 E.,
Sec. 8, lots 2 thru 33;
Sec. 9;
Sec. 10, S½NE¼, S½NW¼, and S½;
Sec. 11, S½NE¼, S½NW¼, and S½;
Sec. 14;
Sec. 15, E½;
Sec. 16, N½, SW¼, and N½SE¼;
Sec. 17, lots 1 thru 8, lots 21 thru 25, and lots 30 thru 44.

The area described contains 4521.97 acres, according to the official plats of the surveys of the said lands on file with the BLM.

The temporary closures will be posted to roads leading into the public lands to notify the public of the closures for these events. The closures area includes State Route 163 to the north, T. 32 S. R. 66 E sections 8 and 17 to the west; private and State land in T. 32 S. R. 66 E sections 20, 21, 22, and 23; and is bracketed by Bruce Woodbury Drive to the south and southwest and Thomas Edison Drive to the east. Under the authority of Section 303(a) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 733(a)), 43 CFR 8360.0–7 and 43 CFR 8364.1), the BLM will enforce the following rules in the area described above:

The entire area as listed in the legal description above is closed to all vehicles and personnel except law enforcement, emergency vehicles, event personnel, event participants, and spectators. Access routes leading to the closed area will be signed to indicate a closure ahead. No vehicle stopping or parking in the closed area except for designated parking areas will be permitted. Event participants and spectators are required to remain within designated areas only.

The BLM will enforce the following restrictions for the duration of the closure to ensure the public safety of participants and spectators. Unless otherwise authorized, the following activities within the closure area are prohibited:

- Camping;
- Possession or consumption of any alcoholic beverage by a person under the age of 21 years;
- Discharging or use of firearms or other weapons;
- Possession or discharging of fireworks;
- Allowing any pet or other animal in one's care to be unrestrained at any time. Animals must be on a leash or other restraint no longer than 3 feet;
- Operation of any vehicle that is not legally registered for street and highway operation (*e.g.,* All Terrain Vehicles, motorcycles, Utility Terrain Vehicles, golf carts, and any OHV, including operation of such a vehicle in spectator viewing areas);

• Parking any vehicle in violation of posted restrictions, or in such a manner as to obstruct or impede normal or emergency traffic movement or the parking of other vehicles, create a safety hazard, or endanger any person, property, or feature. Vehicles so parked are subject to citation, removal, and impoundment at the owner's expense;

• Operating a vehicle through, around, or beyond a restrictive sign, recognizable barricade, fence, or traffic control barrier or device;

• Failing to maintain control of a vehicle to avoid danger to persons, property, or wildlife; and

• Operating a motor vehicle without due care or at a speed greater than 25 mph.

Signs and maps directing the public to designated spectator areas will be provided by the event sponsor.

Exceptions: Temporary closure restrictions do not apply to activities conducted under contract with the BLM, agency personnel monitoring the event, or activities conducted under an approved plan of operation. Authorized users must have in their possession a written permit or contract from the BLM, signed by the authorized officer.

Enforcement: Any person who violates this temporary closure may be tried before a United States Magistrate and fined in accordance with 18 U.S.C. 3571, imprisoned no more than 12 months under 43 U.S.C. 1733(a) and 43 CFR 8360.0–7, or both. In accordance with 43 CFR 8365.1–7, State or local officials may also impose penalties for violations of Nevada law.

(Authority: 43 CFR 8360.0–7 and 8364.1)

Shonna Dooman,

Field Manager—Las Vegas Field Office.

[FR Doc. 2022–07422 Filed 4–6–22; 8:45 am]

BILLING CODE 4310–HC–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–681 and 731–TA–1591 (Preliminary)]

White Grape Juice Concentrate From Argentina; Institution of Anti-Dumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–681 and 731–TA–1591 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of white grape juice concentrate from Argentina, provided for in subheading 2009.69.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of Argentina. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by May 16, 2022. The Commission's views must be transmitted to Commerce within five business days thereafter, or by May 23, 2022.

DATES: March 31, 2022.

FOR FURTHER INFORMATION CONTACT: Ahdia Bavari (202–205–3191), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on March 31, 2022, by Delano Growers Grape Products, LLC, Delano, California.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission is conducting the staff conference through video conferencing on April 21, 2022. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before April 19, 2022. Please provide an email address for each conference participant in the email. Information on conference procedures will be provided separately and guidance on joining the video conference will be available on the Commission's Daily Calendar. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

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 paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before

April 26, 2022, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than noon on April 20, 2022. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations 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 these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: April 4, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07420 Filed 4–6–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1195]

Certain Electronic Candle Products and Components Thereof; Notice of a Commission Determination To Review a Remand Initial Determination; Extension of the Target Date

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in its entirety the remand initial determination (''RID'') issued on December 29, 2021, finding that Complainants failed to establish the economic prong of the domestic industry requirement in the above-referenced section 337 investigation. The Commission also extends the target date to June 6, 2022.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3042. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 *https://www.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: On April 6, 2020, the Commission instituted this investigation based on a complaint filed by complainants L&L Candle Company LLC of Brea, California and Sotera Tschetter, Inc. of St. Paul, Minnesota (together, ''Complainants''). 85 FR 19158–59 (Apr. 6, 2020). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 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 certain electronic candle products and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 8,550,660; 9,366,402; 9,512,971; 9,523,471; and 10,533,718. *Id.* The notice of investigation named as respondents: The Gerson Company of Olathe, Kansas; Gerson International (H.K.) Ltd. of Hong Kong; Sterno Home Inc. of Coquitlam, Canada; Ningbo Huamao International Trading Co., Ltd. of Ningbo City, China; Ningbo Yinzhou Langsheng Artware Co., Ltd of Ningbo City, China; Lifetime Brands, Inc. of Garden City, New York; Scott Brothers Entertainment, Inc. of Las Vegas, Nevada; Nantong Ya Tai Candle Arts & Crafts Co., Ltd. of San Gabriel, California; NapaStyle, Inc. of Napa, California; Veraflame International, Inc. of Vancouver, Canada (''Veraflame''); MerchSource, LLC of Irvine, California; Ningbo Mascube Import Export Company of Ningbo City, China (''Ningbo Mascube''); Decorware International Inc. dba Decorware Inc. of Rancho Cucamonga, California; Shenzhen Goldenwell Smart Technology Co., Ltd. of Shenzhen City, China; Shenzhen Ksperway Technology Co., Ltd. of Shenzhen City, China; Ningbo Shanhuang Electric Appliance Co. of Ningbo City, China (''Ningbo Shanhuang''); Yiwu Shengda Art Co., Ltd. of Yiwu City, China (''Yiwu Shengda''); Shenzhen Tongfang Optoelectronic Technology Co., Ltd. of Shenzhen City, China; TFL Candles of Shenzhen City, China; Guangdong Tongfang Lighting Co., Ltd. of Hong Kong; Tongfang Optoelectronic Company of Hong Kong; and Virtual Candles Limited of Kent, United Kingdom (''Virtual Candles''). *Id.* at 19159. The Office of Unfair Import Investigations (''OUII'') was also named as a party to the investigation. *Id.*

Of the twenty-two respondents, five were terminated based on consent orders, eight were terminated based on settlement agreements, three were terminated based on a voluntary withdrawal of the complaint due to an inability to serve, and one was terminated based on a summary determination of no importation. The Commission found the following five remaining respondents in default for failing to respond to the complaint and notice of investigation and for failing to show cause why they had not done so, or for failing to participate in discovery: Veraflame, Ningbo Mascube, Ningbo Shanhuang, Yiwu Shengda, and Virtual Candles (''the Defaulting Respondents'').

On November 13, 2020, Complainants moved for a summary determination of violation as to the Defaulting Respondents and for a recommendation for the issuance of a general exclusion order. On December 4, 2020, OUII filed a response that questioned whether Complainants had satisfied the economic prong of the domestic industry requirement, but otherwise supported a finding of violation of section 337 and issuing a general

exclusion order. On April 2, 2021, the ALJ issued an initial determination (''ID''), Order No. 41, granting Complainants' motion for summary determination of violation by each of the five Defaulting Respondents. Order No. 41 (Apr. 2, 2021).

On May 19, 2021, the Commission determined on its own motion to review the ID's finding that Complainants satisfied the economic prong of the domestic industry requirement. 86 FR 28143–46 (May 25, 2021). On August 13, 2021, the Commission vacated the findings in the ID on the economic prong of the domestic industry requirement and remanded the investigation to the then Chief Administrative Law Judge (''ALJ'') for the issuance of a remand initial determination.

On December 29, 2021, the then Chief ALJ issued the subject RID, finding that Complainants failed to establish the economic prong of the domestic industry requirement. On January 20, 2022, Complainants filed a petition for review of the RID. On January 28, 2022, OUII filed a response to Complainants' petition.

Having examined the record of this investigation, including the RID, the petition for review, and the response thereto, the Commission has determined to review the RID in its entirety.

The Commission does not request additional briefing from the parties. The target date is extended to June 6, 2022.

The Commission vote for this determination took place on April 1, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: April 1, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07354 Filed 4–6–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1587–1590 (Preliminary)]

Certain Preserved Mushrooms From France, Netherlands, Poland, and Spain; Institution of Antidumping Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping duty investigation Nos. 731–TA–1587–1590 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of certain preserved mushrooms from France, Netherlands, Poland, and Spain, provided for in subheading 2003.10.01 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping duty investigations in 45 days, or in this case by May 16, 2022. The Commission's views must be transmitted to Commerce within five business days thereafter, or by May 23, 2022.

DATES: March 31, 2022.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones (202) 205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)), in response to petitions filed on March 31, 2022, by Giorgio Foods, Inc., Blandon, Pennsylvania.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigation and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission is conducting the staff conference through video conferencing on Thursday, April 21, 2022. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before Tuesday, April 19, 2022. Please provide an email address for each conference participant in the email. Information on conference procedures will be provided separately and guidance on joining the video conference will be available on the Commission's Daily Calendar. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

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 paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before April 26, 2022, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than noon on April 20, 2022. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations 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 these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: April 1, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07353 Filed 4–6–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1264]

In the Matter of Certain High-Potency Sweeteners, Processes for Making Same, and Products Containing Same; Notice of a Commission Determination Not To Review an Initial Determination Granting Summary Determination of No Violation of Section 337; Terminating the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 29) of the presiding administrative law judge granting summary determination of no violation of section 337. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Benjamin S. Richards, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5453. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 *https://www.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 instituted this investigation on May 14, 2021. 86 FR 26544–45 (May 14, 2021). The complaint, as supplemented, was filed by complainants Celanese International Corporation of Irving, Texas; Celanese (Malta) Company 2 Limited of Qormi, Malta; and Celanese Sales U.S. Ltd. of Irving, Texas (collectively ''Celanese'') and alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain high-potency sweeteners, processes for making same, and products containing same by reason of infringement of certain claims of U.S. Patent No. 10,023,546, U.S. Patent No. 10,208,004, U.S. Patent No. 10,590,098, U.S. Patent No. 10,233,163, and U.S. Patent No. 10,590,095. *Id.* The complaint further alleged that a domestic industry exists. *Id.* The Commission's notice of investigation named twelve respondents, including Anhui Jinhe Industrial Co., Ltd. and Jinhe USA LLC (''Jinhe''). *Id.* On August 6, 2021, the Chief Administrative Law Judge (''CALJ'') issued an ID granting a motion by Celanese to add eleven additional respondents to the investigation. Order No. 14, *unreviewed by* Comm'n Notice (Aug. 23, 2021). On August 26, 2021, Celanese filed an amended complaint adding the eleven additional respondents. The Office of Unfair Import Investigations (''OUII'') is also participating in this investigation. 86 FR at 26544.

On September 2, 2021, respondent Jinhe filed a motion for summary determination of no violation based on the contention that all of the asserted patent claims that Celanese relied on to satisfy the technical prong of the domestic industry requirement are invalid under the ''on-sale bar'' provisions of 35 U.S.C. 102(a)(1). On September 13, 2021, Celanese filed a brief in opposition. OUII filed a brief in support of Jinhe's motion on the same day. The CALJ held oral argument on Jinhe's motion on September 28, 2021.

The CALJ issued the subject ID granting Jinhe's motion on January 11, 2022. Specifically, the ID found that the on-sale bar applied to invalidate all of the remaining claims that Celanese relied on to establish a domestic industry. Accordingly, the ID found that the investigation should be terminated with a finding of no violation of section 337 due to Celanese's inability to satisfy the domestic industry requirement of section 337. Celanese petitioned for review of the ID on January 21, 2022. Jinhe and OUII submitted responses opposing Celanese's petition on January 28, 2022.

Having examined the record of this investigation, including the ID, the petition for review, and the responses thereto, the Commission has determined not to review the ID. This investigation is terminated in its entirety.

The Commission vote for this determination took place on April 1, 2022.

While temporary remote operating procedures are in place in response to COVID–19, the Office of the Secretary is not able to serve parties that have not

retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant(s) complete service for any party/parties without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 1, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07352 Filed 4–6–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1282]

Certain Tunable Lenses and Products Containing the Same; Notice of the Commission's Determination Not To Review an Initial Determination Terminating the Investigation on the Basis of Settlement; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 13) terminating the investigation on the basis of settlement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 *https://www.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 instituted this investigation on October 28, 2021, based on a complaint filed by Holochip Corporation of Torrance, California. 86 FR 59757–58 (Oct. 28, 2021). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain tunable lenses and products containing the same by reason of infringement of certain claims of U.S. Patent No. 8,064,142; U.S. Patent No. 8,605,361; U.S. Patent No. 8,665,527; and U.S. Patent No. 9,442,225. The complaint, as amended, further alleged that a domestic industry exists. The notice of investigation named as respondents Optotune AG of Dietikon, Switzerland, and Edmund Optics, Inc. of Barrington, New Jersey. *Id.*

On March 7, 2022, the private parties filed a joint motion to terminate the investigation based on settlement. On March 10, 2022, the presiding ALJ issued Order No. 13, granting the joint motion. The ALJ determined that the motion complied with Commission Rule, 210.21(b), 19 CFR 210.21(b). The ALJ also determined that there is no evidence that termination of this investigation would adversely affect the public interest. No one petitioned for review of the ID.

The Commission has determined not to review the ID. The investigation is terminated.

The Commission vote for this determination took place on April 1, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 1, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07350 Filed 4–6–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1563 (Final)]

Raw Honey From Ukraine; Termination of Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: On March 24, 2022, counsel for petitioners, the American Honey Producers Association and the Sioux Honey Association, filed with the Department of Commerce and the Commission a withdrawal of their petition regarding imports of raw honey from Ukraine. Accordingly, the antidumping duty investigation concerning raw honey from Ukraine (Investigation No. 731–TA–1563 (Final)) is terminated.

DATES: March 31, 2022.

FOR FURTHER INFORMATION CONTACT: Andres Andrade (202–205–2078), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. 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 (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

Authority: This investigation is being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to 19 U.S.C. 1673c(a)(1)(A) and section 207.40(a) of the Commission's rules (19 CFR 207.40(a)). This notice is published pursuant to section 201.10 of the Commission's rules (19 CFR 201.10).

By order of the Commission.

Issued: April 1, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07351 Filed 4–6–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1310]

Certain Interactive Fitness Products Including Stationary Exercise Bikes, Treadmills, Elliptical Machines, and Rowing Machines and Components Thereof; Notice of 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 March 3, 2022, under section 337 of the Tariff Act of 1930, as amended, on behalf of Peloton Interactive, Inc. of New York, New York. A supplement to the complaint was filed on March 21, 2022. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain interactive fitness products including stationary exercise bikes, treadmills, elliptical machines, and rowing machines and components thereof by reason of infringement of certain claims of U.S. Patent No. 11,170,886 (''the '886 Patent''); U.S. Pat. No. 7,938,755 (''the '755 Patent''); U.S. Patent No. 11,183,288 (''the '288 Patent''); U.S. Patent No. 11,145,399 (''the '399 Patent''); and U.S. Pat. No. 10,864,406 (''the '406 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: Katherine Hiner, Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2021).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on April 1, 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, 3–15, 17, 19, 20–22 of the '886 Patent; claims 1, 2, 5–7, 8, 9 of the '755 Patent; claims 1, 2–24, 25, 26–29 of the '288 Patent; claims 1, 2–3, 5–13, 16–17, 19–20, 21, 22–28 of the '399 Patent; and claims 11, 12, 14, 15, 16 of the '406 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 ''stationary bikes, treadmills, elliptical machines, and rowing machines used with interactive fitness programs or containing an air dam'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Peloton Interactive, Inc., 441 9th Avenue, 6th Floor, New York, NY 10001.

(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:

ICON Fitness Corp., 1500 South 1000 West, Logan, UT 84321

IHF Holdings Inc., 1500 South 1000 West, Logan, UT 84321

iFIT Inc. (FKA ICON Health & Fitness, Inc.), 1500 South 1000 West, Logan, UT 84321

NordicTrack, Inc., 1500 South 1000 West, Logan, UT 84321

Free Motion Fitness, Inc., 1500 South 1000 West, Logan, UT 84321

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not be named as a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), 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.

Issued: April 1, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07355 Filed 4–6–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Pistoia Alliance, Inc.

Notice is hereby given that, on December 8, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Pistoia Alliance, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade

Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Semalytix GmbH, Bielefeld, GERMANY; Schrodinger, Portland, NY; SAGE Therapeutics, Cambridge, MA; Rapid Novor, Waterloo, CANADA; Matador Japan KK, Nagano, JAPAN; Claire Bellamy (individual member), Leicestershire, UNITED KINGDOM; Chitrita Goswami (individual member), New Delhi, INDIA; Eurofins Discovery, St. Charles, MO; Centre for Process Innovation, Wilton, UNITED KINGDOM; and Artificial Inc., Palo Alto, CA have been added as parties to this venture.

Also, WorldQuant Predictive, New York, NY; telic, New York, NY; Synthace Ltd, London, UNITED KINGDOM; Sapio Sciences, Baltimore, MD; PHEMI Systems Corp., Vancouver, CANADA; Mcule, Budapest, HUNGARY; GenAIz, Montreal, CANADA; and Apheris AI GmbH, Berlin, GERMANY have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Pistoia Alliance, Inc. intends to file additional written notifications disclosing all changes in membership.

On May 28, 2009, Pistoia Alliance, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 15, 2009 (74 FR 34364).

The last notification was filed with the Department on September 12, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on October 5, 2021 (86 FR 55002).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2022–07339 Filed 4–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–988]

Bulk Manufacturer of Controlled Substances Application: Purisys, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Purisys, LLC. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTAL INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before June 6, 2022. Such persons may also file a written request for a hearing on the application on or before June 6, 2022.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on January 21, 2022, 1550 Olympic Drive, Athens, Georgia 30601–1602, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Gamma Hydroxybutyric Acid	2010	I
Lysergic acid diethylamide	7315	I
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
2,5-Dimethoxyamphetamine	7396	I
3,4-Methylenedioxy amphetamine.	7400	I
5-Methoxy-3,4-methylenedioxy amphetamine.	7401	I
3,4-Methylenedioxy methamphetamine.	7405	I
5-Methoxy-N-N-dimethyl tryptamine.	7431	I
Diethyltryptamine	7434	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
Codeine-N-oxide	9053	I
Dihydromorphine	9145	I
Hydromorphinol	9301	I
Morphine-N-oxide	9307	I
Normorphine	9313	I
Norlevorphanol	9634	I
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Levorphanol	9220	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium tincture	9630	II
Opium, powdered	9639	II
Opium, granulated	9640	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to bulk manufacture the listed controlled substances for internal use intermediates or for sale to its customers. The company plans to manufacture the above-listed controlled substances as clinical trial and starting materials to make compounds for distribution to its customers. No other activities for these drug codes are authorized for this registration.

Matthew J. Strait,

Deputy Assistant Administrator.

[FR Doc. 2022–07368 Filed 4–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB 1140–0092]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Voluntary Magazine Questionnaire for Agencies/ Entities That Store Explosive Materials

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection (IC) is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until June 6, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection

instrument with instructions, or additional information, contact: Anita Scheddel, Program Analyst, Firearms and Explosives Industry Division, Explosives Industry Programs Branch, Mailstop 6N–518, either by mail at 99 New York Ave. NE, Washington, DC 20226, by email at *eipbinformationcollection@atf.gov,* or by telephone at (202) 648–7120.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the 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;
—Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Extension without Change of a Currently Approved Collection.

2. *The Title of the Form/Collection:* Voluntary Magazine Questionnaire for Agencies/Entities That Store Explosive Materials.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: State, Local or Tribal Government.

Other (if applicable): None.

Abstract: This information collection is used to identify the number and locations of public explosives storage facilities (magazines), which will enable Bureau of Alcohol, Tobacco, Firearms and Explosives personnel to respond properly to local emergencies such as natural disasters.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1,000 respondents will respond to this collection once annually, and it will take each respondent approximately 30 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 500 hours, which is equal to 1,000 (total respondents) * 1 (# of response per respondent) * .5 (30 minutes or the time taken to prepare each response).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3.E–405A, Washington, DC 20530.

Dated: April 4, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–07440 Filed 4–6–22; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0335]

Agency Information Collection Activities; Proposed Collection Comments Requested; Extension Without Change, of a Previously Approved Collection National Motor Vehicle Title Information System (NMVTIS)

AGENCY: Bureau of Justice Assistance, Department of Justice.

ACTION: 60-Day Notice.

SUMMARY: The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until June 6, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Gregory Joy, Policy Advisor, Office of Justice Programs, Bureau of Justice Assistance, 810 Seventh Street NW, Washington, DC 20531 *Gregory.joy@usdoj.gov*, 202–514–1369.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the National Motor Vehicle Title Information System (NMVTIS), including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of currently approved collection.

2. *The Title of the Form/Collection:* National Motor Vehicle Title Information System (NMVTIS).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Auto recyclers, junk yards and salvage yards are required to report information into NMVTIS. The Anti-Car Theft Act, defines junk and salvage yards ''as individuals or entities engaged in the business of acquiring or owning junk or salvage automobiles for resale in their entirety or as spare parts or for rebuilding, restoration, or crushing.'' Included in this definition are scrap-vehicle shredders and scrap-metal processors, as well as ''pull- or pick-apart yards,'' salvage pools, salvage auctions, and other types of auctions, businesses, and individuals that handle

salvage vehicles (including vehicles declared a ''total loss'').

Abstract: Reporting information on junk and salvage vehicles to the National Motor Vehicle Title Information System (NMVTIS)—supported by the U.S. Department of Justice (DOJ)—is required by federal law. Under federal law, junk and salvage yards must report certain information to NMVTIS on a monthly basis. This legal requirement has been in place since March 2009, following the promulgation of regulations (28 CFR part 25) to implement the junk- and salvage-yard reporting provisions of the Anti-Car Theft Act (codified at 49 U.S.C. 30501—30505). Accordingly, a junk or salvage yard within the United States must, on a monthly basis, provide an inventory to NMVTIS of the junk or salvage automobiles that it obtained (in whole or in part) in the prior month. 28 CFR 25.56(a).

An NMVTIS Reporting Entity includes any individual or entity that meets the federal definition, found in the NMVTIS regulations at 28 CFR 25.52, for a ''junk yard'' or ''salvage yard.'' According to those regulations, a junk yard is defined as ''an individual or entity engaged in the business of acquiring or owning junk automobiles for—(1) Resale in their entirety or as spare parts; or (2) Rebuilding, restoration, or crushing.'' The regulations define a salvage yard as ''an individual or entity engaged in the business of acquiring or owning salvage automobiles for—(1) Resale in their entirety or as spare parts; or (2) Rebuilding, restoration, or crushing.'' These definitions include vehicle remarketers and vehicle recyclers, including scrap vehicle shredders and scrap metal processors as well as ''pull- or pick-apart yards,'' salvage pools, salvage auctions, used automobile dealers, and other types of auctions handling salvage or junk vehicles (including vehicles declared by any insurance company to be a ''total loss'' regardless of any damage assessment). Businesses that operate on behalf of these entities or individual domestic or international salvage vehicle buyers, sometimes known as ''brokers'' may also meet these regulatory definitions of salvage and junk yards. It is important to note that industries not specifically listed in the junk yard or salvage yard definition may still meet one of the definitions and, therefore, be subject to the NMVTIS reporting requirements.

An individual or entity meeting the junk yard or salvage yard definition is subject to the NMVTIS reporting requirements if that individual or entity handles 5 or more junk or salvage motor vehicles per year and is engaged in the business of acquiring or owning a junk automobile or a salvage automobile for—''(1) Resale in their entirety or as spare parts; or (2) Rebuilding, restoration, or crushing.'' Reporting entities can determine whether a vehicle is junk or salvage by referring to the definitions provided in the NMVTIS regulations at 28 CFR 25.52. An NMVTIS Reporting Entity is required to report specific information to NMVTIS within one month of receiving such a vehicle, and failure to report may result in assessment of a civil penalty of $1,000 per violation.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are currently approximately 8,000 businesses that report on a regular basis into NMVTIS. The estimate for the average amount of time for each business to report varies: 30–60 minutes (estimated). The states and insurance companies already are capturing most of the data needed to be reported, and the reporting consists of electronic, batch uploaded information. So, for those automated companies the reporting time is negligible. For smaller junk and salvage yard operators who would enter the data manually, it is estimated that it will take respondents an average of 30–60 minutes per month to respond.

6. *An estimate of the total public burden (in hours) associated with the collection:* An estimate of the total public burden (in hours) associated with the collection is 48,000 to 96,000 hours.

Total Annual Reporting Burden:

8,000 × 30 minutes per month (12 times per year) = 48,000

8,000 × 60 minutes per month (12 times per year) = 96,000

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 1, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–07327 Filed 4–6–22; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Justice Programs Office

[OMB Number 1121–0259]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Previously Approved Collection

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until June 6, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Gregory Joy, Policy Advisor, Office of Justice Programs, Bureau of Justice Assistance, 810 Seventh Street NW, Washington, DC 20531, *Gregory.joy@usdoj.gov,* 202–514–1369. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Assistance, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension, without change, of a currently approved collection.

2. T*he Title of the Form/Collection:* Public Safety Officer Medal of Valor (Pub. L. 107–12).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

The nomination process is managed through the internet, using the Office of Justice Programs' (OJP) MOV online nomination system at: *https://www.bja.gov/programs/medalofvalor/index.html.*

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* The information that is being collected is solicited from federal, state, local and tribal public safety agencies, who wish to nominate their personnel to receive the Public Safety Officer Medal of Valor (MOV). This information is provided on a voluntary basis, includes agency and nominee information along with details about the events for which the nominees are to be consider when determining who will be recommended to receive the MOV.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Over the last four application submission periods, (2014–2015 thru 2017–2018), there were a total of 550 nominations received. Taking this number into account, the average number of nominations that are anticipated to be received on an annual basis is 137.5. This number does not factor in the ongoing outreach efforts (*e.g.* marketing and social media outreach) that are intended to increase the number of annual submissions. In addition, it is projected that the application submission process takes approximately 25 minutes. This would include, reviewing the fields of required and optional information, arranging the information and populating the online application form.

6. *An estimate of the total public burden (in hours) associated with the collection:* Base upon the average number of submissions over the last 4 years, and the estimated time required to complete each submission, the estimated annual public burden would be 53.54 hours.

a. 137.5 × 25 minutes = 3,437.5 minutes/60 = 57.29 hours

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 1, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–07328 Filed 4–6–22; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Justice Programs Office

[OMB Number 1121–0352]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Previously Approved Collection

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until June 6, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Tom Talbot, Senior Policy Advisor, Office of Justice Programs, Bureau of Justice Assistance, 810 Seventh Street NW, Washington, DC 20531,*Thomas.Talbot@usdoj.gov,* 202–514–9482. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Assistance, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* National Standards to Prevent, Detect, and Respond to Prison Rape (28 CFR Part 115).

3. *The agency form number:* There is no form number associated with this information collection. The applicable component within the Department of Justice is the Bureau of Justice Assistance, in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* On June 20, 2012, the Department of Justice published a Final Rule to adopt national standards to prevent, detect, and respond to sexual abuse in confinement settings pursuant to the Prison Rape Elimination Act of 2003 (PREA), 34 U.S.C. 30305. These national standards, which went into effect on August 20, 2012, require covered facilities to retain certain specified information relating to sexual abuse prevention planning, responsive planning, education and training, investigations and to collect and retain certain specified information relating to allegations of sexual abuse within the facility. Covered facilities include: Federal, state, and local jails, prisons, lockups, community correction facilities, and juvenile facilities, whether administered by such government or by a private organization on behalf of such government. As the agency responsible for PREA implementation on behalf of the U.S. Department of Justice, the Bureau of Justice Assistance within the Office of Justice Programs is submitting this request to extend a currently approved collection.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The recordkeeping and reporting requirements established by the PREA standards are based on incidents of sexual abuse. An estimated 13,119 covered facilities nationwide are required to comply with the PREA

standards. If all covered facilities were to fully comply with all of the PREA standards, the new burden hours associated with the staff time that would be required to collect and maintain the information and records required by the standards would be approximately 1.16 million in the first year of full compliance, or about 89 hours per facility.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden hours associated with this collection is 1.16 million in the first year of full compliance, or about 89 hours per facility.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 1, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–07326 Filed 4–6–22; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Affordable Care Act Advance Notice of Rescission

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before May 9, 2022.

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.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 2712 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act, and the Departments' final regulations (26 CFR 54.9815–2712, 29 CFR 2590.715–2712, 45 CFR 147.2712), provide rules regarding rescissions of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, generally must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. The rescission notice will be used by health plans to provide advance notice to certain individuals that their coverage may be rescinded. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 13, 2021 (86 FR 70866).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Affordable Care Act Advance Notice of Rescission.

OMB Control Number: 1210–0141.

Affected Public: Private Sector—Businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 100.

Total Estimated Number of Responses: 1,744.

Total Estimated Annual Time Burden: 19 hours.

Total Estimated Annual Other Costs Burden: $230.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: April 1, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–07364 Filed 4–6–22; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Summary of Benefits and Coverage and Uniform Glossary Required Under the Affordable Care Act

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before May 9, 2022.

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.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of

the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Affordable Care Act amended the Public Health Service Act (PHS Act) by adding section 2715 ''Development and Utilization of Uniform Explanation of Coverage Documents and Standardized Definitions.'' This section directed the Department of Labor (DOL), the Department of Health and Human Services (HHS), and the Department of the Treasury (collectively, the Departments), in consultation with the National Association of Insurance Commissioners (NAIC) and a working group comprised of stakeholders, to develop standards for use by a group health plan and a health insurance issuer in compiling and providing to applicants, enrollees, policyholders, and certificate holders a summary of benefits and coverage (SBC) explanation that accurately describes the benefits and coverage under the applicable plan or coverage. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 13, 2021 (86 FR 70866).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Summary of Benefits and Coverage and Uniform Glossary Required Under the Affordable Care Act.

OMB Control Number: 1210–0147.

Affected Public: Private Sector—Businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 2,007,766.

Total Estimated Number of Responses: 80,182,298.

Total Estimated Annual Time Burden: 313,490 hours.

Total Estimated Annual Other Costs Burden: $7,605,988.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: April 1, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–07361 Filed 4–6–22; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Standard Job Corps Contractor Information Gathering

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before May 9, 2022.

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.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Economic Opportunity Act established Job Corps in 1964, and it currently operates under the authority of the Workforce Innovation and Opportunity Act (WIOA) of 2014. Sections 116(b)(2)(A)(i), 159(c)(4), and 156(a) of WIOA authorize this information collection. Most information collection requirements placed on Job Corps operators stem directly from operational needs, or are necessary to ensure compliance with Federal performance reporting requirements and the terms of their contract or grant. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 19, 2021 (86 FR 64959).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Standard Job Corps Contractor Information Gathering.

OMB Control Number: 1205–0219.

Affected Public: Private Sector—Businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 2,550.

Total Estimated Number of Responses: 277,298.

Total Estimated Annual Time Burden: 83,640 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: April 1, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–07362 Filed 4–6–22; 8:45 am]

BILLING CODE 4510–FT–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Affordable Care Act Grandfathered Health Plan Disclosure, Recordkeeping Requirement, and Change in Carrier Disclosure

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before May 9, 2022.

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.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 1251 of the Affordable Care Act (Act) provides that certain plans and health insurance coverage in existence as of March 23, 2010, known as grandfathered health plans, are not required to comply with certain statutory provisions in the Act. To maintain its status as a grandfathered health plan, plans must maintain records documenting the terms of the plan in effect on March 23, 2010, and any other documents that are necessary to verify, explain, or clarify status as a grandfathered health plan. The plan must make such records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a State or Federal agency official. The implementing regulations require a grandfathered health plan to include a statement in any plan material provided to participants or beneficiaries stating the plan's intent to be a grandfathered health plan within the meaning of the Act. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 13, 2021 (86 FR 70866).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Affordable Care Act Grandfathered Health Plan Disclosure, Recordkeeping Requirement, and Change in Carrier Disclosure.

OMB Control Number: 1210–0140.

Affected Public: Private Sector—Businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 360,479.

Total Estimated Number of Responses: 8,868,468.

Total Estimated Annual Time Burden: 655 hours.

Total Estimated Annual Other Costs Burden: $125,533.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: April 1, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–07363 Filed 4–6–22; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Consumer Expenditure Surveys: Quarterly Interview and Diary

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of Labor Statistics (BLS)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before May 9, 2022.

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.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Consumer Expenditure (CE) Surveys collect data on consumer expenditures, demographic information, and related data needed by the Consumer Price Index (CPI) and other public and private data users. The continuing surveys provide a constant measurement of changes in consumer expenditure patterns for economic analysis and to obtain data for future CPI revisions. The CE Surveys have been ongoing since 1979. The data from the CE Surveys are used (1) for CPI revisions, (2) to provide a continuous flow of data on income and expenditure patterns for use in economic analysis and policy formulation, and (3) to provide a flexible consumer survey vehicle that is available for use by other Federal Government agencies. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 25, 2022 (87 FR 3841).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–BLS.

Title of Collection: Consumer Expenditure Surveys: Quarterly Interview and Diary.

OMB Control Number: 1220–0050.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 11,250.

Total Estimated Number of Responses: 48,650.

Total Estimated Annual Time Burden: 39,733 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: April 1, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–07365 Filed 4–6–22; 8:45 am]

BILLING CODE 4510–24–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94578; No. SR–NYSEArca–2022–20]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

April 1, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on March 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 fees and credits relating to Complex Orders. The Exchange proposes to implement the fee change effective April 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 modify fees and credits for electronic Complex Orders. Specifically, the Exchange proposes to (1) establish a surcharge applicable to electronic Non-Customer Complex Orders that execute against a Customer Complex Order, as well as discounts available on such surcharge, and (2) introduce credits on electronic executions of Customer Complex interest against Non-Customer Complex interest. The Exchange proposes to implement the rule change on April 1, 2022.

Non-Customer Complex Surcharge

Currently, the Exchange charges a per contract transaction fee based on whether the trade participant is a Customer or Non-Customer, and whether the trade is in a Penny Issue or a Non-Penny Issue.[4]

The Exchange now proposes to establish a surcharge of $0.12 per contract that would be applied to an electronic Non-Customer Complex Order that executes against a Customer Complex Order (the ''Non-Customer Complex Surcharge''). The Exchange notes that the proposed Non-Customer Complex Surcharge is consistent with similar surcharges imposed by other option exchanges.[5]

The Exchange also proposes to offer two alternative discounts on the Non-Customer Complex Surcharge. OTP Holders and OTP Firms (collectively, ''OTP Holders'') that achieve ADV from Non-Customer posted interest in all issues other than SPY [6] equal to at least 0.10% of TCADV from Non-Customer posting would earn a $0.05 per contract discount on the Non-Customer Complex Surcharge. OTP Holders may earn a $0.07 per contract discount applied to the Non-Customer Complex Surcharge by achieving either at least 1.50% of

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Fee Schedule, ELECTRONIC COMPLEX, ORDER EXECUTIONS, TRANSACTION FEE—PER CONTRACT.

[5] *See, e.g.,* NYSE American Options Fee Schedule, Section I.A. (Rates for Options transactions), footnote 5 (assessing $0.12 per contract surcharge to any Electronic Non-Customer Complex Order that executes against a Customer Complex Order); MIAX Options Fee Schedule, Sections 1)a)i)–ii) (assessing a $0.12 per contract surcharge for trading against a Priority Customer Complex Order for Penny and Non-Penny classes).

[6] SPY is the symbol for the SPDR S&P 500 ETF Trust.

TCADV from Customer posted interest in all issues or at least 0.75% of TCADV in Complex executions from all account types. OTP Holders may earn the greater of the discounts for which they qualify.

Customer Complex Credit Tiers

The Exchange also proposes to introduce new credits applicable to electronic executions of Customer Complex interest against Non-Customer Complex interest (the ''Customer Complex Credit Tiers''). OTP Holders would continue to receive a $0.39 credit for such executions in Penny issues and a $0.75 credit for such executions in non-Penny issues (as already set forth in the Fee Schedule) [7] and may qualify for enhanced credits across four tiers if they achieve volume levels based on percentages of TCADV from Complex executions from all account types, as outlined in the table below. The proposed credits would not apply to Customer Complex Orders executed against individual orders in the Consolidated Book, but volume from Complex Orders that execute against individual orders would count towards the qualification basis for the Customer Complex Credit Tiers. The Exchange notes that the proposed credits are similar in structure to incentives relating to Customer Complex Orders offered by other options exchanges.[8]

Tier	Qualification basis (average electronic executions per day)		Credit applied to electronic executions of customer complex interest against non-customer complex interest	
			Penny	Non-penny
Base			($0.39)	($0.75)
Tier 1	At least 0.40% of TCADV from Complex executions, all account types.		(0.41)	(0.77)
Tier 2	At least 0.60% of TCADV from Complex executions, all account types, or	At least 2.75% of TCADV from Customer posted interest in all issues and 2.75% of TCADV from Professional Customer and Non-Customer taking volume.	(0.44)	(0.80)
Tier 3	At least 0.75% of TCADV from Complex executions, all account types.		(0.49)	(0.85)
Tier 4	At least 1.00% of TCADV from Complex executions, all account types.		(0.50)	(0.90)

The Exchange also proposes an alternative qualification for Tier 2. An OTP holder that meets at least 2.75% of TCADV from Customer posting volume in all issues and at least 2.75% of TCADV from Professional Customer and Non-Customer taking volume would also qualify for the credits offered in Tier 2.

Finally, the Exchange proposes that existing Endnotes 8 and 15 in the Fee Schedule would apply to the Customer Complex Credit Tiers. Endnote 8 provides that the calculations for qualifications for monthly posting credits or discounts only include electronic executions and the Exchange will include the activity of either (i) affiliates or (ii) an Appointed OFP or Appointed MM, per Endnote 15. Endnote 15 in turn provides for the inclusion of transaction volume from an OTP Holder's or OTP Firm's affiliates or its Appointed OFP or Appointed MM.[9]

The Exchange believes that the proposed Non-Customer Complex Surcharge, the proposed discounts on the Non-Customer Complex Surcharge, and the proposed Customer Complex Credit Tiers would, on balance, incent OTP Holders to direct Complex Orders (and, in particular, Customer Complex Orders), to the Exchange, thereby creating more trading opportunities for all market participants.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[11] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[13] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in February 2022, the Exchange had less than 14% market share of executed volume of multiply-listed equity and ETF options trades.[14]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants

[7] *See* note 4, *supra.*

[8] *See, e.g.,* Nasdaq ISE, Options 7 Pricing Schedule, Section 4. Complex Order Fees and Rebates (providing for tiered rebates on Priority Customer Complex orders based on qualifying Complex Order volume); Cboe EDGX Options Exchange Fee Schedule (providing for tiered rebates on Customer Complex orders based on qualifying Complex Order volume).

[9] An ''Appointed MM'' is an NYSE Arca Market Maker that has been designated by an Order Flow Provider (''OFP'') (as defined in NYSE Arca Rule 6.1A–O(a)(21)). An ''Appointed OFP'' is an OFP that has been designated by an NYSE Arca Market Maker.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[13] 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.*

[14] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of ETF-based options, *see id.,* the Exchange's market share in equity-based options increased from 10.74% for the month of February 2021 to 13.99% for the month of February 2022.

can shift order flow or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees.

The Exchange believes that the proposed changes are reasonably designed to incent OTP Holders to increase the amount of Customer interest sent to the Exchange, especially posted interest and Complex Order interest. An increase in Customer volume would create more trading opportunities for all market participants and would in turn attract Non-Customer activity to the Exchange. A resulting increase in Non-Customer activity may facilitate tighter spreads, which may lead to an additional increase of order flow from other market participants, further contributing to a deeper, more liquid market to the benefit of all market participants.

The proposed Non-Customer Complex Surcharge is reasonable because it is designed to offset costs associated with the proposed credits on Customer Complex executions offered in the Customer Complex Credit Tiers, which are intended to attract more Customer Complex Orders to the Exchange. To the extent this purpose is achieved, the Exchange believes that the Non-Customer Complex Surcharge would not disincentivize Non-Customer Complex activity because increased Customer Complex order flow would benefit Non-Customers as well by providing more opportunities to trade. The proposed discounts on the Non-Customer Complex Surcharge are also reasonably designed to incent OTP Holders (and their affiliates) to transact more options volume on the Exchange and to provide OTP Holders with an opportunity to decrease the surcharge on electronic Non-Customer Complex Orders that execute against a Customer Complex Order. The resulting increase in volume and liquidity would benefit all market participants by providing more trading opportunities and tighter spreads and may lead to a corresponding increase in order flow from other market participants. The Exchange also believes that the Non-Customer Complex Surcharge, as proposed, is reasonable because it is consistent with similar surcharges imposed by other options exchanges.[15]

The proposed Customer Complex Credit Tiers are reasonably designed to encourage increased Complex Order executions and are similar in structure to incentive programs relating to Customer Complex executions offered by competing options exchanges.[16] The Exchange also believes that the proposed credits, which are intended to attract more Customer Complex Orders to the Exchange, are reasonable because increased Customer volume would in turn provide more opportunities to trade for Non-Customers.

To the extent the proposed rule change continues to attract greater volume and liquidity by encouraging OTP Holders (and their affiliates) to increase their options volume on the Exchange in an effort to achieve the proposed discounts offered on the Non-Customer Complex Surcharge and/or the proposed Customer Complex Credit Tiers, the Exchange believes the proposed changes would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors.

The 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 because it is based on the amount and type of business transacted on the Exchange, and OTP Holders can opt to try to earn the Non-Customer Complex Surcharge discounts or achieve the Customer Complex Credit Tiers or not. The Exchange also believes that the proposed Non-Customer Complex Surcharge is equitable because it is designed to balance costs associated with encouraging Customer Complex Order flow to the Exchange, and an increase in such orders would in turn enhance trading opportunities for Non-Customers. The Exchange further believes that the proposed changes are equitably designed to provide credits to OTP Holders that transact more options volume on the Exchange, and, with respect to the Non-Customer Complex Surcharge, would mitigate the impact of the proposed fee.

Moreover, the proposal is designed to incent OTP Holders to aggregate all Customer posting interest at the Exchange as a primary execution venue and to attract more Complex Order executions on the Exchange. To the extent that the proposed change attracts more Complex Order interest to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes it is not unfairly discriminatory to impose a surcharge on Non-Customer Complex executions against Customer Complex interest because the proposed modification, along with the proposed discounts, would apply to all Non-Customers equally, and as discussed above, the Exchange believes it is not unfairly discriminatory to incent Customer order flow, which would enhance liquidity on the Exchange to the benefit of all market participants. The Exchange also believes that the proposed Customer Complex Credit Tiers are not unfairly discriminatory because they would be available to all similarly-situated market participants on an equal and non-discriminatory basis.

The proposal is based on the amount and type of business transacted on the Exchange, and OTP Holders are not obligated to try to achieve the enhanced qualifications. Rather, the proposal is designed to encourage OTP Holders to utilize the Exchange as a primary trading venue for Customer Complex interest (if they have not done so previously). To the extent that the proposed change attracts more Complex interest from all account types to the Exchange, and, in particular, more Customer Complex interest, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

[15] *See* note 5, *supra.*

[16] *See* note 8, *supra.*

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [17]

Intramarket Competition. The proposed change is designed to attract additional order flow (particularly Complex interest) to the Exchange. The Exchange believes that the proposed surcharge on Non-Customer Complex executions against Customer interest, the proposed discounts to the Non-Customer Complex Surcharge, and the proposed Customer Complex Credit Tiers would, on balance, incent OTP Holders to direct their Complex Orders to the Exchange. Greater liquidity benefits all market participants on the Exchange and increased Complex order flow would increase opportunities for execution of other trading interest. The proposed modifications would apply and be available to all similarly-situated market participants that execute Complex interest, and, accordingly, the proposed changes would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[18] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in February 2022, the Exchange had less than 14% market share of executed volume of multiply-listed equity & ETF options trades.[19]

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees in a manner designed to continue to incent OTP Holders to direct trading interest (particularly Complex interest and Customer posted interest) to the Exchange, to provide liquidity and to attract order flow. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently apply a similar surcharge or offer similarly structured Customer Complex incentives,[20] by encouraging additional orders to be sent to the Exchange for execution.

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) [21] of the Act and subparagraph (f)(2) of Rule 19b–4 [22] 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) [23] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2022–20 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–2022–20. 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–2022–20, and

[17] *See* Reg NMS Adopting Release, *supra* note 12, at 37499.

[18] *See* note 13, *supra.*

[19] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of ETF-based options, see id., the Exchange's market share in equity-based options increased from 10.74% for the month of February 2021 to 13.99% for the month of February 2022.

[20] *See* notes 5 & 8, *supra.*

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(2).

[23] 15 U.S.C. 78s(b)(2)(B).

should be submitted on or before April 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07337 Filed 4–6–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94573; File No. SR–Phlx–2022–14]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 4 of the Pricing Schedule

April 1, 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 March 22, 2022, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Phlx's Pricing Schedule at Options 7, Section 4, ''Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY).''

Additionally, the Exchange proposes to make a technical amendment and add descriptions of three additional terms within Options 7, Section 1, General Provisions.

The Exchange originally filed SR–Phlx–2022–08 on March 1, 2022. On March 10, 2022, the Exchange withdrew SR–Phlx–2022–08 and submitted SR–Phlx–2022–12. On March 22, 2022, the Exchange withdrew SR–Phlx–2022–12 and submitted this filing.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx proposes to amend its Pricing Schedule within Options 7, Section 4, ''Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY).'' Specifically, Phlx proposes to decrease the Professional[3] Floor[4] Options Transaction Charges[5] in multiply-listed Penny and non-Penny Symbols. Additionally, the Exchange proposes amendments to Options 7, Section 1, General Provisions. Each change is described below.

Options 7, Section 4

Today, the Exchange assesses Options Transaction Charges in Multiply Listed options, including options overlying equities, ETFs, ETNs and indexes and excluding options in SPY. The Exchange currently assesses the following Floor Options Transaction Charges in multiply-listed Penny and non-Penny Symbols: $0.25 per contract for a Professional, $0.35 per contract for a Floor Lead Market Maker[6] and Floor Market Maker,[7] and $0.25 per contract for a Broker-Dealer[8] and Firm.[9] Customers[10] are not assessed an Options Transaction Charge in multiply-listed Penny or non-Penny Symbols.

The Exchange proposes to decrease the Floor Options Transaction Charges for Professionals in multiply-listed Penny and non-Penny Symbols from $0.25 to $0.05 per contract. The Exchange believes the decreased Options Transaction Charges will attract a greater amount of Professional orders to Phlx's Trading Floor.

Options 7, Section 1

The Exchange proposes to make a technical amendment within Options 7, Section 1, General Provisions. The Exchange proposes to remove the words ''on and'' from description of ''Market Maker'' within Options 7, Section 1(c). Those words are not necessary. The amended description of Market Maker would state, ''The term 'Market Maker' is defined in Options 1, Section 1(b)(28) as a member of the Exchange who is registered as an options Market Maker pursuant to Options 2, Section 12(a). A Market Maker includes SQTs and RSQTs as well as Floor Market Makers.''

The Exchange proposes to add three additional descriptions to Options 7, Section 1(c). Specifically, the Exchange

[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78a.

[2] 17 CFR 240.19b–4.

[3] The term ''Professional'' applies to transactions for the accounts of Professionals, as defined in Options 1, Section 1(b)(45) means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Phlx's Pricing Schedule at Options 7, Section 1(c).

[4] The term ''floor transaction'' is a transaction that is effected in open outcry on the Exchange's Trading Floor. *See* Phlx's Pricing Schedule at Options 7, Section 1(c).

[5] Floor transaction fees apply to any ''as of'' or ''reversal'' adjustments for manually processed trades originally submitted electronically or through FBMS. *See* Phlx's Pricing Schedule at Options 7, Section 4, footnote 8.

[6] The term ''Floor Lead Market Maker'' is a member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a) and has a physical presence on the Exchange's trading floor. *See* Options 8, Section 2(a)(3).

[7] A Floor Market Maker is a Market Maker who is neither an SQT or an RSQT. A Floor Market Maker may provide a quote in open outcry. *See* Options 8, Section 2(a)(4).

The term ''Streaming Quote Trader'' or ''SQT'' is defined in Options 1, Section 1(b)(54) as a Market Maker who has received permission from the Exchange to generate and submit option quotations electronically in options to which such SQT is assigned. *See* Phlx's Pricing Schedule at Options 7, Section 1(c). The term ''Remote Streaming Quote Trader'' or ''RSQT'' is defined in Options 1, Section 1(b)(49) as a Market Maker that is a member affiliated with an RSQTO with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in options to which such RSQT has been assigned. A Remote Streaming Quote Trader Organization or ''RSQTO,'' which may also be referred to as a Remote Market Making Organization (''RMO''), is a member organization in good standing that satisfies the RSQTO readiness requirements in Options 2, Section 1(a). *See* Phlx's Pricing Schedule at Options 7, Section 1(c).

[8] The term ''Broker-Dealer'' applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category. *See* Phlx's Pricing Schedule at Options 7, Section 1(c).

[9] The term ''Firm'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC. *See* Phlx's Pricing Schedule at Options 7, Section 1(c).

[10] The term ''Customer'' applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of a broker or dealer or for the account of a ''Professional'' (as that term is defined in Options 1, Section 1(b)(45)). *See* Phlx's Pricing Schedule at Options 7, Section 1(c).

proposes to define the terms ''Floor Broker,'' ''Floor Lead Market Maker,'' and ''Floor Market Maker.'' These terms are currently defined within Options 8, Section 2(a)(2)–(4). The Exchange proposes to add these terms to Options 7, Section 1(c) for greater transparency when referencing the Pricing Schedule.

- The Exchange proposes to define a ''Floor Broker'' to mean an individual who is registered with the Exchange for the purpose, while on the Options Floor, of accepting and handling options orders.
- The Exchange proposes to define a ''Floor Lead Market Maker'' to mean a member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a) and has a physical presence on the Exchange's Trading Floor.
- The Exchange propose to define a ''Floor Market Maker'' to mean a Market Maker who is neither an SQT or an RSQT. A Floor Market Maker may provide a quote in open outcry.

The Exchange believes that these amendments to Options 7, Section 1 will bring greater clarity to the Pricing Schedule.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[12] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining 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.'' [13]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* [14] (''NetCoalition'') the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[15] As the court emphasized, the Commission ''intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost.'' [16]

Further, ''[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'. . . .'' [17] Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

Options 7, Section 4

The Exchange's proposal to decrease the Floor Options Transaction Charges for Professionals in multiply-listed Penny and non-Penny Symbols from $0.25 to $0.05 per contract is reasonable because the decreased fee should attract a greater amount of Professional orders to Phlx's Trading Floor. Today, BOX Exchange LLC (''BOX'') assesses a Professional Customer Fee of $0.10 per contract in Penny and Non-Penny Symbols for manual transactions.[18] By decreasing its Professional Floor Options Transaction Charge, the Exchange believes it will be able to compete more effectively with BOX for options order flow because of the lower Professional fee.

The Exchange's proposal to decrease the current Floor Options Transaction Charges for Professionals in multiply-listed Penny and non-Penny Symbols from $0.25 to $0.05 per contract is equitable and not unfairly discriminatory. Today, Customers are not assessed an Options Transaction Charge in multiply-listed Penny or non-Penny Symbols because Customer order flow is unique. Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Floor Lead Marker Makers and Floor Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The Exchange believes that lowering the Professional Floor Options Transaction Charges is similarly beneficial as the lower fees may cause market participants to select Phlx's Trading Floor as a venue to send Professional order flow, which benefits all market participants by attracting valuable liquidity to the market and thereby enhancing the trading quality and efficiency for all market participants.

Today, Floor Lead Market Makers and Floor Market Makers are assessed the highest Penny and non-Penny Options Transaction Charges. Customers are not assessed a Penny or non-Penny Options Transaction Charge. Today, Professionals, Broker-Dealers and Firms pay a Floor Options Transaction Charge of $0.25 per contract. With this proposal, Professionals would continue to be assessed a lower Options Transaction Charges in multiply-listed Penny and non-Penny Symbols as compared to Floor Lead Market Makers and Floor Market Makers. Floor Lead Market Makers and Floor Market Makers have a time and place advantage on the Trading Floor with respect to orders, unlike other market participants. A Professional, Broker-Dealer or a Firm would necessarily require a Floor Broker to represent their trading interest on the Trading Floor as compared to a Floor Lead Market Maker or Floor Market Maker that could directly transact such orders on the Trading Floor. Further, the Exchange believes that in order to attract orders from a Professionals, Broker-Dealers or a Firm, via a Floor Broker, the rates must be competitive with rates at other trading floors. With respect to Firms, the Exchange notes that Firms are subject to a Monthly Firm Fee Cap of $75,000. Firm Floor Option Transaction Charges along with Qualified Contingent Cross Transaction Fees, in the aggregate, for one billing month may not exceed the Monthly Firm Fee Cap per member organization when such members are trading in their own proprietary

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

[13] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[14] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[15] *See NetCoalition,* at 534–535.

[16] *Id.* at 537.

[17] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[18] In addition to the Professional fee of $0.10 per contract, BOX assesses the following Penny and Non-Penny Interval Classes manual transactions fees: $0.25 per contract to Broker Dealers and $0.35 per contract to Market Makers. BOX does not assess Public Customers or Broker Dealers facilitating a Public Customer a Penny and Non-Penny Interval Classes manual transactions fee. *See* BOX's Fee Schedule at Section II.

account.[19] Finally, with respect to Broker-Dealers, today the Exchange waives the Floor Options Transaction Charge for Broker-Dealers executing facilitation orders pursuant to Options 8, Section 30 when such members would otherwise incur this charge for trading in their own proprietary account contra to a Customer (''BD-Customer Facilitation''), if the member's BD-Customer Facilitation average daily volume (including both FLEX and non-FLEX transactions) exceeds 10,000 contracts per day in a given month.[20] The Exchange notes that both Firms and Broker-Dealers have the ability to reduce their Options Transaction Charges as compared to Professionals.

The Exchange believes it is equitable and not unfairly discriminatory to assess a Professional Floor Options Transaction Charge that is less favorable than Customers but more favorable than Firms, and Broker-Dealers and continue to assess a lower fee as compared to Floor Lead Market Makers, Floor Market Makers. Professionals have access to more information than Customers and therefore are being assessed a less favorable Options Transaction Charge[21] as compared to Customers. While Professionals may have the same technological and informational advantages as Broker-Dealers trading for their own account,[22] the Exchange believes that lowering the current Professional Floor Options Transaction Charges to range between that of a Customer and other non-Customer participants (Floor Lead Market Makers, Floor Market Makers, Firms, and Broker-Dealers) is equitable and not unfairly discriminatory because the potential increased volume would create better trading opportunities that benefit all market participants.[23] Specifically, greater volume and liquidity from increased order flow could create more trading opportunities and tighter spreads. Finally, assessing lower fees for Professional Customers compared to Floor Lead Market Makers, Floor Market Makers, Firms, and Broker-Dealers is not novel as BOX currently assesses lower fees for Professional Customers as compared to Broker Dealers and Market Makers.[24] Additionally, with respect to Qualified Contingent Cross Fees, Phlx currently assesses Customers and Professional no fee, while a Lead Market Maker, Market Maker, Firm and Broker-Dealer are assessed $0.20 per contract.[25]

Options 7, Section 1

The Exchange's proposal to amend the description of ''Market Maker'' within Options 7, Section 1(c) is consistent with the Act. The proposed non-substantive amendment removes unnecessary words.

The Exchange's proposal to define the terms ''Floor Broker,'' ''Floor Lead Market Maker,'' and ''Floor Market Maker'' within Options 7, Section 1(c) is consistent with the Act. The addition of these terms, which are currently defined within Options 8, Section 2(a)(2)–(4), will bring greater transparency to the Pricing Schedule.

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.

Inter-Market Competition

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants with another choice of where to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Moreover, the proposal is designed to encourage market participants to execute a greater amount of Professional orders on Phlx's Trading Floor. To the extent that the proposed change attracts additional Professional orders to Phlx's Trading Floor, this increased order flow would continue to make the Exchange a more competitive venue for order execution.

Intra-Market Competition

The proposed amendments do not impose an undue burden on intra-market competition.

The Exchange's proposal to decrease the Floor Options Transaction Charges for Professionals in multiply-listed Penny and non-Penny Symbols from

[19] *See* Options 7, Section 4, which states, ''Firms are subject to a maximum fee of $75,000 ('Monthly Firm Fee Cap'). Firm Floor Option Transaction Charges and QCC Transaction Fees, as defined in this section above, in the aggregate, for one billing month will not exceed the Monthly Firm Fee Cap per member organization when such members are trading in their own proprietary account. All dividend, merger, and short stock interest strategy executions (as defined in this Options 7, Section 4) will be excluded from the Monthly Firm Fee Cap. NDX, NDXP, and XND Options Transactions will be excluded from the Monthly Firm Fee Cap. Reversal and conversion, jelly roll and box spread strategy executions (as defined in this Options 7, Section 4) will be included in the Monthly Firm Fee Cap. QCC Transaction Fees are included in the calculation of the Monthly Firm Fee Cap. Member organizations must notify the Exchange in writing of all accounts in which the member is not trading in its own proprietary account. The Exchange will not make adjustments to billing invoices where transactions are commingled in accounts which are not subject to the Monthly Firm Fee Cap.''

[20] *See* Options 7, Section 4, which states, ''. . . In addition, the Broker-Dealer Floor Options Transaction Charge (including Cabinet Options Transaction Charges) will be waived for members executing facilitation orders pursuant to Options 8, Section 30 when such members would otherwise incur this charge for trading in their own proprietary account contra to a Customer ('BD-Customer Facilitation'), if the member's BD-Customer Facilitation average daily volume (including both FLEX and non-FLEX transactions) exceeds 10,000 contracts per day in a given month. NDX, NDXP, and XND Options Transactions will be excluded from each of the waivers set forth in the above paragraph.''

[21] Customers are not assessed Options Transaction Charges for multiply-listed options in Penny and non-Penny Symbols.

[22] A Professional by definition enters 390 orders per day on average over a calendar month which the Exchange believes exceeds the number of retail Customer orders in a single day.

[23] The Exchange notes that BOX assesses the same fees for Professionals and Broker-Dealers for non-auction transactions within Section I, A of BOX's Fee Schedule, PIP and COPIP transactions within Section I, B of BOX's Fee Schedule, Facilitation and Solicitation transactions within Section I, C of BOX's Fee Schedule, and Complex Orders within Section III, A of BOX's Fee Schedule. *See* BOX's Fee Schedule. BOX has stated in prior rule changes that, ''Professional Customers, while Public Customers by virtue of not being Broker Dealers, generally engage in trading activity more similar to Broker Dealer proprietary trading accounts (submitting more than 390 standard orders per day on average).'' *See* Securities Exchange Act Release No. 73547 (November 6, 2014), 79 FR 67520 at 67523 (November 13, 2014) (SR–BOX–2014–25) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Market LLC (''BOX'') Options Facility). Notwithstanding this justification, BOX assesses lower Professional manual transactions as compared to Broker-Dealers and Market Makers.

[24] BOX assess a Professional a manual fee of $0.10 per contract in Penny and Non-Penny Interval Classes, while assessing $0.25 per contract to Broker Dealers and $0.35 per contract to Market Makers for manual transactions in Penny and Non-Penny Interval Classes. *See* BOX's Fee Schedule at Section II.

[25] *See* Options 7, Section 4 which states, ''QCC Transaction Fees for a Lead Market Maker, Market Maker, Firm and Broker-Dealer are $0.20 per contract. Customers and Professionals are not assessed a QCC Transaction Fee. QCC Transaction Fees apply to electronic QCC Orders, as defined in Options 3, Section 12, and Floor QCC Orders, as defined in Options 8, Section 30(e).''

$0.25 to $0.05 per contract does not create an undue burden on competition. Today, Customers are not assessed an Options Transaction Charge in multiply-listed Penny or non-Penny Symbols because Customer order flow is unique. Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Floor Lead Marker Makers and Floor Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The Exchange believes that lowering the Professional Floor Options Transaction Charges is similarly beneficial as the lower fees may cause market participants to select Phlx's Trading Floor as a venue to send Professional order flow, which benefits all market participants by attracting valuable liquidity to the market and thereby enhancing the trading quality and efficiency for all market participants.

Today, Floor Lead Market Makers and Floor Market Makers are assessed the highest Penny and non-Penny Options Transaction Charges. Customers are not assessed a Penny or non-Penny Options Transaction Charge. Today, Professionals, Broker-Dealers and Firms pay a Floor Options Transaction Charge of $0.25 per contract. With this proposal, Professionals would continue to be assessed a lower Options Transaction Charges in multiply-listed Penny and non-Penny Symbols as compared to Floor Lead Market Makers and Floor Market Makers. Floor Lead Market Makers and Floor Market Makers have a time and place advantage on the Trading Floor with respect to orders, unlike other market participants. A Professional, Broker-Dealer or a Firm would necessarily require a Floor Broker to represent their trading interest on the Trading Floor as compared to a Floor Lead Market Maker or Floor Market Maker that could directly transact such orders on the Trading Floor. Further, the Exchange believes that in order to attract orders from a Professionals, Broker-Dealers or a Firm, via a Floor Broker, the rates must be competitive with rates at other trading floors. With respect to Firms, the Exchange notes that Firms are subject to a Monthly Firm Fee Cap of $75,000. Firm Floor Option Transaction Charges along with Qualified Contingent Cross Transaction Fees, in the aggregate, for one billing month may not exceed the Monthly Firm Fee Cap per member organization when such members are trading in their own proprietary account.[26] Finally, with respect to Broker-Dealers, today the Exchange waives the Floor Options Transaction Charge for Broker-Dealers executing facilitation orders pursuant to Options 8, Section 30 when such members would otherwise incur this charge for trading in their own proprietary account contra to a Customer (''BD-Customer Facilitation''), if the member's BD-Customer Facilitation average daily volume (including both FLEX and non-FLEX transactions) exceeds 10,000 contracts per day in a given month.[27] The Exchange notes that both Firms and Broker-Dealers have the ability to reduce their Options Transaction Charges as compared to Professionals.

Assessing a Professional Floor Options Transaction Charge that is less favorable than Customers but more favorable than Firms, and Broker-Dealers and continuing to assess a lower fee as compared to Floor Lead Market Makers, Floor Market Makers does not impose an undue burden on competition. Professionals have access to more information than Customers and therefore are being assessed a less favorable Options Transaction Charge [28] as compared to Customers. While Professionals may have the similar technological and informational advantages as Broker-Dealers trading for their own account,[29] the Exchange believes that lowering the current Professional Floor Options Transaction Charges to range between that of a Customer and other non-Customer participants (Floor Lead Market Makers, Floor Market Makers, Firms, and Broker-Dealers) does not impose an undue burden on competition because the potential increased volume would create better trading opportunities that benefit all market participants.[30] Specifically, greater volume and liquidity from increased order flow could create more trading opportunities and tighter spreads. Finally, assessing lower fees for Professional Customers compared to Floor Lead Market Makers, Floor Market Makers, Firms, and Broker-Dealers is not novel as BOX currently assesses lower fees for Professional Customers as compared to Broker Dealers and Market Makers.[31] Additionally, with respect to Qualified Contingent Cross Fees, Phlx currently assesses Customers and Professional no fee, while a Lead Market Maker, Market Maker, Firm and Broker- Dealer are assessed $0.20 per contract.[32]

Options 7, Section 1

The Exchange's proposal to amend the description of ''Market Maker'' within Options 7, Section 1 does not impose an undue burden on competition. The proposed non-substantive amendment removes unnecessary words.

The Exchange's proposal to define the terms ''Floor Broker,'' ''Floor Lead Market Maker,'' and ''Floor Market Maker'' within Options 7, Section 1(c) does not impose an undue burden on competition. The addition of these terms, which are currently defined within Options 8, Section 2(a)(2)–(4), will bring greater transparency to the Pricing Schedule.

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

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[33]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2022–14 on the subject line.

[26] *See* note 20 above.
[27] *See* note 21 above.
[28] *See* note 22 above.
[29] *See* note 23 above.
[30] *See* note 24 above.
[31] *See* note 25 above.
[32] *See* note 26 above.
[33] 15 U.S.C. 78s(b)(3)(A)(ii).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2022–14. 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–Phlx–2022–14, and should be submitted on or before April 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07340 Filed 4–6–22; 8:45 am]

BILLING CODE 8011–01–P

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94585; File No. SR–NYSE–2022–18]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Temporary Period for Specified Commentaries to Rules 7.35A and 7.35C and Temporary Rule Relief in Rule 36.30

April 1, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on March 29, 2022, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the temporary period for specified Commentaries to Rules 7.35A and 7.35C and temporary rule relief in Rule 36.30, to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on July 31, 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the temporary period for specified Commentaries to Rules 7.35A and 7.35C and temporary rule relief to Rule 36.30 to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on July 31, 2022. The current temporary period that these Rules are in effect ends on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on March 31, 2022.

Background

To slow the spread of COVID–19 through social-distancing measures, on March 18, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) that, beginning March 23, 2020, the Trading Floor facilities located at 11 Wall Street in New York City would close and the Exchange would move, on a temporary basis, to fully electronic trading.[4] On May 14, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) to reopen the Trading Floor on a limited basis on May 26, 2020 to a subset of Floor brokers, subject to safety measures designed to prevent the spread of COVID–19.[5] On June 15, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) to begin the second phase of the Trading Floor reopening by allowing DMMs to return on June 17, 2020, subject to safety measures designed to prevent the spread of COVID–19.[6] Consistent with these safety measures, both DMMs and Floor broker firms continue to operate with reduced staff on the Trading Floor.

Proposed Rule Change

Beginning in March 2020, the Exchange modified its rules to add Commentaries to Rules 7.35, 7.35A,

[4] Pursuant to Rule 7.1(e), the CEO notified the Board of Directors of the Exchange of this determination. The Exchange's current rules establish how the Exchange will function fully-electronically. The CEO also closed the NYSE American Options Trading Floor, which is located at the same 11 Wall Street facilities, and the NYSE Arca Options Trading Floor, which is located in San Francisco, CA. *See* Press Release, dated March 18, 2020, available here: *https://ir.theice.com/press/press-releases/all-categories/2020/03-18-2020-204202110.*

[5] *See* Securities Exchange Act Release No. 88933 (May 22, 2020), 85 FR 32059 (May 28, 2020) (SR–NYSE–2020–47) (Notice of filing and immediate effectiveness of proposed rule change).

[6] *See* Securities Exchange Act Release No. 89086 (June 17, 2020) (SR–NYSE–2020–52) (Notice of filing and immediate effectiveness of proposed rule change).

7.35B, and 7.35C and rule relief in Rule 36.30,[7] and has extended the expiration date of such Commentaries several times.[8] In July 2021, the Commission approved the Exchange's proposals to make permanent several of the rule changes that were the subject of those Commentaries.[9] The remaining Commentaries, specified below, are in effect until the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on March 31, 2022:

- Commentaries .01, .02, .03, .04, .05, and .07 to Rule 7.35A;
- Commentaries .01 and .02 to Rule 7.35C; and
- Amendments to Rule 36.30.

The first and second phases of the reopening of the Trading Floor are subject to safety measures designed to prevent the spread of COVID–19. To meet these safety measures, Floor brokers and DMM units that have chosen to return to the Trading Floor are operating with reduced staff. The Exchange is therefore proposing to extend Commentaries .01, .02, .03, .04, 05, and .07 to Rule 7.35A, Commentaries .01 and .02 to Rule 7.35C, and the amendments to Rule 36.30 until the earlier of July 31, 2022 or such time that there is a full reopening of the Trading Floor facilities to DMMs.

The Exchange is not proposing any substantive changes to these Rules.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

To reduce the spread of COVID–19, the CEO of the Exchange made a determination under Rule 7.1(c)(3) that beginning March 23, 2020, the Trading Floor facilities located at 11 Wall Street in New York City would close and the Exchange would move, on a temporary basis, to fully electronic trading. On May 14, 2020, the CEO made a determination under Rule 7.1(c)(3) that, beginning May 26, 2020, the Trading Floor would be partially reopened to allow a subset of Floor brokers to return to the Trading Floor. On June 15, 2020, the CEO made a determination under Rule 7.1(c)(3) that, beginning June 17, 2020, DMM units may choose to return a subset of staff to the Trading Floor.

The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system because the Trading Floor has not yet reopened in full to DMMs or Floor brokers. Accordingly, the Exchange believes that the temporary rule changes in effect pursuant to the Commentaries to Rules 7.35A and 7.35C and amendments to Rule 36.30, which are intended to be in effect during the temporary period while the Trading Floor has not yet opened in full to DMMs, should be extended until such time that there is a full reopening of the Trading Floor facilities to DMMs. The Exchange is not proposing any substantive changes to these Rules.

The Exchange believes that, by clearly stating that this relief will be in effect through the earlier of a full reopening of the Trading Floor facilities to DMMs or the close of the Exchange on July 31, 2022, market participants will have advance notice of the temporary period during which the Commentaries to Rules 7.35A and 7.35C and amendments to Rule 36.30 will be in effect.

B. Self-Regulatory Organization's Statement on Burden on Competition

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. The proposed rule change is not designed to address any competitive issues but rather would extend the period during which Commentaries .01, .02, .03, .04, 05, and .07 to Rule 7.35A; Commentaries .01 and .02 to Rule 7.35C; and amendments to Rule 36.30 will be in effect. These Commentaries are intended to be in effect during the temporary period while the Trading Floor has not yet been opened in full to DMMs and Floor brokers and are currently due to expire on March 31, 2022. Because the Trading Floor has not been opened in full to DMMs, the Exchange proposes to extend the

[7] *See* Securities Exchange Act Release Nos. 88413 (March 18, 2020), 85 FR 16713 (March 24, 2020) (SR–NYSE–2020–19) (amending Rule 7.35C to add Commentary .01); 88444 (March 20, 2020), 85 FR 17141 (March 26, 2020) (SR–NYSE–2020–22) (amending Rules 7.35A to add Commentary .01, 7.35B to add Commentary .01, and 7.35C to add Commentary .02); 88488 (March 26, 2020), 85 FR 18286 (April 1, 2020) (SR–NYSE–2020–23) (amending Rule 7.35A to add Commentary .02); 88546 (April 2, 2020), 85 FR 19782 (April 8, 2020) (SR–NYSE–2020–28) (amending Rule 7.35A to add Commentary .03); 88562 (April 3, 2020), 85 FR 20002 (April 9, 2020) (SR–NYSE–2020–29) (amending Rule 7.35C to add Commentary .03); 88705 (April 21, 2020), 85 FR 23413 (April 27, 2020) (SR–NYSE–2020–35) (amending Rule 7.35A to add Commentary .04); 88725 (April 22, 2020), 85 FR 23583 (April 28, 2020) (SR–NYSE–2020–37) (amending Rule 7.35 to add Commentary .01); 88950 (May 26, 2020), 85 FR 33252 (June 1, 2020) (SR–NYSE–2020–48) (amending Rule 7.35A to add Commentary .05); 89059 (June 12, 2020), 85 FR 36911 (June 18, 2020) (SR–NYSE–2020–50) (amending Rule 7.35C to add Commentary .04); 89086 (June 17, 2020), 85 FR 37712 (SR–NYSE–2020–52) (amending Rules 7.35A to add Commentary .06, 7.35B to add Commentary .03, 76 to add Supplementary Material 20, and Supplementary Material .30 to Rule 36); 89925 (September 18, 2020) (SR–NYSE–2020–75) (amending Rule 7.35 to add Commentary .02); and 90810 (December 29, 2020), 86 FR 335 (January 5, 2021) (SR–NYSE–2020–109) (amending Rule 7.35A to add Commentary .07).

[8] *See* Securities Exchange Act Release No. 93780 (December 14, 2021) 86 FR 72012 (December 20, 2021) (SR–NYSE–2021–71) (Notice of filing and immediate effectiveness of proposed rule change to extend the temporary period for specified Commentaries to Rules 7.35A and 7.35C and temporary rule relief in Rule 36.30 to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on March 31, 2022). *See also* Securities Exchange Act Release Nos. 89199 (June 30, 2020), 85 FR 40718 (July 7, 2020) (SR–NYSE–2020–56) (Notice of filing and immediate effectiveness of proposed rule change to extend the temporary period for Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C; Supplementary Material .20 to Rule 76; and temporary rule relief in Rule 36.30 to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on July 31, 2020); 89368 (July 21, 2020), 85 FR 45272 (July 27, 2020) (SR–NYSE–2020–61) (Notice of filing and immediate effectiveness of proposed rule change to lift the temporary suspension to Rule 76 and delete Supplementary Material .20 to Rule 76); 89425 (July 30, 2020), 85 FR 47446 (August 5, 2020) (SR–NYSE–2020–63) (extending the temporary period specified in Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C and Temporary Rule Relief in Rule 36.30 to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on September 30, 2020); 90005 (September 25, 2020), 85 FR 61999 (October 2020) (SR–NYSE–2020–78) (extending same to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020); 90795 (December 23, 2020), 85 FR 86608 (December 30, 2020) (SR–NYSE–2020–106) (extending same to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on April 30, 2021); 91778 (May 5, 2021) 86 FR 25902 (May 11, 2021) (SR–NYSE–2021–29) (extending same to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on August 31, 2021); and 92802 (August 30, 2021), 86 FR 49587 (September 3, 2021) (SR–NYSE–2021–46) (extending same to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2021).

[9] *See* Securities Exchange Act Release Nos. 92374 (July 9, 2021), 86 FR 37367 (July 15, 2021) (SR–NYSE–2020–89) (making permanent the rule changes specified in Commentary .03 to Rule 7.35C); 92373 (July 12, 2021), 86 FR 37779 (July 16, 2021) (SR–NYSE–2020–93) (making permanent the rule changes specified in Commentaries .01 and .02 to Rule 7.35); and 92480 (July 23, 2021), 86 FR 40885 (July 29, 2021) (SR–NYSE–2020–95) (making permanent certain rule changes specified in Commentaries .01 and .06 to Rule 7.35A and Commentaries .01 and .03 to Rule 7.35B).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

temporary period for these temporary rules to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on July 31, 2022.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[15] 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 so that the proposal may become operative immediately upon filing.

The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow the rules discussed above to remain in effect during the temporary period during which the Trading Floor has not yet been reopened in full to DMMs because of health precautions related to the Covid-19 pandemic. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[16]

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) [17] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2022–18 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–NYSE–2022–18. 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–NYSE–2022–18 and should be submitted on or before April 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07343 Filed 4–6–22; 8:45 am]

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[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78s(b)(2)(B).

[18] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94577; File No. SR–NSCC–2022–002]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make Certain Changes to Rule 52 to Support Processing of Interval Fund Repurchase Orders, Remove Underwriting Tender Offer Provisions and Make Certain Other Clarifications

April 1, 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 March 24, 2022, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) [3] of the Act and subparagraph (f)(4) [4] of Rule 19b–4 thereunder. 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

(a) The proposed rule change of National Securities Clearing Corporation (''NSCC'') is annexed hereto as Exhibit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

5 and consists of modifications to Rule 52 of the NSCC's Rules & Procedures (the ''Rules'') [5] to (i) make certain changes to support processing of interval fund repurchase orders, (ii) remove the underwriting/tender offer provisions which are no longer in use and (iii) re-number Rule 52 and make certain other clarifications. The proposed changes are described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change consists of modifications to Rule 52 of the Rules [6] to (i) make certain changes to support processing of interval fund repurchase orders, (ii) remove the underwriting/tender offer provisions which are no longer in use and (iii) re-number Rule 52 and make certain other clarifications. The proposed changes are described in greater detail below.

(i) Interval Fund Repurchase Orders

NSCC is proposing to enhance Rule 52 to support processing of future-dated interval fund repurchase orders by allowing NSCC Members [7] to submit orders prior to the day the order is intended to take place (''Trade Date'').

Interval Funds

Interval funds are closed-end funds that periodically offer to repurchase shares from their shareholders in compliance with Rule 23c–3 under the Investment Company Act of 1940.[8] Interval funds make periodic offers to buy back shares from shareholders as disclosed in the fund's prospectus and annual shareholder reports. Each offer will specify the repurchase period (start and end dates) during which the fund will accept shareholder repurchase requests to sell their shares back to the fund. The repurchase occurs on the last day of the repurchase period, or a later specified Trade Date.

Fund/SERV® Order Processing

NSCC Members can submit interval fund repurchase orders on behalf of shareholders to the Fund Members using Fund/SERV. Fund/SERV is an NSCC service described in Rule 52 that provides for processing and settling of Fund/SERV Eligible Funds,[9] which include certain mutual fund, bank collective fund and other pooled investment product transactions between fund companies, including interval funds, and their distributors.[10]

Currently, Fund/SERV does not allow NSCC Members to submit interval fund repurchase orders prior to the Trade Date. Fund/SERV currently allows NSCC Members to submit repurchase orders for interval funds that are Fund/SERV Eligible Funds by submitting a repurchase order on the Trade Date, or to the extent established by each Fund Member, any day thereafter (referred to as ''As-Of'' orders).[11]

In 2018, the Broker Dealer Advisory Committee of the Investment Company Institute formed an Interval Funds Task Force (''IFTF'') [12] to explore opportunities to improve interval fund operational efficiencies and reduce operating risk. The IFTF memorialized the operational challenges of interval funds in a series of whitepapers.[13] One of the challenges that the IFTF identified with respect to interval funds was the inability of funds to submit repurchase orders prior to the Trade Date through Fund/SERV.

Since NSCC Members are unable to submit the repurchase orders through Fund/SERV until the Trade Date, they must currently track all of the repurchase orders manually on their books until the applicable Trade Date. There is operational risk involved with holding these orders, rather than delivering them when received, including a risk that the NSCC Member holding the order fails to submit the order on the Trade Date. Likewise, interval fund providers would like to be informed of these orders as soon as possible, to help them understand liquidity demands and anticipate whether they may need to prorate repurchase activity and to provide more time to correct an order if it contains incorrect information. Therefore, there is an appreciable benefit to interval funds, shareholders, and intermediaries to improve the straight through processing capabilities for interval fund repurchases through Fund/SERV. NSCC is proposing to allow NSCC Members to submit orders prior to the Trade Date to support submission of interval fund repurchase orders. Such orders would be submitted prior to the Trade Date but dated as of the Trade Date.

NSCC is also proposing to amend the Rules to provide for an acknowledgment process by NSCC Members relating to interval fund repurchase orders. Currently, the Rules provide that NSCC Members may only confirm or reject orders [14] or accept, confirm or reject corrections of orders.[15] In order to provide NSCC Members confidence that their repurchase orders have been received, NSCC is proposing to allow NSCC Members that receive interval fund repurchase orders to acknowledge orders and corrections relating to interval fund repurchase orders, in addition to confirming and rejecting such orders or corrections.

NSCC is also proposing to extend the confirmation deadline to accommodate interval fund repurchase orders that are submitted prior to the Trade Date. Currently NSCC provides that if any orders are not confirmed or rejected within a certain time period established by NSCC from time to time (''Confirmation Deadline'') such orders will be deleted from the system.[16] NSCC has established that the Confirmation Deadline is 10 business days after the submission date. Since the submission date is currently on or after the Trade Date, the Confirmation Deadline is always at least 10 business days after the Trade Date. To accommodate repurchase orders that are submitted prior to the Trade Date, the acknowledgement process will provide that if an interval fund repurchase order with a future Trade Date is acknowledged prior to the Confirmation

[5] Capitalized terms not defined herein are defined in the Rules, *available at https://dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

[6] Rule 52, *id.*

[7] For purposes of this filing, ''NSCC Members'' shall mean Members and Limited Members.

[8] 17 CFR 270.23c–3.

[9] Fund/SERV Eligible Fund is defined as a fund or other pooled investment entity included in the list for which provision is made in Section 1.(c) of Rule 3. Definition of Fund/SERV Eligible Fund, Rule 1, *supra* note 5.

[10] *See* Part A of Rule 52, *supra* note 5.

[11] Part A, Section 2 of Rule 52, *supra* note 5.

[12] The Investment Company Institute is a trade association representing mutual funds, exchange-traded funds, closed-end funds and unit investment trusts. *See https://www.ici.org.* The members of the IFTF include fund companies offering interval funds, intermediaries, services providers and The Depository Trust & Clearing Corporation, NSCC's holding company.

[13] *See* Interval Funds: Operational Challenges and the Industry's Way Forward (*ici.org*) and Consider This: Interval Fund Operational Practices (*ici.org*).

[14] *See* Part A, Section 4 of Rule 52, *supra* note 5.

[15] *See* Part A, Section 8 of Rule 52, *supra* note 5.

[16] *See* Part A, Section 4 of Rule 52, *supra* note 5. Confirmation Deadline is not a defined term in the Rules and is being defined in this filing for ease of reference.

Deadline, the Confirmation Deadline will be extended to 10 business days after the Trade Date and the order will remain in the system until the extended Confirmation Deadline, provided the order was not previously confirmed or rejected. Therefore, as with other orders, the Confirmation Deadline would remain at least 10 business days after the Trade Date for such interval fund repurchase orders.

(ii) Removal of Underwriting/Tender Offer Provisions

In 1990 NSCC added provisions to Fund/SERV intended to support the processing of orders relating to mutual fund underwritings and tender offers (the ''Underwriting/Tender Offer Provisions'').[17] The provisions were intended to provide for automated processing of certain processes that were specific to underwritings and tender offers.[18] Previous to the addition, certain processes required manual intervention due to the extended settlement timeframe and ability to withdraw orders in underwritings and tender offers.[19] Forms and system developments were made to support the use of Underwriting/Tender Offer Provisions, and certain NSCC Members used the underwriting/tender offer functionality after it was implemented.

Over the years, however, NSCC Members began using the underwriting/tender offer functionality less and less. NSCC believes that this is likely due to enhancements to the non-underwriting/tender offer order functionality of Fund/SERV that reduced the need for the underwriting/tender offer functionality, NSCC Members becoming more familiar with the non-underwriting/tender offer functionality of Fund/SERV and finding that the non-underwriting/tender offer functionality of Fund/SERV is sufficient to process the orders relating to underwritings and tender offers. NSCC Members have not used the underwriting/tender offer functionality for over a decade and NSCC no longer provides online forms to support the full functionality due to lack of NSCC Member use of the functionality and costs to maintain the functionality. Given that the interval fund repurchase process is similar in some respects to the offer process for underwritings and tender offers, NSCC considered updating the underwriting/tender offer functionality to support interval fund repurchase orders. NSCC decided, however, that it would be more efficient to update the non-underwriting/tender offer order functionality of Fund/SERV to support interval fund repurchases as proposed in this filing rather than to overhaul the Underwriting/Tender Offer Provisions and the underwriting/tender offer functionality.

Since the Underwriting/Tender Offer Provisions are no longer being used by NSCC Members and NSCC does not believe that the Underwriting/Tender Offer Provisions will be used by NSCC Members in the future, NSCC is proposing to remove the Underwriting/Tender Offer Provisions from the Rules.

(iii) Clarifications

In order to improve readability of Rule 52, NSCC is proposing to re-number and make certain other clarifications to Rule 52.

Certain section numbers in Rule 52 are reserved for future use and NSCC is proposing to remove those placeholders and renumber the existing sections.

In addition, Part A, Section 11(a) of Rule 52 currently provides that certain orders and money only related charges will settle in accordance with the time frames as established by NSCC from time to time, or in such extended or shortened time frame as established by agreement of the submitting parties; provided, that such modified time frame shall be no shorter than T (the trade date) and longer than T+7.[20] The provision relating to the time frame being no longer than T+7 is a legacy provision that is no longer applicable or necessary. Historically, NSCC's technology on its platform did not allow for the settlement timeframe to be longer than T+7. Such technology restriction no longer exists. As such, NSCC is proposing to delete the provision that the time frame as modified by the submitting parties may be no longer than T+7.

(iv) Proposed Rule Changes

NSCC is proposing to amend Part A, Section 2 of Rule 52 to provide that orders may be submitted prior to the Trade Date to support the processing of interval fund repurchase orders. NSCC is also proposing to amend Part A, Sections 4 and 8 of Rule 52 to provide for the acknowledgment of interval fund repurchase orders and corrections as described above.

NSCC is proposing to delete the Underwriting/Tender Offer Provisions in Part A, Section 17 of Rule 52 and delete a reference to Part A, Section 17 currently in Part A, Section 16 of Rule 52. NSCC is also proposing to delete a number of section number references in Rule 52 that are currently reserved for future use and renumber the existing section numbers to reflect the deletion of such section numbers and the deletion of the Underwriting/Tender Offer Provisions. NSCC is also proposing to delete the phrase ''and no longer than T+7'' in Part A, Section 11(a) of Rule 52 as such legacy phrase is no longer applicable or necessary.

(v) Implementation

NSCC expects to implement the proposed rule changes on March 28, 2022. As proposed, a legend would be added to Rule 52 stating there are changes that became effective upon filing with the Commission but have not yet been implemented. The proposed legend would also indicate that the proposed rule change would be implemented on March 28, 2022, indicate the file number of this proposal, and indicate that once this proposal is implemented the legend would automatically be removed.

2. Statutory Basis

NSCC believes that the proposal is consistent with the requirements of the Securities Exchange Act of 1934 (''Act'') and the rules and regulations thereunder applicable to a registered clearing agency. In particular, NSCC believes that the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Act[21] and Rule 17Ad–22(e)(21) promulgated under the Act.[22]

Section 17A(b)(3)(F) of the Act,[23] requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions. The proposed changes to support interval fund repurchase orders are consistent with this provision because such changes would enhance the ability of NSCC Members to process interval fund repurchase orders. Providing a more efficient and streamlined process with respect to placing, acknowledging and settling interval fund repurchase orders would promote the prompt and accurate clearance and settlement of securities transactions by NSCC consistent with Section 17A(b)(3)(F) of the Act.[24]

The removal of the Underwriting/Tender Offer Provisions, the deletion of the section numbers in Rule 52 that are reserved for future use, the renumbering in Rule 52 described above and the removal of the phrase ''and no longer

[17] *See* Securities Exchange Release No. 28456 (September 20, 1990) (SR–NSCC–90–14), 55 FR 40028 (October 1, 1990). *See also* Part A, Section 17 of Rule 52, *supra* note 5.

[18] *Id.*

[19] *Id.*

[20] *See* Part A, Section 11(a) of Rule 52, *supra* note 5.

[21] 15 U.S.C. 78q–1(b)(3)(F).

[22] 17 CFR 240.17Ad–22(e)(21).

[23] 15 U.S.C. 78q–1(b)(3)(F).

[24] *Id.*

than T+7'' in Part A of Section 11(a) are also consistent with this provision because the proposed changes would enhance clarity and transparency for participants with respect to services offered by NSCC allowing NSCC Members to have a better understanding of the Rules relating to Mutual Fund Services. Having clear and accurate Rules would help NSCC Members to better understand their rights and obligations regarding NSCC's services. NSCC believes that when NSCC Members better understand their rights and obligations regarding NSCC's services, they can act in accordance with the Rules. NSCC believes that better enabling NSCC Members to comply with the Rules would promote the prompt and accurate clearance and settlement of securities transactions by NSCC consistent with Section 17A(b)(3)(F) of the Act.[25]

In addition, the proposed rule change is designed to comply with Rule 17Ad 22(e)(21) promulgated under the Act.[26] Rule 17Ad–22(e)(21) under the Act requires NSCC to, inter alia, establish, implement, maintain and enforce written policies and procedures reasonably designed to be efficient and effective in meeting the requirements of its participants and the markets it serves. The proposed rule change would enhance the ability of NSCC Members to process interval fund repurchase orders providing a more efficient and streamlined process with respect to placing, acknowledging and settling interval fund repurchase orders. Therefore, by establishing a more efficient and effective process for NSCC Members to process interval fund repurchase orders, NSCC believes that the proposed change is consistent with the requirements of Rule 17Ad–22(e)(21), promulgated under the Act.[27]

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe that the proposed changes would have an adverse impact, or impose a burden, on competition. These proposed changes would improve the ability of NSCC Members to process interval fund repurchase orders and enhance the clarity and transparency of the Rules and would not be adding any obligations on NSCC Members that are using NSCC's services. As such, the proposed changes would not impede any NSCC Members from engaging in the services or have an adverse impact on any NSCC Members. Moreover, the proposed changes may promote competition because the proposed changes would provide NSCC Members a more efficient method of processing interval fund repurchase orders.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at https://www.sec.gov/regulatory-actions/how-to-submit-comments.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

NSCC reserves the right not to respond to any comments received.

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)[28] of the Act and paragraph (f)[29] of Rule 19b–4 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.

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–NSCC–2022–002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2022–002. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's website (*https://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSCC–2022–002 and should be submitted on or before April 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07344 Filed 4–6–22; 8:45 am]

BILLING CODE 8011–01–P

[25] *Id.*

[26] 17 CFR 240.17Ad–22(e)(21).

[27] *Id.*

[28] 15 U.S.C 78s(b)(3)(A).

[29] 17 CFR 240.19b–4(f).

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94587; File No. SR–OCC–2022–004]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change by The Options Clearing Corporation Concerning Settlement Timing

April 1, 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 March 22, 2022, The Options Clearing Corporation (''OCC'' or ''Corporation'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared 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 by OCC would revise the required settlement time from 9:00 a.m. Central Time (''CT'') to 8:00 a.m. CT. In order to make this change, OCC is proposing changes to the OCC By-Laws (''By-Laws'') and Rules. The proposed changes to OCC's By-Laws and Rules are included as Exhibits 5A–5C to file number SR–OCC–2022–004. Material proposed to be added is underlined and material proposed to be deleted is marked in strikethrough text. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the OCC 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

OCC is filing this proposed rule change to change the time frame for collecting Margin[4] and Clearing Fund deficits as well as increases in the Clearing Fund cash requirement (''Settlement Funds''). The proposed changes are generally intended to shorten the collection period for Settlement Fund deficits and align the time for satisfying start of day settlement to 8:00 a.m. CT (''SOD Settlement Time''). OCC believes the proposed changes will reduce operational complexity by creating a more uniform settlement time for Clearing Fund deficits. The earlier SOD Settlement Time will also provide OCC with additional time to address a default event and implement protective actions. To provide increased transparency, the proposal also grants OCC discretion to extend funding deadlines when warranted by the circumstances (*e.g.,* operational or system difficulties).

The contents of the proposed rule change are summarized as follows.

Background

Under OCC's Rules, there are different windows for the collection of Settlement Funds depending on the reason for the deficit, and the settlement time for satisfying such deficits may vary. For example, OCC Rule 1005(a) currently requires Clearing Members to satisfy any general deficits within one hour of receiving notice from OCC; OCC Rule 1005(b) currently requires Clearing Members to satisfy any deficits related to a monthly or intra-month resizing of the Clearing Fund by 9:00 a.m. CT on the second business day following notice from OCC; and whenever an amount is paid out of the Clearing Fund, OCC Rule 1006(h) requires Clearing Members to replenish the Clearing Fund following a charge thereto by 9:00 a.m. CT on the first business day following notice from OCC. In certain cases, such as the monthly Clearing Fund sizing process, the current Rules provide a two day period for Clearing Members to deposit any additional required Clearing Fund assets, while simultaneously Clearing Members are eligible to withdraw any excess contributions based upon the new requirement. To address these issues, OCC proposes to change OCC's rules concerning the collection of Settlement Funds. The proposed changes would, in general, allow OCC to reduce operational complexity by creating a more uniform settlement time for Clearing Fund deficits.

In addition, OCC proposes to align the collection of Settlement Funds with a consistent SOD Settlement Time. OCC's current SOD Settlement Time is 9:00 a.m. CT; however, the Board approved changing the SOD Settlement Time to 8:00 a.m. CT. By aligning the SOD Settlement Time for margin and Clearing Fund deficiencies, OCC believes the proposed change would provide a clear and consistent process for collecting Settlement Funds. Moving to an earlier settlement time would also provide OCC with more time to address a default event and implement necessary protective actions, including securing funds from its liquidity providers.

Changes to By-Laws

Currently, two definitions in OCC's By-Laws (Article I, Definitions; Article XV, Foreign Currency Options, Definitions) refer to the term ''settlement time'' as 9:00 a.m. CT (10:00 a.m. Eastern Time (''ET'')). OCC proposes moving the definition in Article I of OCC's By-Laws to Chapter I, Rule 101 of OCC's Rules. This defined term does not appear elsewhere in the By-Laws, but is routinely used in OCC's Rules. OCC also proposes updating both definitions to instead provide for ''settlement time'' to be 8:00 a.m. CT (9:00 a.m. ET). Additionally, OCC proposes to clarify in the definition that would move to OCC's Rules that ''settlement time'' does not include settlements related to any cross-margin program with a Participating CCO. OCC Rule 706 allows OCC to specify the settlement time for cross-margin accounts with Participating CCOs. This filing will not change the start-of-day settlement time for the OCC/CME cross-margin account, which is currently 7:30 a.m. CT, but will clarify any potential ambiguity about the start-of-day settlement time for these accounts.

Changes to Rules

Daily Margin Report

OCC Rule 605 currently requires Clearing Members to satisfy margin deficits by 9:00 a.m. CT (10:00 a.m. ET).

[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 website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

[4] Current OCC Rule 706(b) allows OCC to specify the settlement time for cross-margin accounts with Participating CCOs. As of the date of this filing, OCC only maintains cross-margin accounts with one Participating CCO, the Chicago Mercantile Exchange (''CME''). OCC's Operations Manual specifies that the settlement time for OCC/CME cross margin debits is 7:30 a.m. CT. This filing will not change the start-of-day settlement time for OCC/CME cross-margin debits. For the avoidance of doubt, the settlement time for OCC's internal cross-margin program under Article VI, Section 25 of OCC's By-Laws will be 8:00 a.m. CT.

OCC proposes to update Rule 605 to reference the above referenced defined term ''Settlement Time.''

Interpretation and Policy .01 to Rule 605 currently provides that the Daily Margin Report will not include the amount of margin required for variance futures and requires OCC to advise Clearing Members of margin requirements for variance futures by 9:00 a.m. CT (10:00 a.m. ET). When OCC clears variance futures, the margin requirements for such products would be included in the Daily Margin Report. Accordingly, OCC proposes to delete Interpretation and Policy .01 to Rule 605.

Monthly and Intra-Month Resizing

OCC Rule 1005(b) currently requires that Clearing Members satisfy any deficits due to a monthly or intra-month Clearing Fund resizing by the SOD Settlement Time on the second business day following notification of the resizing. The two-day collection period was intended to provide Clearing Members with sufficient notice of any changes to their Clearing Fund contribution requirements. However, this two-day collection period complicates the monitoring of OCC's prefunded credit and liquidity resources.

To address these issues, Management proposes to amend Rule 1005(b) to require that deficits due to the standard monthly resizing of the Clearing Fund be satisfied by the SOD Settlement Time on the first business day of each month. The proposed change would reduce the time to collect Clearing Fund deficits required to meet the new monthly Clearing Fund size. This change would reduce operational complexity related to the monitoring of OCC's prefunded credit and liquidity resources by providing transparency and certainty to OCC around OCC's available liquidity resources during the resizing process. Management also proposes to shorten the collection period for intra-month resizing to the next SOD Settlement Time following notification of the re-sizing to align with the monthly resizing period and other Clearing Fund deficit collection times and help ensure that OCC maintains adequate prefunded financial resources at all times. To provide additional transparency, Rule 1005(b) also grants OCC discretion to extend funding deadlines when warranted by the circumstances (*e.g.,* operational or system difficulties).

General Deficits

OCC Rule 1005(a) currently requires that general Clearing Fund deficits (*e.g.,* deficits caused by a decrease in the value of a Clearing Member's contribution or due to an adjusted contribution pursuant to Rule 1004 [5]) must be satisfied within one hour of being notified of the deficit. As a practical matter, these deficits are currently generally collected in the morning each business day but outside of the start of day settlement cycle, which means that OCC currently processes two separate collections from certain Clearing Members.

OCC proposes to revise its rules to align the collection of general Clearing Fund deficits with the proposed SOD Settlement Time to provide consistency in settlement times throughout OCC's rules. Under revised Rule 1005(a), OCC would collect a general deficit arising under Rule 1005(a) at the Settlement Time, provided that it notified the Clearing Member of such deficit at least one hour prior to the Settlement Time on the day the notice was provided. Notice of general deficits under Rule 1005(a) would typically be provided to Clearing Members through OCC's overnight reporting process but may also be issued in response to market conditions or adjustments arising from mergers, consolidations, position transfers, business expansions, membership approval or other similar events. To achieve the operational efficiency contemplated by the proposal, the proposed revisions to Rule 1005(a) would align the collection period for general deficits to the Settlement Time in the ordinary course, and continue to provide Clearing Members with one hour to satisfy a deficit if notice was not provided at least one hour before the Settlement Time on a particular day. To provide additional transparency, Rule 1005(a) also grants OCC discretion to extend funding deadlines when warranted by the circumstances (*e.g.,* operational or system difficulties).

Adjustments to Clearing Fund Contributions

Rule 1004 provides that any deficiency arising from an adjustment due to a Clearing Member merger, consolidation, position transfer, business expansion, membership approval or other similar event shall be satisfied in accordance with Rule 1005(a). Rule 1004 currently provides an exception that allows a Clearing Member to satisfy an obligation that would be due on the first business day of a calendar month to be satisfied on the second business day if the deficit coincides with a regular monthly sizing collection. The proposal would eliminate this exception because regular monthly sizing deficits would no longer be collected two business days after notification under the proposed formulation of Rule 1005.

Replenishment and Assessments

OCC Rule 1006(h) currently requires that Clearing Members make good any charges to the Clearing Fund, whether in the form of replenishments or assessments, by 9:00 a.m. the following business day. OCC proposes to amend Rule 1006(h) to align the collection period for replenishments and assessments with the proposed SOD Settlement Time. OCC believes that using the defined term ''Settlement Time'' rather than stating a specific time in Rule 1006(h) will help achieve the consistency intended by this proposal. As described above, aligning the time for satisfying settlement and Clearing Fund obligations to the new definition of Settlement Time will reduce operational complexity by creating a more uniform settlement time. Moving to the earlier time (*i.e.,* 8:00 a.m. CT) would also provide OCC with more time to address a default event and implement necessary protective actions, including securing funds from its liquidity providers. OCC also proposes to make corresponding changes to Rule 1006(h)(B), which reiterates that each Clearing Member shall have and shall at all times maintain the ability to make good any deficiency described in Rule 1006(h) during a cooling-off period.

OCC also proposes to amend Rule 1006(h)(A) and Rule 1006(h)(B) to allow the Corporation to specify a later time for which Clearing Members must make good on any charges to the Clearing Fund. The purpose of this change is to provide increased transparency by granting OCC discretion to extend funding deadlines when warranted by the circumstances (*e.g.,* operational or system difficulties).

Deficits Due to Amendment of OCC's Rules

Currently, under Rule 1002(e), if a Clearing Member's contribution to the Clearing Fund increases due to an amendment of OCC's Rules, the increase shall not become effective until the Clearing Member is given at least two business days prior written notice of the amendment. This notification period provides time for any Clearing Member to notify OCC in writing that it wishes to terminate its clearing membership and close out or transfer its open positions before the effective date of the

[5] Under Rule 1004, Clearing Fund contributions may be adjusted due to a Clearing Member merger, consolidation, position transfer, business expansion, membership approval or other similar event.

amendment. Clearing Members that do not notify OCC of such termination must satisfy the increased contribution by 9:00 a.m. CT on the second business day following notification of the amendment.

OCC proposes to allow a five-business day notification period to allow Clearing Members additional time to determine whether to terminate clearing membership as a result of any such rule change and close out or transfer all open positions before the effective date of the amendment. The purpose of this change is to update Rule 1002(e) to better reflect OCC's current practice pursuant to which Clearing Members are generally afforded more than five-business days' notice of any change in Clearing Fund requirements that result from an amendment of OCC's Rules through the regulatory filing process. As this change codifies an existing practice, OCC does not believe it will modify Clearing Member behavior or otherwise have an adverse impact on OCC.

OCC also proposes to revise Rule 1002(e) to align with the proposed SOD Settlement Time. As described above, this change is intended to reduce operational complexity by creating a more uniform settlement time for Clearing Fund deficits, including those described in Rule 1002(e), that aligns with the current collection period for other obligations to OCC.

Temporary Increase in Clearing Fund Cash Requirement

Interpretation and Policy .03 to Rule 1002 requires Clearing Members to satisfy any increase in their required cash contribution resulting from an increase in overall Clearing Fund Cash Requirement no later than the second business day following notification of the increase. OCC proposes to revise Rule 1002 to require that Clearing Members satisfy an increase in required cash contributions by the first SOD Settlement Time following notification of the increase. The purpose of this change is to reduce operational complexity by creating a more uniform settlement time that aligns with the current collection period for other obligations to OCC.

Conforming Changes to Policies and Agreements

In connection with the proposed changes described above, OCC will need to make conforming changes to the Clearing Fund Methodology Policy. These changes include updating the policy to reflect the timing for satisfying an increase to the Clearing Fund Cash Requirements and eliminating the policy language describing the exception set forth in Rule 1004 as described more fully above. These changes are intended to update the Clearing Fund Methodology Policy to conform with the proposed changes to OCC's rules described above and support the reduced operational complexity that OCC expects to achieve by creating a more uniform SOD Settlement Time.

(2) Statutory Basis

OCC believes the proposed rule change is consistent with Section 17A of the Act [6] and the rules thereunder applicable to OCC. Section 17A(b)(3)(A) of the Act [7] requires, among other things, that a clearing agency be so organized and have the capacity to be able to facilitate the prompt and accurate clearance and settlement of securities transactions and derivatives agreements, contracts, and transactions for which it is responsible. OCC believes the proposed rule change is consistent with this requirement because the change would improve OCC's capacity to facilitate clearance and settlement by allowing OCC to collect financial resources consistent with its calculated requirements as soon as reasonably possible. OCC believes this change will facilitate the prompt and accurate settlement of the transactions for which it is responsible by harmonizing various settlement deadlines thereby reducing operational complexity. The change would also facilitate the prompt and accurate settlement of transactions by providing OCC assurance about available funds earlier on each business day.

OCC also believes that the proposed rule change is consistent with the requirement in Rule 17Ad–22(e)(3)(i) [8] to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for managing legal, credit, liquidity, operational, general business, investment, custody and other risks that arise in or are borne by OCC. OCC believes the proposed SOD Settlement Time changes will contribute to OCC's sound risk management framework for managing the risks borne by OCC. For example, OCC believes the proposed changes will reduce its liquidity risk by assuring start of day settlement requirements are met earlier on each business day. Additionally, OCC believes adding consistency to its start of day settlement time requirements will reduce operational risk by simplifying the requirements around settlement for both Clearing Members and OCC. While cross-margin deficits will still be required to be met by 7:30 a.m. CT, all other Settlement Funds will be required by 8:00 a.m. CT. OCC believes this reduction in complexity around required settlement timing will reduce risk and contribute to OCC's sound risk management framework. The proposal would also improve OCC's process for addressing delays arising from operational issues or system difficulties by granting OCC discretion to extend certain funding deadlines when warranted by the circumstances.

The proposal is also consistent with the requirement in Rule 17Ad–22(e)(8) to establish, implement, maintain, and enforce policies and procedures reasonably designed to define the point at which settlement is final to be no later than the end of the day on which the payment or obligation is due. Under the proposal, settlement finality for transactions cleared by OCC occurs when a settlement bank either accepts or confirms the settlement instruction. Moving to the earlier time would promote settlement finality by allowing OCC to more quickly identify issues that could potentially impact its ability to settle transactions (*e.g.,* a Clearing Member default) and providing OCC with additional time to take protective actions, including securing funds from its liquidity providers.

The proposed rule change is not inconsistent with the existing rules of OCC, including any other rules proposed to be amended.

(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 Act.[9] OCC does not believe that the proposed rule change would impact or impose any burden on competition. In connection with these changes, OCC will continue to provide daily reporting to Clearing Members with projected requirements to provide notice and transparency. While the proposed rule changes would reduce the time that Clearing Members have to respond to start of day settlement requirements, OCC does not believe the proposed change would present an undue burden on OCC's Clearing Members.

Additionally, the proposed rule changes would apply to all Clearing Members consistently and would not

[6] 15 U.S.C. 78q–1.

[7] 15 U.S.C. 78q–1(b)(3)(A).

[8] 17 CFR 240.17Ad–22(e)(3)(i).

[9] 15 U.S.C. 78q–1(b)(3)(I).

provide any Clearing Member with a competitive advantage over any other Clearing Member. Further, the proposed rule change would not affect Clearing Member's access to OCC's services or impose any direct burdens on Clearing Members. Accordingly, the proposed rule change would not unfairly inhibit access to OCC's services or disadvantage or favor any particular user in relationship to another user.

For the foregoing reasons, OCC believes that the proposed rule change is in the public interest, would be consistent with the requirements of the Act applicable to clearing agencies, and would not impact or impose a 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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

OCC shall post notice on its website of proposed changes that are implemented. The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change 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–2022–004 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–2022–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-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–2022–004 and should be submitted on or before April 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07341 Filed 4–6–22; 8:45 am]

BILLING CODE 8011–01–P

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94575; File No. SR–NYSEArca–2022–15]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges

April 1, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on March 21, 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 Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges (''Fee Schedule'') to introduce a new credit that would apply to transactions executed on the Exchange using Discretionary Pegged Orders. The Exchange proposes to implement the fee change effective March 21, 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to introduce a new credit that would apply to transactions executed on the Exchange using Discretionary Pegged Orders.

The Exchange proposes to implement the fee change effective March 21, 2022.

Background

The Exchange operates in a highly competitive market. The Securities and Exchange Commission (''Commission'') has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [4]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [5] Indeed, equity trading is currently dispersed across 16 exchanges,[6] numerous alternative trading systems,[7] and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly available information, no single exchange currently has more than 18% market share.[8] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange currently has less than 9% market share of executed volume of equities trading.[9]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products. While it is not possible to know a firm's reason for shifting order flow, the Exchange believes that one such reason is because of fee changes at any of the registered exchanges or non-exchange venues to which a firm routes order flow. With respect to non-marketable order flow that would provide liquidity on an Exchange, ETP Holders can choose from any one of the 16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide liquidity on an exchange.

Proposed Rule Change

Pursuant to Commission approval, the Exchange adopted a new order type known as a Discretionary Pegged Order (''DPO order'').[10] A DPO order is a Pegged Order [11] to buy (sell) that upon entry is assigned a working price [12] equal to the lower (higher) of the midpoint of the PBBO [13] (''Midpoint Price'') or the limit price of the order. In order to trade with contra-side orders on the NYSE Arca Book, a DPO order to buy (sell) will exercise the least amount of price discretion necessary from its working price to its discretionary price (defined as the lower (higher) of the Midpoint Price or the DPO order's limit price), except during periods of quote instability. DPO orders are not displayed, must be designated Day [14] and are eligible to be designated for the Core Trading Session [15] only.

In anticipation of the scheduled implementation of the DPO order functionality,[16] the Exchange proposes to introduce a new credit to the Fee Schedule, effective March 21, 2022. Specifically, the Exchange proposes to introduce a credit of $0.0005 per share for DPO orders that add liquidity. To reflect the new credit, the Exchange proposes to amend Section IV of the Fee Schedule titled ''Other Standard Rates for Securities with a Per Share Price $1.00 or Above'' by adopting a new bullet that would state ''($0.0005) credit for Discretionary Pegged Orders that add liquidity.''

The Exchange believes the proposed rule change to adopt a new credit for DPO orders that add liquidity will incentivize ETP Holders to use the DPO order functionality and direct liquidity-providing orders to the Exchange, which would provide additional liquidity for incoming orders and offer additional opportunities for midpoint execution.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[18] 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.

As discussed above, the Exchange operates in a highly fragmented and competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current

[4] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (File No. S7–10–04) (Final Rule) (''Regulation NMS'').

[5] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[6] *See* Cboe U.S Equities Market Volume Summary, available at *https://markets.cboe.com/us/equities/market_share. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[7] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[8] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[9] *See id.*

[10] *See* NYSE Arca Rule 7.31–E(h)(3). *See also* Securities Exchange Act Release No. 78181 (June 28, 2016), 81 FR 43297 (July 1, 2016) (SR–NYSEArca–2016–44) (Notice of Filing of Amendment No. 1, and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Add a New Discretionary Pegged Order).

[11] A ''Pegged Order'' is defined in Rule 7.31–E(h) as a Limit Order that does not route with a working price that is pegged to a dynamic reference price. If the designated reference price is higher (lower) than the limit price of a Pegged Order to buy (sell), the working price will be the limit price of the order.

[12] The term ''working price'' is defined in Rule 7.36–E(a)(3) as the price at which an order is eligible to trade at any given time, which may be different from the limit price or display price of the order. The term ''limit price'' is defined in Rule 7.36–E(a)(2) as the highest (lowest) specified price at which a Limit Order to buy (sell) is eligible to trade.

[13] The term ''PBBO'' is defined in Rule 1.1(dd) as the highest Protected Bid and the lowest Protected Offer.

[14] Pursuant to NYSE Arca Rule 7.31–E(b)(1), any order to buy or sell designated Day, if not traded, expires at the end of the designated session on the day on which it was entered.

[15] The Core Trading Session for each security begins at 9:30 a.m. Eastern Time and ends at the conclusion of Core Trading Hours. *See* NYSE Arca Rule 7.34–E(a)(2). The term ''Core Trading Hours'' means the hours of 9:30 a.m. Eastern Time through 4:00 p.m. Eastern Time or such other hours as may be determined by the Exchange from time to time. *See* NYSE Arca Rule 1.1.

[16] *See https://www.nyse.com/trader-update/history#110000415898.*

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(4) and (5).

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.'' [19]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue to reduce use of certain categories of products, in response to fee changes. With respect to non-marketable orders which provide liquidity on an Exchange, ETP Holders can choose from any one of the 16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces reasonably constrain exchange transaction fees that relate to orders that would provide liquidity on an exchange. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

In particular, the Exchange believes the proposed rule change is reasonable because it is designed to enhance the Exchange's market quality by encouraging ETP Holders to add more liquidity on the Exchange, which would benefit all market participants by deepening the Exchange's liquidity pool. The Exchange believes it is reasonable to introduce a fee incentive for the use of DPO orders, which is designed to exercise discretion in order to provide price improvement to contra-side orders. As noted above, a DPO order is designed to be a non-displayed order that could execute at the midpoint of the PBBO, and thus would enhance order execution opportunities at the Exchange. The Exchange believes the proposed credit will therefore incentivize ETP Holders to utilize the new functionality.

The Exchange believes it is reasonable to provide the proposed credit as an incentive to ETP Holders when they use the DPO order to provide liquidity to the Exchange, which would benefit all market participants. The Exchange believes the proposed change to adopt a new credit is reasonable as it would provide an incentive to ETP Holders to use the order type to provide meaningful added levels of liquidity, thereby contributing to market quality on the Exchange.

As noted above, the Exchange operates in a highly competitive environment, particularly for attracting non-displayed and midpoint order flow. Additionally, many of the Exchange's competitors for this order flow are alternative trading systems (ATSs) which are not registered national securities exchanges and therefore operate with far more regulatory freedom. For example, ATSs can segregate and/or eliminate undesirable order flow based on client demand, a function that is not available to the Exchange.

Additionally, the Exchange is one of many venues and off-exchange venues to which market participants may direct their order flow, and it represents a small percentage of the overall market.

The Exchange believes its proposal equitably allocates its fees among its market participants.

The Exchange believes that the proposal represents an equitable allocation of fees and is not unfairly discriminatory because it would apply uniformly to all ETP Holders, in that all ETP Holders will be eligible for the proposed new credit and will have the opportunity to utilize the DPO order and receive the applicable credit when such orders add liquidity on the Exchange. The proposed credit would apply automatically and uniformly to all ETP Holders that use the new functionality. The proposed credit is designed as an incentive to all liquidity providers to submit liquidity providing orders by using the DPO order type and each will receive the associated credit when such orders add liquidity on the Exchange. While the Exchange has no way of knowing whether this proposed rule change would serve as an incentive to utilize the new order type, the Exchange anticipates a number of ETP Holders will benefit from the proposed rule change when they utilize the new functionality. As stated, the proposed new credit is designed to provide an incentive for ETP Holders to submit additional liquidity across all Tapes by using the DPO order type.

The Exchange believes that the proposal is not unfairly discriminatory. The Exchange believes it is not unfairly discriminatory to provide the proposed credit as the credit would be provided on an equal basis to all ETP Holders that use the DPO order type to add liquidity in all securities. As noted above, the proposed credit is designed to serve as an incentive to all ETP Holders to utilize the DPO order type to add liquidity on the Exchange and each would receive the corresponding new credit. The Exchange also notes that the proposed rule change will not adversely impact any ETP Holder's pricing or their ability to qualify for other fees and credits on the Exchange. Rather, should an ETP Holder not use the new functionality, the ETP Holder will merely not receive the corresponding rebate.

In the prevailing competitive environment, ETP Holders are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Moreover, this proposed rule change neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that this proposal does not permit unfair discrimination because the changes described in this proposal would be applied to all similarly situated ETP Holders. Accordingly, no ETP Holder already operating on the Exchange would be disadvantaged by the proposed allocation of fees. The Exchange further believes that the proposed rule change would not permit unfair discrimination among ETP Holders because the DPO order type functionality would be available to all ETP Holders and each such ETP Holder would receive the proposed new credit when adding liquidity on the Exchange through the use of the new order type.

Finally, the submission of orders to the Exchange is optional for ETP Holders in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard. The Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[20] the Exchange believes that the proposed rule change would not 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 rule change would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth and enhancing order execution opportunities for ETP Holders. 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.'' [21]

[19] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[20] 15 U.S.C. 78f(b)(8).

[21] *See* Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

Intramarket Competition. The Exchange believes the proposed amendment to its Fee Schedule would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change represents a significant departure from previous pricing offered by the Exchange or its competitors. The proposed change is designed to attract additional liquidity to the Exchange in all securities through the use of a new order type. The Exchange believes that the proposed adoption of a new credit would incentivize market participants to direct liquidity adding order flow to the Exchange, bringing with it additional execution opportunities for market participants. Greater overall order flow and more trading opportunities at multiple price points benefits all market participants on the Exchange by enhancing market quality and continuing to encourage ETP Holders to send orders to the Exchange, thereby contributing towards a robust and well-balanced market ecosystem.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As noted above, the Exchange's market share of intraday trading (*i.e.,* excluding auctions) is currently less than 9%. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

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) [22] of the Act and subparagraph (f)(2) of Rule 19b–4 [23] 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) [24] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2022–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2022–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2022–15, and should be submitted on or before April 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07345 Filed 4–6–22; 8:45 am]

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[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f)(2).

[24] 15 U.S.C. 78s(b)(2)(B).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–359, OMB Control No. 3235–0410]

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rules 17h–1T and 17h–2T

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rules 17h–1T and 17h–2T (17 CFR 240.17h–1T and 17 CFR 240.17h–2T), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17h–1T requires a covered broker-dealer to maintain and preserve records and other information concerning certain entities that are associated with the broker-dealer. This

requirement extends to the financial and securities activities of the holding company, affiliates and subsidiaries of the broker-dealer that are reasonably likely to have a material impact on the financial or operational condition of the broker-dealer. Rule 17h–2T requires a covered broker-dealer to file with the Commission quarterly reports and a cumulative year-end report concerning the information required to be maintained and preserved under Rule 17h–1T.

The collection of information required by Rules 17h–1T and 17h–2T, collectively referred to as the ''risk assessment rules,'' is necessary to enable the Commission to monitor the activities of a broker-dealer affiliate whose business activities are reasonably likely to have a material impact on the financial or operational condition of the broker-dealer. Without this information, the Commission would be unable to assess the potentially damaging impact of the affiliate's activities on the broker-dealer.

There are currently 235 respondents that must comply with Rules 17h–1T and 17h–2T. Each of these 235 respondents are estimated to require 10 hours per year to maintain the records required under Rule 17h–1T, for an aggregate estimated annual burden of 2,350 hours (235 respondents × 10 hours). In addition, each of these 235 respondents must make five annual responses under Rule 17h–2T. These five responses are estimated to require 14 hours per respondent per year for an aggregate estimated annual burden of 3,290 hours (235 respondents × 14 hours).

In addition, new respondents must draft an organizational chart required under Rule 17h–1T and establish a system for complying with the risk assessment rules. The staff estimates that drafting the required organizational chart requires one hour and establishing a system for complying with the risk assessment rules requires three hours. Based on the reduction in the number of filers in recent years, the staff estimates there will be zero new respondents, and thus, a corresponding estimated burden of zero hours for new respondents. Thus, the total compliance burden per year is approximately 5,640 burden hours (2,350 hours + 3,290 hours).

The retention period for the recordkeeping requirement for the information, reports and records required under Rule 17h–1T is not less than three years. There is no specific retention period or recordkeeping requirement for Rule 17h–2T. The collection of information is mandatory. All information obtained by the Commission pursuant to the provisions of Rules 17h–1T and 17h–2T from a broker or dealer concerning a material associated person is deemed confidential information for the purposes of section 24(b) of the Exchange Act.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: >*www.reginfo.gov*<. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) >*MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov*< and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: April 1, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07336 Filed 4–6–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94574; File No. SR–MIAX–2022–12]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule To Extend the SPIKES Options Market Maker Incentive Program Until June 30, 2022

April 1, 2022.

Pursuant to the provisions of 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 March 23, 2022, Miami International Securities Exchange LLC (''MIAX'' 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 Options Fee Schedule (the ''Fee Schedule'') to extend the SPIKES Options Market Maker Incentive Program (the ''Incentive Program'') until June 30, 2022.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX'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 proposes to extend the Incentive Program until June 30, 2022.

Background

On October 12, 2018, the Exchange received approval from the Commission to list and trade on the Exchange options on the SPIKES® Index, a new index that measures expected 30-day volatility of the SPDR S&P 500 ETF Trust (commonly known and referred to by its ticker symbol, ''SPY'').[3] The Exchange adopted its initial SPIKES transaction fees on February 15, 2019 and adopted a new section of the Fee Schedule—Section 1(a)(xi), SPIKES—for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 84417 (October 12, 2018), 83 FR 52865 (October 18, 2018) (SR–MIAX–2018–14) (Order Granting Approval of a Proposed Rule Change by Miami International Securities Exchange, LLC to List and Trade on the Exchange Options on the SPIKES® Index).

those fees.[4] Options on the SPIKES Index began trading on the Exchange on February 19, 2019.

Incentive Program Extension

On September 30, 2021, the Exchange filed its initial proposal to implement a SPIKES Options Market Maker Incentive Program for SPIKES options to incentivize Market Makers[5] to improve liquidity, available volume, and the quote spread width of SPIKES options beginning October 1, 2021, and ending December 31, 2021.[6] Technical details regarding the Incentive Program were published in a Regulatory Circular on September 30, 2021.[7] On October 12, 2021, the Exchange withdrew SR–MIAX–2021–45 and refiled its proposal to implement the Incentive Program to provide additional details.[8] In that filing, the Exchange specifically noted that the Incentive Program would expire at the end of the period (December 31, 2021) unless the Exchange filed another 19b–4 Filing to amend the fees (or extend the Incentive Program).[9] On December 23, 2021, the Exchange filed its proposal to, among other things, extend the Incentive Program for three months, with the Incentive Program ending on March 31, 2022.[10] In that filing, the Exchange specifically noted that the Incentive Program would expire at the end of the period (March 31, 2022) unless the Exchange filed another 19b–4 Filing to amend the terms (or extend the Incentive Program).[11] The Exchange now proposes to extend the Incentive Program for an additional three months, with the Incentive Program ending on June 30, 2022.[12]

The Exchange proposes to extend the Incentive Program for SPIKES options to continue to incentivize Market Makers to improve liquidity, available volume, and the quote spread width of SPIKES options. Currently, to be eligible to participate in the Incentive Program, a Market Maker must meet certain minimum requirements related to quote spread width in certain in-the-money (ITM) and out-of-the-money (OTM) options as determined by the Exchange and communicated to Members via Regulatory Circular.[13] Market Makers must also satisfy a minimum time in the market in the front 2 expiry months of 70%, and have an average quote size of 25 contracts. The Exchange established two separate incentive compensation pools that are used to compensate Market Makers that satisfy the criteria pursuant to the Incentive Program.

The first pool (Incentive 1) has a total amount of $40,000 per month, which is allocated to Market Makers that meet the minimum requirements of the Incentive Program. Market Makers are required to meet minimum spread width requirements in a select number of ITM and OTM SPIKES option contracts as determined by the Exchange and communicated to Members via Regulatory Circular.[14] A complete description of how the Exchange calculates the minimum spread width requirements in ITM and OTM SPIKES options can be found in the published Regulatory Circular.[15] Market Makers are also required to maintain the minimum spread width, described above, for at least 70% of the time in the front two (2) SPIKES options contract expiry months and maintain an average quote size of at least 25 SPIKES options contracts. The amount available to each individual Market Maker is capped at $10,000 per month for satisfying the minimum requirements of the Incentive Program. In the event that more than four Market Makers meet the requirements of the Incentive Program, each qualifying Market Maker is entitled to receive a pro-rated share of the $40,000 monthly compensation pool dependent upon the number of qualifying Market Makers in that particular month.

The second pool (Incentive 2 Pool) is capped at a total amount of $100,000 per month which is used during the Incentive Program to further incentivize Market Makers who meet or exceed the requirements of Incentive 1 (''qualifying Market Makers'') to provide tighter quote width spreads. The Exchange ranks each qualifying Market Maker's quote width spread relative to each other qualifying Market Maker's quote width spread. Market Makers with tighter spreads in certain strikes, as determined by the Exchange and communicated to Members via Regulatory Circular,[16] are eligible to receive a pro-rated share of the compensation pool as calculated by the Exchange and communicated to Members via Regulatory Circular,[17] not to exceed $25,000 per Member per month. Qualifying Market Makers are ranked relative to each other based on the quality of their spread width (*i.e.,* tighter spreads are ranked higher than wider spreads) and the Market Maker with the best quality spread width receives the highest rebate, while other eligible qualifying Market Makers receive a rebate relative to their quality spread width.

The Exchange now proposes to extend the Incentive Program until June 30, 2022. The Exchange does not propose to make any amendments to how it calculates any of the incentives provided for in Incentive Pools 1 or 2. The details of the Incentive Program can continue to be found in the Regulatory Circular that was published on September 30, 2021 to all Exchange Members.[18] The purpose of this extension is to continue to incentivize Market Makers to improve liquidity, available volume, and the quote spread width of SPIKES options. The Exchange will announce the extension of the Incentive Program to all Members via a Regulatory Circular.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[19] in general, and furthers the objectives of Section 6(b)(4) of the Act[20] in particular, in that it is an equitable allocation of reasonable 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 designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and

[4] *See* Securities Exchange Release No. 85283 (March 11, 2019), 84 FR 9567 (March 15, 2019) (SR–MIAX–2019–11). The Exchange initially filed the proposal on February 15, 2019 (SR–MIAX–2019–04). That filing was withdrawn and replaced with SR–MIAX–2019–11. On September 30, 2020, the Exchange filed its proposal to, among other things, reorganize the Fee Schedule to adopt new Section 1(b), Proprietary Products Exchange Fees, and moved the fees and rebates for SPIKES options into new Section 1(b)(i). *See* Securities Exchange Act Release No. 90146 (October 9, 2020), 85 FR 65443 (October 15, 2020) (SR–MIAX–2020–32); Securities Exchange Act Release No. 90814 (December 29, 2020), 86 FR 327 (January 5, 2021) (SR–MIAX–2020–39).

[5] The term ''Market Makers'' refers to ''Lead Market Makers'', ''Primary Lead Market Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100.

[6] *See* SR–MIAX–2021–45.

[7] *See* MIAX Options Regulatory Circular 2021–56, SPIKES Options Market Maker Incentive Program (September 30, 2021) *available at https://www.miaxoptions.com/sites/default/files/circularfiles/MIAX_Options_RC_2021_56.pdf.*

[8] *See* Securities Exchange Act Release No. 93424 (October 26, 2021), 86 FR 60322 (November 1, 2021) (SR–MIAX–2021–49).

[9] *See id.,* at note 4.

[10] *See* Securities Exchange Act Release No. 93881 (December 30, 2021), 87 FR 517 (January 5, 2022) (SR–MIAX–2021–63).

[11] *See id.,* at footnote 20.

[12] The Exchange notes that at the end of the extension period, the Incentive Program will expire unless the Exchange files another 19b–4 Filing to amend the terms or extend the Incentive Program.

[13] *See supra* note 7.

[14] *See id.*

[15] *See id.*

[16] *See id.*

[17] *See id.*

[18] *See id.*

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(4) and (5).

open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to extend the Incentive Program for Market Makers in SPIKES options. The Incentive Program is reasonably designed because it will continue to incentivize Market Makers to provide quotes and increased liquidity in select SPIKES options contracts. The Incentive Program is reasonable, equitably allocated and not unfairly discriminatory because all Market Makers in SPIKES options may continue to qualify for Incentive 1 and Incentive 2, dependent upon each Market Maker's quoting in SPIKES options in a particular month. Additionally, if a SPIKES Market Maker does not satisfy the requirements of Incentive Pool 1 or 2, then it simply will not receive the rebate offered by the Incentive Program for that month.

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to continue to offer this financial incentive to Market Makers in SPIKES options because it will continue to benefit all market participants trading in SPIKES options. SPIKES options is a Proprietary Product on the Exchange and the continuation of the Incentive Program encourages Market Makers in SPIKES options to satisfy a heightened quoting standard, average quote size, and time in market. A continued increase in quoting activity and tighter quotes may yield a corresponding increase in order flow from other market participants, which benefits all investors by deepening the Exchange's liquidity pool, potentially providing greater execution incentives and opportunities, while promoting market transparency and improving investor protection.

The Exchange believes that the Incentive Program is equitable and not unfairly discriminatory because it will continue to promote an increase in SPIKES options liquidity, which may facilitate tighter spreads and an increase in trading opportunities to the benefit of all market participants. The Exchange believes it is reasonable to operate the Incentive Program for a continued limited period of time to strengthen market quality for all market participants. The resulting increased volume and liquidity will benefit those Members who are eligible to participate in the Incentive Program and will also continue to benefit those Members who are not eligible to participate in the Incentive Program by providing more trading opportunities and tighter spreads.

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.

Intra-Market Competition

The Exchange believes that the proposed extension of the Incentive Program would continue to increase intra-market competition by incentivizing Market Makers to quote SPIKES options, which will continue to enhance the quality of quoting and increase the volume of contracts available to trade in SPIKES options. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity for SPIKES options. Enhanced market quality and increased transaction volume in SPIKES options that results from the anticipated increase in Market Maker activity on the Exchange will benefit all market participants and improve competition on the Exchange.

Inter-Market Competition

The Exchange does not believe that the proposed rule changes will impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed extension of the Incentive Program applies only to the Exchange's Proprietary Products (including options on SPIKES), which are traded exclusively on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[21] and Rule 19b–4(f)(2) [22] 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–MIAX–2022–12 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–MIAX–2022–12. 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–MIAX–2022–12 and should

[21] 15 U.S.C. 78s(b)(3)(A)(ii).

[22] 17 CFR 240.19b–4(f)(2).

be submitted on or before April 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07338 Filed 4–6–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94583; File No. SR–OCC–2022–005]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change Concerning Revisions to OCC's Partial Tear-Up Rules

April 1, 2022.

Pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 22, 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

The proposed rule change would: (i) Amend OCC Rule 1111(e) to clarify the nature of the claim issued to Clearing Members that receive a pro rata payment as a result of a Partial Tear-Up; and (ii) amend OCC Rule 1111(g) to impose a limit on the amount of the special charge that can be levied on Clearing Members to re-allocate losses, costs and fees among resulting from a Partial Tear-Up among all non-defaulting Clearing Members. The proposed changes to OCC Rules are included in Exhibit 5 of File No. SR–OCC–2022–005. Material proposed to be added to OCC's Rules as currently in effect is underlined and material proposed to be deleted is marked in strikethrough text. All capitalized terms not defined herein have the same meaning as set forth in the OCC 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

In 2018, OCC adopted enhanced and new tools for recovery scenarios, including a Partial Tear-Up process designed to return OCC to a matched book by extinguishing positions that remain open after OCC has attempted one or more auctions.[4] The process for determining and terminating Partial Tear-Up Positions is set forth in OCC Rule 1111(e). In adopting Rule 1111(e), OCC noted that its Partial Tear-Up process would be initiated if OCC determined that potential losses from remaining positions of the defaulting member would exceed OCC's financial resources and that the process was designed to be initiated in advance of the exhaustion of OCC's financial resources in order to maintain its ability to meet obligations to non-defaulting members.[5] OCC also acknowledged that the process may be used to allocate losses in the event OCC's resources are insufficient to pay the Partial Tear-Up Price.[6] When the Partial Tear-Up process is used to allocate losses, Rule 1111(e)(iii) currently provides that each Clearing Member will receive a pro rata payment based on OCC's remaining resources and an unsecured claim against OCC for the difference between the pro rata amount received and the Partial Tear-Up Price.

An unsecured claim issued pursuant to Rule 1111(e) provides a mechanism for OCC to compensate Clearing Members that receive a pro rata payment when warranted by particular circumstances (*e.g.,* when funds are subsequently recovered from a defaulted Clearing Member or the estate of the defaulted Clearing Member). However, OCC Rules do not specify a specific payment obligation for these claims. The purpose of the proposed amendment to Rule 1111(e) is to provide clarity regarding the nature of the claim issued following a Partial Tear-Up. More specifically, the revisions to Rule 1111(e) would clarify that: (i) A Clearing Member receiving a pro rata payment following a partial tear-up will have a claim for the value of the difference between the pro rata amount received and the Partial Tear-Up Price; and (ii) such a claim shall be an unsecured claim on any recovery from a suspended or defaulted Clearing Member (or from the estate of a suspended or defaulted Clearing Member). Clarification of the nature of the claim arising out of Rule 1111(e) would, in turn, clarify that such claims would not provide a basis for triggering close-out netting under Article VI, Section 27 of OCC's By-Laws.[7]

As part of its Partial Tear-Up process, OCC also adopted Rule 1111(g), which provides the Board with discretionary authority to levy a special charge against remaining non-defaulting Clearing Members for the purpose of re-allocating the losses, costs and fees imposed on holders of torn-up positions. Following the adoption of OCC Rule 1111, OCC received a letter from the Futures Industry Association (''FIA'') requesting that OCC limit the amount of the special charge that could be levied by the Board pursuant to Rule 1111(g) to the amount of a Clearing Member's required contribution to the Clearing Fund.[8] OCC has considered this request and proposes to amend Rule 1111(g) to cap the amount of the special charge levied under the rule to the amount of the Clearing Members required contribution to the Clearing Fund at the time of the special charge. The purpose of this change is to improve Clearing Members' ability to measure, monitor and manage their potential exposure to OCC.

[23] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b).

[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] *See* Exchange Act Release No. 34–83916 (August 23, 2018); 83 FR 44076 (August 29, 2018) (File No. SR–OCC–2017–020).

[5] 83 FR at 44078.

[6] *Id.*

[7] OCC By-Laws Art. VI, Section 27(a)(i), regarding default or insolvency of OCC, requires OCC to notify various stakeholders if OCC fails to comply with an undisputed obligation to pay money or deliver property to a Clearing Member under the By-Laws or Rules for a period of thirty days from the date that OCC receives notice from the Clearing Member of the past due obligation.

[8] The letter OCC received from the FIA has been provided as Exhibit 3A to File No. SR–OCC–2022–005.

(2) Statutory Basis

Section 17A(b)(3)(F) [9] of the Exchange Act requires, among other things, that the rules of a clearing agency be designed, in general, to protect investors and the public interest. OCC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act.[10] As noted above, the proposed revisions to OCC Rule 1111(e) protect investors and the public interest by more clearly describing the nature of the claim issued to Clearing Members that receive a pro rata payment following a Partial Tear-Up. The clarity provided by these amendments would protect investors and the public interest by eliminating the potential for ambiguity or uncertainty regarding the nature of a claim issued under Rule 1111(e), which could undermine OCC's resiliency. The proposal to limit the amount of the special charge levied under Rule 1111(g) would also improve Clearing Members' ability to measure and monitor their potential exposure to OCC allowing Clearing Members to more effectively manage their risk. Accordingly, OCC believes the proposed revisions to Rule 1111(g) would protect investors and the public interest by enhancing Clearing Members' ability to measure, monitor and manage their risk. The proposed rule change is not inconsistent with the existing rules of OCC, including any other rules proposed to be amended.

In addition, SEC Rule 17Ad–22(e)(23)(ii) [11] provides that a clearing agency must establish, implement, maintain and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency. The proposed revisions to both Rule 1111(e) and Rule 1111(g) would provide additional clarity that would help Clearing Members identify and evaluate the risks, fees and other costs that they may incur as a result of the participation in OCC's services. The proposed revisions to Rule 1111(e) clarify the nature of the claim that would be issued to Clearing Members if a Partial Tear-Up was used to allocate losses, and the change to Rule 1111(g) would implement a cap on the charge that could be levied under this provision. Both of these changes should improve Clearing Members' ability to assess the potential risks, fees and costs that they may incur by participating in OCC. Accordingly, OCC believes that the proposed rule change is reasonably designed to provide participants sufficient information to identify and evaluate the risks, fees, and other material costs of participating in OCC's services, in accordance with SEC Rule 17Ad–22(e)(23)(ii).[12]

(B) Clearing Agency's Statement on Burden of Competition

Section 17A(b)(3)(I) of the Act [13] requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. OCC does not believe that the proposal to clarify the nature of the claim issued to a Clearing Member that received a pro rata payment following a Partial Tear-Up would impose any burden on competition because it would merely confirm the current meaning of OCC's rules as opposed to changing it. The proposed clarification would not inhibit access to OCC's services in any way, applies to all Clearing Members and does not disadvantage or favor any particular user in relationship to another user. OCC does not believe that the proposed limit to the amount of the special charge that can be levied under Rule 1111(g) would impose any burden on competition. All Clearing Members would benefit from the improved clarity provided by the proposed limit, which would in no way inhibit access to OCC's services and does not disadvantage or favor any particular user in relationship to another user. Accordingly, OCC does not believe that the proposed rule change would have any impact or impose a 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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

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–2022–005 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2022–005. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules#rule-filings.*

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.

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] 17 CFR. 240.17AD–22(e)(23)(ii).

[12] 17 CFR. 240.17AD–22(e)(23)(ii).

[13] 15 U.S.C. 78q–1(b)(3)(I).

All submissions should refer to File Number SR–OCC–2022–005 and should be submitted on or before April 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07342 Filed 4–6–22; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before June 6, 2022.

ADDRESSES: Send all comments to Lori Gillen, HUBZone Program, Small Business Administration, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Lori Gillen, HUBZone Program Director *lori.gillen@sba.gov* or Curtis B. Rich Agency Clearance Officer 202–205–7030 *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: The collected information is submitted by small business concerns seeking certification as a certified HUBZone small business. SBA uses the information to verify a concern's eligibility for the HUBZone programs, to comply a database of qualified small business concerns, as well as for the re-certification and examination of certified HUBZone small business concerns. Finally, SBA uses the information to prepare reports for the Executive and legislative branches.

OMB Control Number 3245–0320

Title: ''HUBZone Program Electronic Application, Recertification, and Program Examination.''

Description of Respondents: Small business concerns seeking certification as a certified HUBZone small business concern.

Form Number: N/A.

Annual Responses: 3,621.

Annual Burden: 11,425.5.

Curtis Rich,

Management Analyst.

[FR Doc. 2022–07371 Filed 4–6–22; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17383 and #17384; WASHINGTON Disaster Number WA–00104]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Washington

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Washington (FEMA–4650–DR), dated 03/29/2022.

Incident: Severe Winter Storms, Straight-line Winds, Flooding, Landslides, and Mudslides.

Incident Period: 01/01/2022 through 01/15/2022.

DATES: Issued on 03/29/2022.

Physical Loan Application Deadline Date: 05/30/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 12/29/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 03/29/2022, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Cowlitz, Franklin, Grays Harbor, Jefferson, Klickitat, Lewis, Mason, Pacific, Skagit, Skamania, Thurston, Wahkiakum. the Skokomish Indian Tribe, Quinault Indian Nation, Shoalwater Bay Indian Tribe of the Shoalwater Bay Indian Reservation, Squaxin Island Tribe of the Squaxin Island Reservation, Hoh Indian Tribe, Nisqually Indian Tribe, Confederated Tribes of the Chehalis Reservation, Swinomish Indian Tribal Community, and the Upper Skagit Indian Tribe.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17383 B and for economic injury is 17384 0.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez,

Associate Administrator for Disaster Assistance.

[FR Doc. 2022–07372 Filed 4–6–22; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–0455]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Certification of Airmen for the Operation of Light-Sport Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request Office of Management and Budget (OMB) approval to renew an information collection. This collection involves the submission of forms and other reporting and recordkeeping activities. The information to be collected is necessary to ensure compliance with regulations governing the manufacture and certification of light-sport aircraft, the training and certification of light-sport pilots and instructors, and the certification of light-sport aircraft Designated Pilot Examiners.

DATES: Written comments should be submitted by June 6, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Dwayne C. Morris, 800 Independence Ave. SW, Washington, DC 20591.

By email: chris.morris@faa.gov.

FOR FURTHER INFORMATION CONTACT: Craig Holmes by email at: *craig.holmes@faa.gov;* phone: 202–267–1607.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0690.

Title: Certification of Airmen for the Operation of Light-Sport Aircraft.

Form Numbers: FAA form 8130–15, 8710–11, 8710–12.

Type of Review: Renewal.

Background: This information collection requires applicants for certification as sport pilots to complete FAA form 8710–11, log training, take and pass a knowledge test, and requires organizations to develop and maintain training courses for sport pilots. The total of sport pilot applicants is estimated to be 500, with a burden of 3,400 hours. In addition, applications for certification as sport pilot instructors are required to take and pass a knowledge test, submit to a flight review, and purchase a training course. This affects an estimated 40 applicants, with a total annual burden of 120 hours.

This collection also requires light-sport aircraft owners and manufacturers to submit FAA form 8130–15, which is used to process an applicant's request to obtain a Special Airworthiness certificate for Light Sport Aircraft. FAA Airworthiness inspectors and designated inspectors review the required data submissions to determine that aviation products and their manufacturing facilities comply with ASTM requirements, and that the products have no unsafe features. The FAA estimates that approximately 297 respondents are required to complete FAA form 8130–15, with a total annual burden of 99 hours.

Finally, this collection requires applicants for the authorities and privileges of Designated Pilot Examiners to submit FAA form 8710–12, Light-Sport Standardization Board-Designated Pilot Examiner Candidate Application. The FAA uses the form to obtain essential information concerning the applicants' professional and personal qualifications, and to screen and select the designees who act as representatives of the Administrator in performing various certification and examination functions. The FAA estimates a total of 20 respondents per year, with a total annual burden of 10 hours.

Respondents: Manufacturers, aircraft owners, pilots, flight instructors with a sport pilot rating, and maintenance personnel.

Frequency: On occasion.

Estimated Average Burden per Response: Applicants for certification as sport pilots: 500 applicants; approximately 7 hours per applicant. Applicants for certification as sport pilot instructors: 40 applicants; approximately 3 hours per applicant. Applicants for Special Airworthiness Certificate for Light-Sport Aircraft: 297 applicants; approximately ⅓ hour per response. Applicants for certification as Designated Pilot Examiners: 20 applicants; approximately ½ hour per response.

Estimated Total Annual Burden: Sport pilot applicants: 3,400 hours. Sport pilot instructor applicants: 120 hours. Special Light-Sport Airworthiness certification applicants: 99 hours. Designated Pilot Examiner applicants: 10 hours. Total burden: 3,629.

Issued in Washington, DC, on April 1, 2022.

Dwayne C. Morris,

Project Manager, Flight Standards Service, General Aviation and Commercial Division.

[FR Doc. 2022–07332 Filed 4–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2021–1086]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Aviation Maintenance Technician Schools

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves Aviation Maintenance Technician School (AMTS) applicants and certificate holders. The information to be collected will be used to ensure AMTS applicants and certificate holder meet the requirements of part 147 prior to being certificated, and on an ongoing basis following FAA certification.

DATES: Written comments should be submitted by May 9, 2022.

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: Tanya Glines by email at: *Tanya.glines@faa.gov;* phone: 202–380–5896.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0040.

Title: Aviation Maintenance Technician Schools.

Form Numbers: FAA Form 8310–6.

Type of Review: This is a renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on November 23, 2021 (86 FR 66615). A correction to the 60 day notice was published on February 4, 2022 (87 FR 6646) to correct a typographical error in the Docket Number of the original notice. Although no comments were received after the 60 day notice, the FAA did revise (increase) the estimated burden following that notice, due to calculation errors. 14 CFR part 147 results in the collection of information, including reporting and recordkeeping requirements, related to AMTS. The information collected is provided to the certificate holder/applicant's

responsible FAA Flight Standards office in order to allow the FAA to determine compliance with the part 147 requirements for obtaining and/or retaining an FAA air agency certificate. For applicants, when all part 147 requirements have been met, an FAA air agency certificate is issued, with the appropriate ratings. For FAA-certificated AMTS, the FAA uses the information collected to determine if the AMTS provides appropriate training using an FAA-approved curriculum, keeps records that demonstrate each students training, and to ensure that AMTS graduates receive an appropriate document showing the graduate is eligible to take the FAA tests required to obtain a mechanic certificate.

Respondents: Approximately 10 AMTS applicants, and 182 FAA-certificated applicants respond to this collection annually.

Frequency: AMTS applicants respond one time, prior to certification. FAA-certificated AMTS respond occasionally after certification, and have ongoing recordkeeping requirements.

Estimated Average Burden per Response: 112 hours.

Estimated Total Annual Burden: 64,025 hours/year.

Issued in Washington, DC, on April 1, 2022.

Tanya A. Glines,

Aviation Safety Inspector, Office of Safety Standards, Aircraft Maintenance Division, General Aviation Branch.

[FR Doc. 2022–07335 Filed 4–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0347]

Commercial Driver's License Standards: Application for Exemption; Navistar, Inc. (Navistar)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that Navistar, Inc. (Navistar) has requested a 5-year exemption from the Federal requirement to hold a U.S. commercial driver's license (CDL) for Mr. Anders Björkman, an engineer with Scania's Powertrain Control systems group in Sweden. Navistar and Scania are both subsidiaries of Germany's TRATON Group. Mr. Björkman holds a valid Swedish commercial license and needs to test drive Navistar CMVs on U.S. roads to better understand product requirements in ''real world'' environments and to verify results.

DATES: Comments must be received on or before May 9, 2022.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket ID FMCSA–2018–0347 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b) DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4225. Email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2018–0347), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number, ''FMCSA–2018–0347'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be

published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must specify the effective period of the exemption (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulation(s) Requirements

Under 49 CFR 383.23, no person shall operate a commercial motor vehicle (CMV) unless such person has taken and passed the knowledge and driving skills tests for a commercial learner's permit or CDL that meet the Federal standards in subparts F, G, and H of part 383 for the CMV that person operates or expects to operate.

Applicant's Request

Navistar has applied for an exemption for Anders Björkman from 49 CFR 383.23, which prescribes licensing requirements for drivers operating CMVs in interstate or intrastate commerce. Mr. Björkman is a citizen of Sweden and therefore cannot apply for a CDL in any of the U.S. States due to his lack of residency in this country.

The exemption would allow Mr. Björkman to operate CMVs in interstate or intrastate commerce as part of Navistar field tests designed to meet future vehicle safety and to promote the development of new and advanced emissions reduction systems and fuel efficiency improvements. According to Navistar, Mr. Björkman will typically drive for no more than 8 hours per day for 2 consecutive days, and that 50 percent of the test driving will be on two-lane State highways, while 50 percent will be on interstate highways. The driving will consist of no more than 300 miles per day, and in all cases Mr. Björkman will be accompanied by a holder of a U.S. CDL who is familiar with the routes to be traveled.

IV. Equivalent Level of Safety

Mr. Björkman holds a valid Swedish commercial license, and as explained by Navistar in its exemption request, the requirements for that license ensure that, operating under the exemption, he would likely achieve a level of safety equivalent to, or greater than the level that would be achieved by the current regulation. Furthermore, Mr. Björkman is familiar with the operations of CMVs worldwide and, a U.S. CDL holder who is familiar with the FMCSA regulations as well as the specific routes to be driven will always accompany Mr. Björkman when he is driving a CMV.

V. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on Navistar's application for an exemption from the CDL requirements in 49 CFR 383.23. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

A copy of Navistar's application for exemption is available in the docket for this notice.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2022–07373 Filed 4–6–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2022–0002]

National Transit Database Census Reporting Clarifications

AGENCY: Federal Transit Administration, United States Department of Transportation (DOT).

ACTION: Final notice; response to comments.

SUMMARY: This notice responds to comments received and finalizes on changes to the Federal Transit Administration's (FTA) National Transit Database (NTD) reporting requirements published in the **Federal Register** on January 19, 2022.

DATES: FTA will implement the reporting changes in Report Year 2021.

FOR FURTHER INFORMATION CONTACT: Thomas Coleman, National Transit Database Program Manager, FTA Office of Budget and Policy, *thomas.coleman@dot.gov.*

SUPPLEMENTARY INFORMATION: The National Transit Database (NTD) is the Federal Transit Administration's (FTA's) primary database for statistics on the transit industry. Pursuant to 49 U.S.C. 5334(k), FTA published a notice in the **Federal Register** on January 19, 2022, (87 FR 2980) seeking public comment on changes to the NTD reporting requirements as they relate to Urbanized Areas. The comment period closed on February 18, 2022.

FTA received one comment. The commenter asked whether the reporting changes will apply to transit systems that have a Fiscal Year of July through June.

FTA Response: The reporting changes affect all transit systems that submit basic information (B–10) and Federal Funding Allocation (FFA–10) forms. The changes will apply to such transit systems in Report Year 2021, regardless of their individual Fiscal Year end dates.

In this notice, FTA adopts the proposed policy without change. Accordingly, transit systems must submit the B–10 and FFA–10 forms using 2010 Census data by the normal NTD annual report deadline. If the Census Bureau releases new Urbanized Area definitions prior to October 1, 2022, then transit operators must submit new B–10 and FFA–10 forms using 2020 Census data as an addendum to the annual report. Collecting this addendum based on 2020 Census data is necessary to allow FTA to meet the Urbanized Area definition found in 49 U.S.C. 5302(24) and produce apportionment data files that support the apportionment of formula funds. If the Census Bureau releases new Urbanized Area definitions on or after October 1, 2022, then FTA will not require the form addendum and will instead integrate the new urbanized area definitions into the 2022 reporting process.

To minimize the reporting burden, transit operators will not have to fill in the addendum from scratch. The addendum will pull in as much data as possible from the initial FFA–10 and B–10 forms completed using 2010 Census UZA definitions, based on unchanged or minimally changed UZA boundaries.

Nuria I. Fernandez,

Administrator.

[FR Doc. 2022–07448 Filed 4–6–22; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0073]

Agency Information Collection Activities; Notice and Request for Comment; Survey on Driver Awareness of Motorcycles

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for approval of a new information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a new information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes a collection of information for which NHTSA intends to seek OMB approval on Driver Awareness of Motorcycles.

DATES: Comments must be submitted on or before June 6, 2022.

ADDRESSES: You may submit comments identified by the Docket No. NHTSA–2020–0073 using any of the following methods:

- *Electronic submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.

Instructions: All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Kathryn Wochinger, Ph.D., Office of Behavioral Safety Research (NPD–310), (202) 366–4300, National Highway Traffic Safety Administration, W46–487, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) how to enhance the quality, utility, and clarity of the information to be collected; and (d) how to 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 responses. In compliance with these requirements, NHTSA asks for public comment on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: Driver Awareness of Motorcycles.

OMB Control Number: New.

Form Numbers: NHTSA Forms 1577, 1578, 1579, 1580, 1581, 1582, 1583, and 1588.

Type of Request: Approval of a new information collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: NHTSA is seeking approval to collect information from two samples of randomly selected adults who are aged 18 years or older and have driven a motor vehicle at least once in the past three months for a new one-time voluntary survey to report their knowledge, attitudes, and awareness of safe-driving behaviors towards motorcycles. One sample consists of adult drivers residing in Florida and the other sample consists of adult drivers residing in Pennsylvania. Surveys would be conducted with respondents using an address-based sampling design that encourages respondents to complete the survey online. NHTSA will contact a total of 33,460 to achieve a target of at least 2,486 complete voluntary responses consisting of 1,243 completed instruments from the Florida sample and 1,243 completed instruments from the Pennsylvania sample. The large geographic and demographic sizes of Florida and Pennsylvania allow for complex driving environments in which motorcycles and passenger vehicles operate in a range of traffic conditions. Notably, neither State has a universal motorcycle helmet use law, but each has a sizable population of registered motorcycles and varied helmet use rates. For example, in 2019, 52 percent of motorcyclists killed in Florida and 51 percent of motorcyclists killed in Pennsylvania were not helmeted.[1]

The estimated burden of this collection is 3,289 hours with 2,709 hours associated with survey invitations and reminders and 580 hours associated with survey completions. NHTSA will summarize the results of the collection using aggregate statistics in a final report to be distributed to NHTSA program and regional offices, State Highway Safety Offices, and other traffic safety and motorcycle safety stakeholders. This collection supports NHTSA's mission by obtaining information needed for the development of traffic safety countermeasures,

[1] National Center for Statistics and Analysis. (2021, April). Motorcycles: 2019 data (Traffic Safety Facts, Report No. DOT HS 813 112). National Highway Traffic Safety Administration.

particularly in the areas of communications and outreach, for the purpose of reducing fatalities, injuries, and crashes associated with multi-vehicle motorcycle crashes.

Description of the Need for the Information and Proposed Use of the Information: NHTSA was established by the Highway Safety Act of 1970 to reduce deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. To further its mission, NHTSA is authorized to conduct research as a foundation for the development of traffic safety programs. Title 23, United States Code, Section 403, gives the Secretary of Transportation (NHTSA by delegation) authorization to use funds appropriated to conduct research and development activities, including demonstration projects and the collection and analysis of highway and motor vehicle safety data and related information, with respect to all aspects of highway and traffic safety systems and conditions relating to vehicle, highway, driver, passenger, motorcyclist, bicyclist, and pedestrian characteristics; accident causation and investigations; and human behavioral factors and their effect on highway and traffic safety. Motorcycle safety is a behavioral area for which NHTSA has developed programs to meet its injury reduction goals. Motorcycle safety is an increasing safety concern in highway transportation. For example, per vehicle miles traveled in 2019, motorcyclist fatalities occurred nearly 29 times more frequently than passenger car occupant fatalities in traffic crashes, and an estimated 84,000 motorcyclists were injured in 2019, which is a 2-percent increase from 82,000 motorcyclists injured in 2018; the most harmful event for 55 percent of the 5,114 motorcycles involved in fatal crashes in 2019 was a collision with another motor vehicle; and in two-vehicle crashes, 76 percent of the motorcycles involved in fatal crashes were struck in the front.[1] Thus, strategies for improving motorcycle safety include addressing other motorists' perceptions and awareness of motorcycles.

This collection supports NHTSA's efforts to increase motorcyclist safety by examining factors related to the interactions between motorcycles and other motorists and their vehicles. The information from this collection will assist NHTSA in (a) assessing the extent and limitations of motorist knowledge of safe behaviors toward motorcycles, and (b) identifying the issues to emphasize in traffic safety campaigns and driver education. The collected information will help identify the beliefs, attitudes, and perceptions underlying driving behaviors towards motorcycles and inform the development of countermeasures to improve the safety of interactions between motor vehicles, specifically, motorcycles, and other vehicle types (primarily passenger cars and Sport Utility Vehicles (SUVs)).

The survey data will be used to assist NHTSA in its ongoing responsibilities for: (a) Planning and designing research and program activities to improve motorcycle safety; (b) providing support to groups involved in developing and implementing motorcycle safety outreach programs and driver safety campaigns; and (c) identifying areas in driver awareness and knowledge that need attention. NHTSA will use the information to produce a technical report that presents the results of the study. The technical report will provide aggregate (summary) statistics and tables as well as the results of statistical analysis of the information, but it will not include any personally identifiable information (PII). The project data will serve as a resource for NHTSA and stakeholders to identify gaps in knowledge among the driving public. The technical report will be shared with State highway offices, local governments, and those who develop traffic safety communications that aim to improve motorcycle safety.

Affected Public: Participants will be U.S. adults (18 years and older) who reside in Florida or Pennsylvania and who have driven a motor vehicle (car, van, SUV, or pickup truck) at least once in the past three months. Businesses are ineligible for the sample and would not be surveyed.

Estimated Number of Respondents: 2,486 consisting of 1,243 in the Florida sample and 1,243 in the Pennsylvania sample. The project will invite 33,460 people to participate using address data from the most recent U.S. Postal Service (USPS) computerized Delivery Sequence File (DSF) of residential addresses. No more than one respondent will be selected per household.

Frequency of Collection: The study will be conducted one time during the three-year period for which NHTSA is requesting approval and there will be no recurrence.

Estimated Total Annual Burden Hours: NHTSA estimates the total burden of this information collection by estimating the burden to those who NHTSA contacts who respond and are eligible for participation (eligible respondents that take the survey) and those contacted that choose not to take the survey (non-responders) or are not eligible to participate. The estimated time to contact 33,460 potential participants (participants and non-responders) for the survey is one minute per person per contact attempt. Contact attempts will be made in five waves with fewer potential participants contacted in each subsequent wave. Potential participants will receive an initial postcard informing them of the project and inviting participation. The first contact is a postcard introducing the project and inviting participation. The second contact is an invitation letter with instructions for completing the survey online (as the methodology follows a ''push-to-web'' design to provide incentive to complete the survey online). The third contact is a reminder postcard. The fourth is a letter with a paper questionnaire and the fifth is a final reminder postcard. The sixth and final wave is a ''thank you'' letter that will include the contingent incentive to respondents who have provided a completed response. NHTSA estimates that 2,486 people will respond to the survey request. The estimated time to contact (1 minute) and complete the survey (14 minutes) is 15 minutes per person. The total burden estimated for this information collection is 3,289 hours. Table 1 provides a description for each of the forms used in the survey protocol as well as their mailing wave. Details of the burden hours for each wave in the survey are included in Table 2. When rounded up to the nearest whole hour for each data collection effort, the total estimated annual burden is 3,289 hours for the project activities.

TABLE 1—NHTSA FORM NUMBER, DESCRIPTION, AND MAILING WAVE

NHTSA form No.	Description	Mailing wave
1577	Initial Postcard—serves as a notice of selection, explains survey rationale	1
1578	Invitation Letter—provides instructions and hyperlink to the online survey and includes the $1 non-contingent incentive.	2
1579	Reminder Postcard #1—the first reminder, includes instructions and hyperlink to the online survey	3

TABLE 1—NHTSA FORM NUMBER, DESCRIPTION, AND MAILING WAVE—Continued

NHTSA form No.	Description	Mailing wave
1580	Reminder Letter #1—the second reminder with the paper survey, prepaid return envelope, PIN, and hyperlink to the online survey.	4
1581	Reminder Postcard #2—last reminder, includes hyperlink to the online survey	5
1582	Questionnaire—the online version, provided on a secure website	2, 3, 4, 5
1583	Questionnaire—the paper version, for responders not using the online questionnaire	4
1588	Thank You Letter—includes the contingent incentive	6

Table 2 shows the estimated burden for each contact (wave) by participation type (non-respondent, eligible, and ineligible). In the first wave, 33,460 potential respondents are expected to spend 1 minute each reading the postcard, resulting in an estimated burden of 558 hours. This calculation is applied for each subsequent wave, as detailed in Table 2.

TABLE 2—ESTIMATED TOTAL BURDEN FOR DATA COLLECTION

Mailing wave (form No.)	Number of contacts	Participant type	Estimated burden per sample unit (in minutes)	Frequency of burden	Number of sample units	Burden hours *	Total burden hours *
Wave 1—NHTSA Form 1577	33,460	Contacted potential participant	1	1	33,460	558	558
Wave 2—NHTSA Form 1578	33,460	Non-respondent	1	1	31,787	530	870
		Ineligible respondent	1	1	335	6	
		Eligible respondent	15	1	1,338	334	
Wave 3—NHTSA Form 1579	31,787	Non-respondent	1	1	30,833	514	708
		Ineligible respondent	1	1	191	3	
		Eligible respondent	15	1	763	191	
Wave 4—NHTSA Form 1580	30,833	Non-respondent	1	1	30,524	509	572
		Ineligible respondent	1	1	62	1	
		Eligible respondent	15	1	247	62	
Wave 5—NHTSA Form 1581	30,524	Non-respondent	1	1	30,351	506	541
		Ineligible respondent	1	1	35	1	
		Eligible respondent	15	1	138	34	
Wave 6—NHTSA Form 1588	2,486	Completed responders	1	1	2,486	41	41
Total							3,289

* Rounded up to the nearest hour.

Table 3 provides total burden hours associated with each NHTSA form. For example, 2,486 anticipated responders who provide completed questionnaires (NHTSA Forms 1582 and 1583) are expected to spend 14 minutes each, resulting in an estimated burden of 580 hours.

TABLE 3—ESTIMATED TOTAL BURDEN BY NHTSA FORM FOR THE DATA COLLECTION

Information collection	Number of responses	Burden per response (minutes)	Burden per respondent (minutes)	Total burden hours *
Questionnaire—NHTSA Forms 1582 and 1583	2,486	14	14	580
Initial Postcard—NHTSA Form 1577	33,460	1	1	558
Invitation Letter—NHTSA Form 1578	33,460	1	1	558
Postcard Reminder—NHTSA Form 1579	31,787	1	1	530
Reminder Letter—NHTSA Form 1580	30,833	1	1	514
Final Postcard Reminder—NHTSA Form 1581	30,524	1	1	508
Thank You Letter—NHTSA Form 1588	2,486	1	1	41
Total				3,289

* Rounded up to the nearest hour.

Estimated Total Annual Burden Cost: NHTSA estimates that there are no costs to respondents beyond the time spent participating in the study.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Issued in Washington, DC.

Nanda Narayanan Srinivasan,

Associate Administrator, Research and Program Development.

[FR Doc. 2022–07358 Filed 4–6–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0016]

Agency Information Collection Activities; Notice and Request for Comment; Consumer Complaint Information

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a reinstatement of a previously approved collection of information.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a reinstatement of a previously approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes a collection of information for which NHTSA intends to seek OMB approval on information gathered through consumer complaints.

DATES: Written comments should be submitted by June 6, 2022.

ADDRESSES: You may submit comments identified by Docket No. NHTSA–2022–0016 through one of the following methods:

- *Electronic Submissions:* Go to the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.

Instructions: All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Randy Reid, Office of Defects Investigation (NEF–100), 212–366–2315, National Highway Traffic Safety Administration, W48–335, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, email: *randy.reid@dot.gov.* Please identify the relevant collection of information by referring to its OMB Control Number (2127–0008).

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) how to enhance the quality, utility, and clarity of the information to be collected; and (d) how to 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 responses. In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: Consumer Complaint Information.

OMB Control Number: 2127–0008.

Type of Request: Reinstatement of a previously approved information collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: Chapter 301 of title 49 of the United States Code authorizes the Secretary of Transportation (NHTSA by delegation) to require manufacturers of motor vehicles and motor vehicle equipment to conduct owner notification and remedy, *i.e.,* a recall campaign, when it has been determined that a safety defect exists in the performance, construction, components, or materials in motor vehicles and motor vehicle equipment. Pursuant to Title 49 of the United States Code of Federal Regulations (CFR) Parts 573 and 577, manufacturers are required to notify NHTSA, as well as motor vehicle and motor vehicle equipment owners, dealers, and distributors, that a determination has been made to remedy a defect through the issuance of a safety recall. Manufacturers often initiate safety recalls voluntarily, while other recalls are influenced by NHTSA investigations or ordered by NHTSA via a court ruling. A manufacturer of each such motor vehicle or item of replacement equipment presented for remedy pursuant to such notification is required to remedy the safety defect at no charge to the owner. The manufacturer shall cause the vehicle to be remedied by any of the following means: (1) By repairing such vehicle or equipment; (2) by replacing such motor vehicle or equipment with an identical or similar product; or (3) by refunding the purchase price less depreciation.

In order to help NHTSA identify safety-related defects, the agency solicits information from vehicle owners. This information is used to identify and evaluate possible safety-related defects and provide the necessary evidence of the existence of such a defect. NHTSA also uses the information to monitor the adequacy of a manufacturer's recall efforts. Consumers of motor vehicles or

motor vehicle equipment voluntarily submit complaints through NHTSA's Vehicle Safety Hotline, NHTSA's website (*www.nhtsa.gov*), or through correspondence.

Description of the Need for the Information and Proposed Use of the Information: NHTSA uses input from consumers to help identify potential safety-related defects that could lead to a safety recall or recall inadequacies. The complaints disclose consumers' allegations of a safety defect that they experienced with their vehicle or vehicle equipment, including defects that resulted in injuries, crashes, property damage, or death. All complaints are converted to a Vehicle Owner Questionnaire (VOQ) format and reviewed by NHTSA investigation/engineer staff. A NHTSA investigator may respond to a consumer submitting a complaint if more information is required. NHTSA staff review complaints/VOQs and determines whether further action by the agency is warranted. The agency has used this information to develop technical foundations of evidence with which to prove to manufacturers and a court that safety-related defects exist which require remedy. The information collection provides valuable information that helps NHTSA identify unreasonable safety risks in specific makes, models, and model years of vehicles and equipment and helps the agency determine when to open an investigation or initiate a recall. In this way, the information collection helps to reduce the number of crashes, fires, injuries, and fatalities that occur on our Nation's highways.

Affected Public: Consumers of motor vehicles and motor vehicle equipment.

Estimated Number of Respondents: 55,433.

There is an average of 58,350 complaints submitted per year (average of 160 complaints submitted each day). Some individuals submit multiple complaints to NHTSA. To estimate the total of unique respondents per year, NHTSA estimates that the number of unique respondents is 95 percent of the number of unique complaints. Therefore, NHTSA estimates that there will be approximately 55,433 respondents each year (58,250 × .95).

Frequency: On-occasion.

The submission of complaints is triggered by the occurrence of a problem with a consumer's vehicle.

Number of Responses: 58,350.

Estimated Total Annual Burden Hours: 9,725 hours.

Respondents have averaged 58,350 consumer complaints per year to NHTSA between January 2018 and December 2020. NHTSA anticipates that a respondent can complete a VOQ in approximately 10 minutes. The consumer is asked to provide his/her name, complete mailing address, product information, failed component information, and incident information, copies of supporting documentation, and his/her signature. NHTSA estimates the total annual burden respondents to be 9,725 hours (58,350 respondents × 10 minutes per VOQ = 9,725 annual hourly burden). To calculate the opportunity cost to respondents associated with the collection, NHTSA used the national average hourly earnings of all employees on private nonfarm payrolls which the Bureau of Labor Statistics lists at $30.44.[1] Therefore, opportunity cost associated with annual burden hours associated with respondents submitting complaints is estimated to be $296,029 (9,725 hours × $30.44 per hour = $296,029 annual opportunity cost burden).

TABLE 1—ANNUAL HOUR BURDEN ESTIMATES

Annual number of respondents/responses	Estimated time per response (minutes)	Average hourly opportunity cost	Opportunity cost per submission	Total annual burden hours	Total annual opportunity costs
58,350	10	$30.44	$5.07	9,725	$296,029

Estimated Total Annual Burden Cost: $0.

Participation in this collection is voluntary, and there are no costs to respondents beyond the time spent submitting a complaint.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49; and DOT Order 1351.29.

Stephen Ridella,

Director, Office of Defects Investigation, NHTSA.

[FR Doc. 2022–07425 Filed 4–6–22; 8:45 am]

BILLING CODE 4910–59–P

[1] See Table B–3. Average hourly and weekly earnings of all employees on private nonfarm payrolls, June 2021, available at *https://www.bls.gov/news.release/empsit.t19.htm* (accessed September 16, 2021).

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them. OFAC is also publishing the name of an entity whose property and interests in property have been unblocked and removed from the list of Specially Designated Nationals and Blocked Persons.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT:
OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On March 31, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

BILLING CODE 4810–AL–P

Individuals

1. DUBROVINSKIY, Viacheslav Yuryevich (Cyrillic: ДУБРОВИНСКИЙ, Юрьевич Вячеслав), Russia; DOB 30 Mar 1966; POB Gomel, Belarus; nationality Russia; citizen Russia; Gender Male; Tax ID No. 500912223914 (Russia) (individual) [RUSSIA-EO14024] (Linked To: OOO SERNIYA INZHINIRING).

   Designated pursuant to Section 1(a)(iii)(C) of Executive Order 14024 of April 15, 2021, "Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation," (E.O. 14024) for being or having been a leader, official, senior executive officer, or member of the board of directors of OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

2. KRUGOVOV, Anton Alekseevich (Cyrillic: КРУГОВОВ, Антон Алексеевич) (a.k.a. KRUGOVOV, Anton Alekseyevich), Russia; DOB 08 Aug 1981; POB Kurchatov, Russia; nationality Russia; citizen Russia; Gender Male; Passport 718255951 (Russia); National ID No. 2006744304 (Russia) (individual) [RUSSIA-EO14024] (Linked To: MAJORY LLP; Linked To: OOO SERNIYA INZHINIRING).

   Designated pursuant to Section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of MAJORY LLP, a person whose property and interests in property are blocked pursuant to E.O. 14024.

   Also designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

3. GRININ, Yevgeniy Aleksandrovich (Cyrillic: ГРИНИН, Евгений Александрович) (a.k.a. GRININ, Evgenij Aleksandrovich), Russia; DOB 15 Apr 1978; Gender Male; National ID No. 253105350001 (United Kingdom); Tax ID No. 550305192743 (Russia) (individual) [RUSSIA-EO14024] (Linked To: OOO SERNIYA INZHINIRING; Linked To: PHOTON PRO LLP).

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

   Also designated pursuant to Section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of PHOTON PRO LLP, a person whose property and interests in property are blocked pursuant to E.O. 14024.

4. ZAKHAROV, Andrey Georgiyevich (Cyrillic: ЗАХАРОВ, Андрей Георгиевич), Russia; DOB 08 Jan 1969; nationality Russia; Gender Male; Tax ID No. 771609756695 (Russia) (individual) [RUSSIA-EO14024] (Linked To: OOO SERNIYA INZHINIRING).

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

5. NIKOLAEVA, Irina Viktorovna (Cyrillic: НИКОЛАЕВА, Ирина Викторовна) (a.k.a. KITAEVA, Irina Viktorovna), Russia; DOB 15 Jul 1983; POB Troitsk, Russia; nationality Russia; citizen Russia; Gender Female; National ID No. 4607444893 (Russia); Tax ID No. 504603132375 (Russia) (individual) [RUSSIA-EO14024] (Linked To: OOO SERNIYA INZHINIRING).

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

6. YERSHOV, Sergey Aleksandrovich (Cyrillic: ЕРШОВ, Сергей Александрович) (a.k.a. ERSHOV, Sergei Aleksandrovich), Russia; DOB 16 Oct 1952; nationality Russia; Gender Male; Tax ID No. 502601808086 (Russia) (individual) [RUSSIA-EO14024] (Linked To: OOO SERNIYA INZHINIRING; Linked To: OOO SERTAL).

   Designated pursuant to Section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

   Also designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or

indirectly, OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

Also designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, OOO SERTAL, a person whose property and interests in property are blocked pursuant to E.O. 14024.

7. TOPCHI, Tamara Aleksandrovna, Russia; DOB 04 Mar 1979; POB Voronezh, Russia; nationality Russia; citizen Russia; Gender Female; National ID No. 2003490198 (Russia) (individual) [RUSSIA-EO14024] (Linked To: INVENTION BRIDGE SL).

   Designated pursuant to Section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of INVENTION BRIDGE SL, a person whose property and interests in property are blocked pursuant to E.O. 14024.

8. PODGORNOVA, Yevgeniya Aleksandrovna (f.k.a. BOLTACHEVA, Yevgeniya Aleksandrovna), Russia; DOB 16 Jul 1980; nationality Russia; Gender Female; Passport 754582022 (Russia) (individual) [RUSSIA-EO14024] (Linked To: OOO SERNIYA INZHINIRING).

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

9. BERNOVA, Evgeniya Vladimirovna (a.k.a. ARTAMANOVA, Evgeniya Vladimirovna), Malta; Russia; France; Germany; DOB 26 Mar 1974; POB Potsdam, Germany; nationality Russia; alt. nationality Malta; citizen Russia; Gender Female; Passport 1185334 (Malta); alt. Passport 716415548 (Russia); National ID No. 4502572626 (Russia) (individual) [RUSSIA-EO14024] (Linked To: MALBERG LIMITED).

   Designated pursuant to Section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of MALBERG LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 14024.

   Also designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

10. SOBOLEV, Nikita Aleksandrovich, Malta; DOB 07 Jun 1986; nationality Russia; Gender Male; Passport 550193782 (Russia); National ID No. 238667A (Malta) (individual) [RUSSIA-EO14024] (Linked To: MALBERG LIMITED).

    Designated pursuant to Section 1(a)(iii)(C) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of

directors of MALBERG LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 14024.

11. BOBKOV, Sergei Alekseevich (Cyrillic: БОБКОВ, Сергей Алексеевич) (a.k.a. BOBKOV, Sergey Alekseyevich), Russia; DOB 21 Jun 1980; POB Moscow, Russia; nationality Russia; citizen Russia; Gender Male; Tax ID No. 7726000947136 (Russia) (individual) [CAATSA - RUSSIA] (Linked To: STATE RESEARCH CENTER OF THE RUSSIAN FEDERATION FGUP CENTRAL SCIENTIFIC RESEARCH INSTITUTE OF CHEMISTRY AND MECHANICS).

    Designated pursuant to Section 224(a)(1)(B) of the Countering America's Adversaries Through Sanctions Act, Public Law 115-44 (CAATSA), for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the STATE RESEARCH CENTER OF THE RUSSIAN FEDERATION FGUP CENTRAL SCIENTIFIC RESEARCH INSTITUTE OF CHEMISTRY AND MECHANICS (TSNIIKHM), a person designated under Section 224(a)(1)(A) of CAATSA.

12. GLADKIKH, Evgeny Viktorovich (Cyrillic: ГЛАДКИХ, Евгений Викторович) (a.k.a. GLADKIKH, Yevgeniy Viktorovich), Moscow, Russia; DOB 05 Sep 1985; citizen Russia; Gender Male (individual) [CAATSA - RUSSIA] (Linked To: STATE RESEARCH CENTER OF THE RUSSIAN FEDERATION FGUP CENTRAL SCIENTIFIC RESEARCH INSTITUTE OF CHEMISTRY AND MECHANICS).

    Designated pursuant to Section 224(a)(1)(B) of CAATSA, for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, TSNIIKHM, a person designated under Section 224(a)(1)(A) of CAATSA.

13. MALEVANYY, Konstantin Vasilyevich (Cyrillic: МАЛЕВАНЫЙ, Константин Василевич), Moscow, Russia; DOB 08 Jan 1971; POB Vlasikha Village, Moscow Region, Russia; nationality Russia; citizen Russia; Gender Male; National ID No. 4515428051 (Russia) (individual) [CAATSA - RUSSIA] (Linked To: STATE RESEARCH CENTER OF THE RUSSIAN FEDERATION FGUP CENTRAL SCIENTIFIC RESEARCH INSTITUTE OF CHEMISTRY AND MECHANICS).

    Designated pursuant to Section 224(a)(1)(B) of CAATSA, for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, TSNIIKHM, a person designated under Section 224(a)(1)(A) of CAATSA.

Entities

1. OOO SERNIYA INZHINIRING (Cyrillic: ООО СЕРНИЯ ИНЖИНИРИНГ) (a.k.a. SERNIA ENGINEERING), d. 57A etazh 2 pom. 211 kom. 211-13, ul. Vavilova, Moscow 117292, Russia; Tax ID No. 971529478 (Russia); Government Gazette Number 06644891 (Russia); Registration Number 1177746132563 (Russia) [RUSSIA-EO14024].

Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

2. OOO SERTAL (Cyrillic: ООО СЕРТАЛ), Ul. Yablachkova D. 21 Korpus 3, Et 3 Pom VIII Kom 1I, Moscow 127322, Russia; P.O. Box 708, Moscow 119330, Russia; Tax ID No. 9715216050 (Russia); Registration Number 1157746840569 (Russia) [RUSSIA-EO14024].

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

3. MAJORY LLP, 25 City Road Spaces City Road, Epworth House, Office 320, London EC4A 1BR, United Kingdom; Suite 3.15 One Fetter Lane, London EC1Y 1AA, United Kingdom; Organization Established Date 16 Jul 2015; Company Number OC400827 (United Kingdom) [RUSSIA-EO14024].

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

4. PHOTON PRO LLP, 25 City Road Spaces City Road, Epworth House, Office 320, London EC1Y 1AA, United Kingdom; Suite 3.15 One Fetter Lane, London EC4A 1BR, United Kingdom; Organization Established Date 04 Dec 2018; Company Number OC425116 (United Kingdom) [RUSSIA-EO14024].

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

5. OOO ROBIN TREID (Cyrillic: ООО РОБИН ТРЕЙД) (a.k.a. ROBIN TRADE LIMITED), Ul. Yablachkova D. 21 Korpus 3, Et 3 Pom. VIII, Moscow 127322, Russia; Organization Established Date 19 May 2016; Tax ID No. 9715259583 (Russia); Registration Number 1167746480153 (Russia) [RUSSIA-EO14024].

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

6. ALEXSONG PTE LTD (f.k.a. CHAMPION WAY PTE LTD), Albert Street 60 #10-40, City-Beach Road, Singapore 189969, Singapore; Registration Number 199104462G (Singapore) [RUSSIA-EO14024].

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

7. INVENTION BRIDGE SL, Calle Provenca 281 Planta 2 Despacho 9, Barcelona 08037, Spain; Organization Established Date 09 Mar 2016; C.I.F. B66732785

(Spain); Registration Number HB 483203 (Spain) [RUSSIA-EO14024] (Linked To: OOO SERNIYA INZHINIRING).

Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, OOO SERNIYA INZHINIRING, a person whose property and interests in property are blocked pursuant to E.O. 14024.

8. OOO NAUCHNO-TEKHNICHESKII TSENTR METROTEK (Cyrillic: ООО НАУЧНО-ТЕХНИЧЕСКИЙ ЦЕНТР МЕТРОТЕК), Ul. Yablochkova D. 21, Korpus 3, Moscow 127322, Russia; Tax ID No. 9715250083 (Russia); Registration Number 1167746288976 (Russia) [RUSSIA-EO14024] (Linked To: ZAKHAROV, Andrey Georgiyevich).

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, ANDREY GEORGIYEVICH ZAKHAROV, a person whose property and interests in property are blocked pursuant to E.O. 14024.

9. OOO PAMKIN KHAUS (Cyrillic: ООО ПАМКИН ХАУС), Ul. Yablochkova D. 21, Korpus 3, Pom. VIII, Kom. 1S, Moscow 127322, Russia; Tax ID No. 7715848680 (Russia); Registration Number 1117746048122 (Russia) [RUSSIA-EO14024] (Linked To: ZAKHAROV, Andrey Georgiyevich).

   Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, ANDREY GEORGIYEVICH ZAKHAROV, a person whose property and interests in property are blocked pursuant to E.O. 14024.

10. OOO FOTON PRO (Cyrillic: ООО ФОТОН ПРО), Ul. Lodygina D. 3, Korpus Golit. Korp, Et/Pom/Rab 2/206/2, Saransk 430034, Russia; Tax ID No. 1327025929 (Russia); Registration Number 1151327002452 (Russia) [RUSSIA-EO14024] (Linked To: GRININ, Yevgeniy Aleksandrovich).

    Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, YEVGENIY ALEKSANDROVICH GRININ, a person whose property and interests in property are blocked pursuant to E.O. 14024.

11. MALBERG LIMITED, Phoenix Business Centre, the Penthouse, Old Railway Track, Santa Venera SVR 9022, Malta; Cl, Depiro Point, Depiro Street, Sliema SLM 2033, Malta; Organization Established Date 09 Mar 2015; V.A.T. Number 22375337 (Malta); Registration Number C 69456 (Malta) [RUSSIA-EO14024].

    Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

12. DJECO GROUP LP, 38 Thistle Street, International House, Edinburgh, Scotland EH2 1EN, United Kingdom; Organization Established Date 02 Jul 2019;

Company Number SL033858 (United Kingdom) [RUSSIA-EO14024] (Linked To: BERNOVA, Evgeniya Vladimirovna).

Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, EVGENIYA VLADIMIROVNA BERNOVA, a person whose property and interest in property is blocked pursuant to E.O. 14024.

13. DJECO GROUP HOLDING LTD, Phoenix Business Centre, the Penthouse, Old Railway Track, Santa Venera SVR9022, Malta; Organization Established Date 25 Jun 2019; V.A.T. Number 26573325 (Malta); Registration Number C 92321 (Malta) [RUSSIA-EO14024] (Linked To: BERNOVA, Evgeniya Vladimirovna).

Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, EVGENIYA VLADIMIROVNA BERNOVA, a person whose property and interest in property is blocked pursuant to E.O. 14024.

14. MALTARENT LTD, Phoenix Business Centre, the Penthouse, Old Railway Track, Santa Venera SVR9022, Malta; Organization Established Date 28 Apr 2015; V.A.T. Number 22481501 (Malta); Registration Number C 70327 (Malta) [RUSSIA-EO14024] (Linked To: BERNOVA, Evgeniya Vladimirovna).

Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, EVGENIYA VLADIMIROVNA BERNOVA, a person whose property and interest in property is blocked pursuant to E.O. 14024.

15. SCI GRIBER, Parc Saramartel, Villa La Tarente, Promenade Du Soleil, Antibes 06160, France; Organization Established Date 28 Aug 2009; Tax ID No. 514818269 (France) [RUSSIA-EO14024] (Linked To: BERNOVA, Evgeniya Vladimirovna).

Designated pursuant to Section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, EVGENIYA VLADIMIROVNA BERNOVA, a person whose property and interest in property is blocked pursuant to E.O. 14024.

16. SERNIA-FILM CO, LTD, Ul 2-YA Filevskaya D 7/19, Korp 6, Moscow 121096, Russia; Organization Established Date 13 Nov 1995; Tax ID No. 7730070772 (Russia); Registration Number 1027739603055 (Russia) [RUSSIA-EO14024] (Linked To: MALBERG LIMITED).

Designated pursuant to Section 1(a)(vi)(B) of E.O. 14024 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MALBERG LIMITED, a person whose property and interest in property is blocked pursuant to E.O. 14024.

17. JOINT STOCK COMPANY MIKRON (a.k.a. MIKRON JSC; f.k.a. NII MOLEKULYARNOI ELEKTRONIKI I ZAVOD MIKRON PAO; f.k.a. NIIME AND MIKRON; f.k.a. OTKRYTOE AKTSIONERNOE OBSHCHESTVO NII

MOLEKULYARNOY ELECKTRONIKI I ZAVOD MIKRON; a.k.a. PJSC MIKRON; a.k.a. PUBLICHNOE AKTSIONERNOE OBSCHESTVO MIKRON), 1st Zapadny Proezd 12/1, Zelenograd 124460, Russia; d. 6 str. 1, ul. Akademika Valieva, Zelenograd, Moscow 124460, Russia; Organization Established Date 13 Jan 1994; Tax ID No. 7735007358 (Russia); Government Gazette Number 07589295 (Russia); Registration Number 1027700073466 (Russia) [RUSSIA-EO14024].

Designated pursuant to Section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

18. MOLECULAR ELECTRONICS RESEARCH INSTITUTE, JOINT STOCK COMPANY (a.k.a. AKTSIONERNOE OBSHCHESTVO NAUCHNOISLEDOVATELSKIY INSTITUT MOLEKULYARNOY ELEKTRONIKI; a.k.a. AKTSIONERNOE OBSHCHESTVO NAUCHNO-ISSLEDOVATELSKI INSTITUT MOLEKULYARNOI ELEKTRONIKI; a.k.a. JOINT STOCK COMPANY NIIME; a.k.a. NAUCHNO ISSLEDOVATELSKI INSTITUT MOLEKULYARNOI ELEKTRONIKI AO; a.k.a. NIIME, AO), 1st Zapadny Proezd 12/1, Zelenograd 124460, Russia; d. 6 str. 1, ul. Akademika Valieva, Zelenograd, Moscow 124460, Russia; Organization Established Date 03 Sep 1964; Tax ID No. 7735579027 (Russia); Government Gazette Number 92611467 (Russia); Registration Number 1117746568829 (Russia) [RUSSIA-EO14024].

Designated pursuant to Section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

19. T-PLATFORMS (Cyrillic: Т-ПЛАТФОРМЫ) (a.k.a. AO T-PLATFORMS), Ul. Krupskoi D.4, Korp.2, Moscow 119311, Russia; Website t-platforms.ru; Tax ID No. 7736588433 (Russia); Trade License No. 5087746658984 (Russia) [RUSSIA-EO14024].

Designated pursuant to Section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

20. AO NII VEKTOR (a.k.a. JOINT STOCK COMPANY SCIENTIFIC-RESEARCH INSTITUTE VEKTOR), ul. Akademika Pavlova d. 14-A, Saint Petersburg 197376, Russia; Ul. Kantemirovskaya D. 10, Saint Petersburg 197342, Russia; Website nii-vektor.ru; Email Address nii@nii-vektor.ru; Organization Established Date 1908; Tax ID No. 7813491943 (Russia); Trade License No. 1117847020400 (Russia) [RUSSIA-EO14024].

Designated pursuant to Section 1(a)(i) of E.O. 14024 for operating or having operated in the technology sector of the Russian Federation economy.

21. QUANTLOG OY, Kalevankatu 20, Helsinki 00100, Finland; Tax ID No. 3160340-2 (Finland) [CYBER2] (Linked To: KOVALEVSKIJ, Nikita Gennadievitch).

Designated pursuant to Section 1(a)(iii)(C) of Executive Order 13694 of April 1, 2015 "Blocking the Property of Certain Persons Engaging in Significant

Malicious Cyber-Enabled Activities," 80 FR 18077, 3 C.F.R, 2015 Comp., p. 297, as amended by Executive Order 13757 of December 28, 2016, "Taking Additional Steps to Address the National Emergency With Respect to Significant Malicious Cyber-Enabled Activities," 82 FR 1, 3 C.F.R, 2016 Comp., p. 659 (E.O. 13694, as amended) for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, NIKITA GENNADIEVITCH KOVALEVSKIJ, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

On March 31, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following entity is unblocked, and removed the entity from the SDN List.

Entity

1. LIMITED LIABILITY COMPANY OZON BANK (a.k.a. LLC OZON BANK), 3rd Floor, Olimpiyskiy Prospekt 14, Moscow 129090, Russia; Website bank.ozon.ru; Tax ID No. 7750005771 (Russia); Registration Number 1137711000020 (Russia) [RUSSIA-EO14024] (Linked To: SOVCOMBANK OPEN JOINT STOCK COMPANY).

Dated: March 31, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–07418 Filed 4–6–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On April 1, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Entities

1. MINISTRY OF ROCKET INDUSTRY (Korean: 로케트공업부) (a.k.a. ROCKET INDUSTRY DEPARTMENT), Pyongchon, Korea, North; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Target Type Government Entity [NPWMD] (Linked To: MUNITIONS INDUSTRY DEPARTMENT).

   Designated pursuant to section 1(a)(iv) of Executive Order 13382 of June 28, 2005, "Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters," 70 FR 38567, 3 CFR, 2006 Comp., p. 170 (E.O. 13382), for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, MUNITIONS INDUSTRY DEPARTMENT, a person whose property and interests in property are blocked pursuant to this order.

2. HAPJANGGANG TRADING CORPORATION (Korean: 합장강무역회사), Korea, North; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Target Type State-Owned Enterprise [NPWMD] (Linked To: MINISTRY OF ROCKET INDUSTRY).

   Designated pursuant to section 1(a)(iv) of E.O. 13382, for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, MINISTRY OF ROCKET INDUSTRY, a person whose property and interests in property are blocked pursuant to this order.

3. KOREA ROUNSAN TRADING CORPORATION, Korea, North; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Target Type State-Owned Enterprise [NPWMD] (Linked To: MINISTRY OF ROCKET INDUSTRY).

   Designated pursuant to section 1(a)(iv) of E.O. 13382, for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, MINISTRY OF ROCKET INDUSTRY, a person whose property and interests in property are blocked pursuant to this order.

4. SUNGNISAN TRADING CORPORATION (Korean: 조선승리산무역회사) (a.k.a. KOREA SUNGRISAN TRADING CORPORATION), Chungsong 2-dong, Nangnang District, Pyongyang, Korea, North; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section

510.214; Target Type State-Owned Enterprise [NPWMD] (Linked To: MINISTRY OF ROCKET INDUSTRY).

Designated pursuant to section 1(a)(iv) of E.O. 13382, for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, MINISTRY OF ROCKET INDUSTRY, a person whose property and interests in property are blocked pursuant to this order.

5. UNCHON TRADING CORPORATION (Korean: 운천무역회사) (a.k.a. UNCHEN TRADING CORP.; a.k.a. UNCHON TRADING CORP.), Korea, North; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions: North Korea Sanctions Regulations section 510.214; Target Type State-Owned Enterprise [NPWMD] (Linked To: MINISTRY OF ROCKET INDUSTRY).

Designated pursuant to section 1(a)(iv) of E.O. 13382, for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, MINISTRY OF ROCKET INDUSTRY, a person whose property and interests in property are blocked pursuant to this order.

Authority: E.O. 13382, 70 FR 38567, 3 CFR, 2006 Comp., p. 170.

Dated: April 1, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control U.S. Department of the Treasury.

[FR Doc. 2022–07393 Filed 4–6–22; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. Due to a delay in the approval process and a late start with our initial meetings, we are getting a late start to the TAP year. Because of this we will not be able to meet the 15 calendar-day notice requirement. We anticipate all future **Federal Register** notices to be timely moving forward. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, April 12, 2022.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Lines Project Committee will be held Tuesday, April 12, 2022, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information, please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: April 1, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–07330 Filed 4–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Internal Revenue Service Advisory Council; Meeting

AGENCY: Internal Revenue Service, Department of Treasury.

ACTION: Notice of meeting.

SUMMARY: The Internal Revenue Service Advisory Council will hold a public meeting.

DATES: The meeting will be held Wednesday, April 27, 2022.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Ms. Anna Brown, Office of National Public Liaison, at 202–317–6564 or send an email to *PublicLiaison@irs.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988), that a public meeting of the Internal Revenue Service Advisory Council (IRSAC) will be held on Wednesday, April 27, 2022, to discuss topics that may be recommended for inclusion in a future report of the Council. The meeting will take place 3:00–4:00 p.m. Eastern Time.

The meeting will be held via Zoom. To register and for meeting link instructions, members of the public may contact Ms. Anna Brown at 202–317–6564 or send an email to *PublicLiaison@irs.gov.* Attendees are encouraged to join

at least 5–10 minutes before the meeting begins.

Time permitting, after the close of this discussion by IRSAC members, interested persons may make oral statements germane to the Council's work. Persons wishing to make oral statements should contact Ms. Anna Brown at *PublicLiaison@irs.gov* and include the written text or outline of comments they propose to make orally. Such comments will be limited to five minutes in length. In addition, any interested person may file a written statement for consideration by the IRSAC by sending it to *PublicLiaison@irs.gov.*

Dated: April 4, 2022.

John A. Lipold,

Designated Federal Officer, Internal Revenue Service Advisory Council.

[FR Doc. 2022–07437 Filed 4–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Requesting Comments on Form 1099–LTC

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 1099–LTC, Long-Term Care and Accelerated Death Benefits.

DATES: Written comments should be received on or before June 6, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *omb.unit@irs.gov.* Include OMB Control No. 1545–1519 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Jon Callahan, (737) 800–7639, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *jon.r.callahan@irs.gov.*

SUPPLEMENTARY INFORMATION: The IRS is currently seeking comments concerning the following information collection tools, reporting, and record-keeping requirements:

Title: Long-Term Care and Accelerated Death Benefits.

OMB Number: 1545–1519.

Form Number: Form 1099–LTC.

Abstract: Under the terms of IRC sections 7702B and 101(g), qualified long-term care and accelerated death benefits paid to chronically ill individuals are treated as amounts received for expenses incurred for medical care. IRC section 6050Q requires the payer to report all such benefit amounts, specifying whether or not the benefits were paid in whole or in part on a per diem or other periodic basis without regard to expenses. Form 1099–LTC is used if any long-term care benefits, including accelerated death benefits are paid. Payers include insurance companies, governmental units, and viatical settlement providers.

Current Actions: There is no change to the existing collection. However, the estimated number of responses has increased based on the most current filing data.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and governments.

Estimated Number of Respondents: 3,000.

Estimated Number of Responses: 410,600.

Estimated Time per Respondent: 13 minutes.

Estimated Total Annual Burden Hours: 94,438.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 4, 2022.

Jon R. Callahan,

Tax Analyst.

[FR Doc. 2022–07429 Filed 4–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. Due to a delay in the approval process and a late start with our initial meetings, we are getting a late start to the TAP year. Because of this we will not be able to meet the 15 calendar-day notice requirement. We anticipate all future **Federal Register** notices to be timely moving forward. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, April 12, 2022.

FOR FURTHER INFORMATION CONTACT: Fred Smith at 1–888–912–1227 or (202) 317–3087.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Tuesday, April 12, 2022, at 1:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Fred Smith. For more information, please contact Fred Smith at 1–888–912–1227 or (202) 317–3087, or write TAP Office,

1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.*

Dated: April 1, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–07329 Filed 4–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. Due to unavoidable delays in this year's approval process, we will not be able to meet the 15-calendar notice threshold, but this meeting will still be open. This meeting will still be held via teleconference.

DATES: The meeting will be held Thursday, April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app. (1988) that an open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be held Thursday, April 14, 2022, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: April 1, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–07347 Filed 4–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Special Projects Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. Due to unavoidable delays in this year's approval process, we will not be able to meet the 15-calendar notice threshold, but this meeting will still be open. This meeting will still be held via teleconference.

DATES: The meeting will be held Wednesday, April 13, 2022.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or 202–317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app. (1988) that an open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be held Wednesday, April 13, 2022, at 11:00 a.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: April 1, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–07348 Filed 4–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, April 28, 2022.

FOR FURTHER INFORMATION CONTACT: Gilbert Martinez at 1–888–912–1227 or (737) 800–4060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Thursday, April 28, 2022, at 1:30 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information, please contact Gilbert Martinez at 1–888–912–1227 or (737–800–4060), or write TAP Office 3651 S IH–35, STOP 1005 AUSC, Austin, TX 78741, or post comments to the website: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: April 4, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–07449 Filed 4–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Requesting Comments on Form 6198

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on proposed and/or

continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 6198, At-Risk Limitations.

DATES: Written comments should be received on or before June 6, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *omb.unit@irs.gov.* Include OMB Control No. 1545–0712 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Jon Callahan, (737) 800–7639, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *jon.r.callahan@irs.gov.*

SUPPLEMENTARY INFORMATION: The IRS is currently seeking comments concerning the following information collection tools, reporting, and record-keeping requirements:

Title: At-Risk Limitations.

OMB Number: 1545–0712.

Form Number: Form 6198.

Abstract: Internal Revenue Code section 465 requires taxpayers to limit their at-risk loss to the lesser of the loss or their amount at risk. Form 6198 is used by taxpayers to determine their deductible loss and by the IRS to verify the amount deducted.

Current Actions: There is no change to the existing collection. However, the estimated number of responses was updated to eliminate duplication of the burden associated with individual respondents captured under OMB control number 1545–0074 and business respondents captured under OMB control number 1545–0123.

Type of Review: Extension of a currently approved collection.

Affected Public: Estates, trusts, and not-for-profit organizations.

Estimated Number of Responses: 26,451.

Estimated Time per Respondent: 3 hours, 58 minutes.

Estimated Total Annual Burden Hours: 105,010.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 4, 2022.

Jon R. Callahan,

Tax Analyst.

[FR Doc. 2022–07428 Filed 4–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Voluntary Service National Advisory Committee, 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 Voluntary Service (VAVS) National Advisory Committee (NAC) will meet on April 27–29, 2022 at the DoubleTree by Hilton located at 3203 Quebec Street in Denver, Colorado 80207. The meeting sessions will begin and end as follows:

Meeting date(s):	Meeting time(s):
Wednesday, April 27, 2022.	9:00 a.m. to 7:30 p.m. Mountain Time (MT).
Thursday, April 28, 2022.	8:30 a.m. to 4:30 p.m. MT.
Friday, April 29, 2022	9:00 a.m. to 7:30 p.m. MT.

The meeting sessions are open to the public.

The Committee, comprised of 55 major Veteran, civic, and service organizations, advises the Secretary, through the Under Secretary for Health, on the coordination and promotion of volunteer activities and strategic partnerships within VA health care facilities, in the community, and on matters related to volunteerism and charitable giving.

Agenda topics will include the NAC goals and objectives; review of minutes from the May 26–28, 2021 meeting; an update on VA Center for Development and Civic Engagement (CDCE) activities; Veterans Health Administration update; subcommittee reports; review of standard operating procedures; review of organization data; Federal Advisory Committee Act training provided by the VA Advisory Committee Management Office; human-centered design; maximizing social media; and any new business.

No time will be allocated at this meeting for receiving oral presentations from the public. However, the public may submit written statements for the Committee's review to Dr. Sabrina C. Clark, Designated Federal Officer, VA Center for Development and Civic Engagement (15CDCE), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, or email at *Sabrina.Clark@VA.gov.* Any member of the public wishing to attend the meeting or seeking additional information should contact Dr. Clark at 202–461–7300.

Dated: April 4, 2022.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–07410 Filed 4–6–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the Advisory Committee on Structural Safety of Department of Veterans Affairs (VA) Facilities

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA), Office of Construction and Facilities Management, is seeking nominations of qualified candidates to be considered for appointment to the Advisory Committee on Structural Safety of Department Facilities (''the Committee'').

DATES: Nominations for membership on the Committee must be received no later than 5:00 p.m. EST on April 29, 2022.

ADDRESSES: All nominations should be submitted to Mr. Juan Archilla by email at *juan.archilla@va.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Juan Archilla, Office of Construction & Facilities Management (CFM), Department of Veterans Affairs, via email at *juan.archilla@va.gov,* or via telephone at (202) 632–5967. A copy of the Committee charter and list of the current membership can be obtained by contacting Mr. Archilla or by accessing the website: *http://www.va.gov/ADVISORY/Advisory_Committee_on_Structural_Safety_of_Department_of_Veterans_Affairs_facilities_Statutory.asp.*

SUPPLEMENTARY INFORMATION: In carrying out the duties set forth, the Committee responsibilities include:

(1) Providing advice to the Secretary of VA on all matters of structural safety in the construction and altering of medical facilities and recommending standards for use by VA in the construction and alteration of facilities.

(2) Reviewing of appropriate State and local laws, ordinances, building codes, climatic and seismic conditions, relevant existing information, and current research.

(3) Recommending changes to the current VA standards for structural safety, on a state or regional basis.

(4) Recommending the engagement of the services of other experts or consultants to assist in preparing reports on present knowledge in specific technical areas.

(5) Reviewing of questions regarding the application of codes and standards and making recommendations regarding new and existing facilities when requested to do so by VA.

Authority: The Committee was established in accordance with 38 U.S.C. 8105, to provide advice to the Secretary on all matters of structural safety in the construction and altering of medical facilities and recommends standards for use by VA in the construction and alteration of facilities. Nominations of qualified candidates are being sought to fill current and upcoming vacancies on the Committee.

Membership Criteria and Professional Qualifications: CFM is requesting nominations for current and upcoming vacancies on the Committee. The Committee is composed of approximately five members, in addition to ex-officio members. The Committee is required to include at least one architect and one structural engineer who are experts in structural resistance to fire, earthquake, and other natural disasters and who are not employees of the Federal Government. To satisfy this requirement and ensure the Committee has the expertise to fulfill its statutory objectives, VA seeks nominees from the following professions at this time:

(1) ARCHITECT: Candidate must be a licensed Architect experienced in the design requirements of health care facilities. Expert knowledge in codes and standards for health care and life safety is required;

(2) FIRE SAFETY ENGINEER: Candidate must be an expert in fire protection engineering and building codes and standards, in particular related to the National Fire Protection Association (NFPA). A practicing, licensed Professional Engineer with expert knowledge in fire protection systems and experience with life safety requirements is required;

(3) GEOTECHNICAL ENGINEER: Candidate must be an expert in earthquake geotechnical engineering and foundation engineering, with experience in the topics of liquefaction, earthquake ground motions, soil-structure interaction, and soil improvement. A practicing, licensed Professional Engineer with a focus on geotechnical engineering is required;

(4) PRACTICING STRUCTURAL ENGINEER: Candidate must have experience in both new building seismic analysis and design and strengthening of existing buildings in high seismic regions. Expert knowledge of building codes and standards, with a focus on seismic safety, is required. Experience designing for structural resistance to other natural disasters is desired. A licensed Structural Engineer or Professional Engineer with a focus on structural engineering is required; and

(5) RESEARCH STRUCTURAL ENGINEER: Candidate must have experience leading experimental and/or computational research in the field of structural engineering to advance building structural performance and/or design methods against natural disasters, such as earthquakes, fire, hurricanes, tornados, etc.

Prior experience serving on nationally recognized professional and technical committees is also desired.

Requirements for Nomination Submission: Nominations should be type written (one nomination per nominator). Nomination package should include: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee indicating a willingness to serve as a member of the Committee; (2) the nominee's contact information, including name, mailing address, telephone numbers, and email address; (3) the nominee's curriculum vitae, and (4) a summary of the nominee's experience and qualification relative to the *professional qualifications* criteria listed above.

Membership Terms: Individuals selected for appointment to the Committee shall be invited to serve a two-year term. At the Secretary's discretion, members may be reappointed to serve an additional term. All members will receive travel expenses and a per diem allowance in accordance with the Federal Travel Regulation for any travel made in connection with their duties as members of the Committee.

The Department makes every effort to ensure that the membership of its Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that a broad representation of geographic areas, gender, racial and ethnic minority groups, and the disabled are given consideration for membership. Appointment to this Committee shall be made without discrimination because of a person's race, color, religion, sex (including gender identity, transgender status, sexual orientation, and pregnancy), national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: April 4, 2022.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–07415 Filed 4–6–22; 8:45 am]

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Part II

Department of Health and Human Services

42 CFR Chapter I

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter 1

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services, (HHS).

ACTION: Notification of mandatory guidelines.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') is proposing to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) which published in the **Federal Register** of October 25, 2019.

DATES: Submit comments on or before June 6, 2022.

ADDRESSES: In commenting, please refer to file code SAMHSA 2022–001. Because of staff and resource limitations, SAMHSA cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this document to *https://www.regulations.gov.* Follow ''Submit a comment'' instructions.
- *By regular mail.* You may mail written comments to the following address: SAMHSA, Center for Substance Abuse Prevention (CSAP), Division of Workplace Programs (DWP), 5600 Fishers Lane, Room 16N02, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the following address: SAMHSA, CSAP, DWP, 5600 Fishers Lane, Room 16N02, Rockville, MD 20857.
- *By hand or courier.* You may deliver your written comments by hand or courier to the following address prior to the close of the comment period: SAMHSA, CSAP, DWP, 5600 Fishers Lane, Room 16N02, Rockville, MD 20857. If you intend to deliver your comments to the Rockville address, please call (240) 276–2600 in advance to schedule your arrival with one of our staff members. Because access to the SAMHSA building is secure, persons without Federal Government identification are encouraged to schedule their delivery or to leave comments with the security guard at the front desk located in the main lobby of the building.

All comments received before the close of the comment period will be available for viewing by the public. Please note that all comments are posted in their entirety, including personal or confidential business information that is included in the comment. SAMHSA will post all comments before the close of the comment period on the following website: *https://www.regulations.gov.* Use the website's search function to view the associated comments.

Comments received before the close of the comment period will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at SAMHSA, CSAP, DWP, 5600 Fishers Lane, Rockville, MD 20857, Monday through Friday of each week, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, please call (240) 276–2600.

FOR FURTHER INFORMATION CONTACT: Eugene D. Hayes, Ph.D., MBA, SAMHSA, CSAP, DWP; 5600 Fishers Lane, Room 16N02, Rockville, MD 20857, by telephone (240) 276–1459 or by email at *Eugene.Hayes@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

This notification of proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) includes revisions that will: Establish a process whereby the Department annually publishes the authorized drug testing panel (*i.e.,* drugs, analytes, or cutoffs) to be used for Federal workplace drug testing programs; revise the definition of a substituted specimen to include specimens with a biomarker concentration inconsistent with that established for a human specimen, establish a process whereby the Department publishes an authorized biomarker testing panel (*i.e.,* biomarker analytes and cutoffs) for Federal workplace drug testing programs; update and clarify the oral fluid collection procedures; revise the Medical Review Officer (MRO) verification process for positive codeine and morphine specimens; and require MROs to submit semiannual reports to the Secretary or designated HHS representative on Federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. In addition, some wording changes have been made for clarity and for consistency with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG), 82 FR 7920 (January 23, 2017), or to apply to any authorized specimen type.

The Department is publishing a separate **Federal Register** Notification (FRN) elsewhere in this issue of the **Federal Register** proposing revisions to the OFMG, including the same or similar revisions proposed for the UrMG, where appropriate.

Background

The Department of Health and Human Services, pursuant to the Department's authority under Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order 12564, establishes the scientific and technical guidelines for Federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for Federal agencies. Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates that 275,000 urine specimens are tested annually by Federal agencies. No Federal agencies are testing oral fluid specimens at this time.

As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** (FR) on April 11, 1988 (53 FR 11979). The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 (59 FR 29908), September 30, 1997 (62 FR 51118), November 13, 1998 (63 FR 63483), April 13, 2004 (69 FR 19644), and November 25, 2008 (73 FR 71858). SAMHSA published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) on January 23, 2017 (82 FR 7920), and HHS published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) on October 25, 2019 (84 FR 57554).

Proposed Revisions to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs

Authorized Drug Testing Panel

The Guidelines pertain to a matter of Federal agency personnel and, therefore, are not subject to the notification and comment procedures under the Administrative Procedures Act. In light of the potential impact on entities outside of the Federal Government, the Department has chosen to submit the Guidelines to notification and comment,

and will continue to do so. In this revision, the Department is proposing to change the way a specific part of the Guidelines (*i.e.,* the drug testing panel) is published and the frequency with which it is published.

Since the original Guidelines were published in 1988, several recommendations have been made for drugs to be added to or removed from Federal workplace drug testing programs. The Department has revised the Guidelines in the past to add or remove drugs from the authorized drug testing panel and to revise test cutoffs (*i.e.,* Section 3.4 of the UrMG). The time required to revise the Guidelines through the Federal review process has impeded the Department's ability to respond to drug use trends. Individuals may change their drug use, and illicit drug manufacturers may change their manufacturing methods, to avoid testing positive for drugs included in proposed Guidelines, especially as the number of new drugs and drug analogues increases. A less flexible drug testing panel may delay needed drug analyte or cutoff changes based on the state of the science (*e.g.,* new technologies, research including dosing studies). Therefore, the Department proposes to publish the drug testing panel in the **Federal Register** on an annual basis, including any revisions to the panel, without the need (perceived or otherwise) to undergo notification and comment. Should the Department remove a drug from the drug testing panel, a Federal agency may test specimens for that drug in accordance with Section 3.2 (*i.e.,* on a case-by-case basis for reasonable suspicion or post accident testing, or routinely with a waiver from the Secretary). This process is expected to improve the effectiveness of Federal agency drug testing programs in support of the Federal Drug-Free Workplace Program. The drug testing panel in Section 3.4 of the final OFMG will remain in effect until the effective date of a newly published drug testing panel.

The Department will continue to monitor drug use trends and review information on new drugs of abuse from sources such as Federal regulators, researchers, the drug testing industry (including HHS-certified laboratories), and public and private sector employers, to determine whether drugs should be added or removed from the panel. Any changes to analytes and cutoffs made in accordance with the newly established drug testing panel publishing process will be based on a thorough review of relevant information, including the current state of the science, laboratory capabilities, cost associated with the change, and benefits of the change to Federal agencies. The Department will set a date for the panel changes to take effect and include the effective date in the annual drug testing panel FRN, in order to allow time for drug testing service providers (*e.g.,* immunoassay kit manufacturers, oral fluid collection device manufacturers) to develop or revise their products, and for HHS-certified laboratories to develop or revise assays, complete validation studies, and revise procedures. The prior version of the panel will remain in effect until the effective date of the panel changes.

For consistency and to avoid misinterpretation of drug test results, the Department is requiring HHS-certified laboratories and HHS-certified instrumented initial test facilities (collectively referred to hereafter as ''HHS-certified test facilities'') and Medical Review Officers (MROs) to report results using the nomenclature (*i.e.,* analyte names and abbreviations) published with the drug testing panel.

Authorized Biomarker Testing Panel

A biomarker is an endogenous substance used to validate a biological specimen. The purpose of a biomarker test is to determine whether a submitted specimen is a human specimen. The current OFMG (effective January 1, 2020) allow additional specimen validity testing using biomarkers upon MRO request, to provide information to assist the MRO in the verification process. The current OFMG also require HHS-certified laboratories to report a specimen as invalid when the biomarker is not present or when its concentration is not consistent with that established for human oral fluid but does not allow these specimens to be reported as substituted. The Department proposes to revise the OFMG to define such specimens as substituted, and to allow only biomarker tests that have been authorized by SAMHSA for use in Federal agency workplace drug testing programs.

To ensure that scientifically valid biomarker tests, analytes, and cutoffs are standardized for Federal workplace drug testing, the Department will institute an approval process for biomarker tests, based on review of data from the scientific and/or medical literature, before authorizing the use of the biomarker test. The Department will accept scientific information submitted for review from various sources (*e.g.,* HHS-certified test facilities, drug testing industry stakeholders, researchers). The Department will include the authorized biomarker testing panel (*i.e.,* a table of authorized biomarkers, with test analytes and cutoffs), in the FRN to be published each January (as described earlier in this preamble). Federal agencies may choose to test some or all of their workplace specimens for one or more authorized biomarkers.

An HHS-certified laboratory or (for urine only) an HHS-certified instrumented initial test facility (IITF) may request authorization from SAMHSA to conduct a biomarker test that has not been included on the list of authorized biomarkers. The test facility must submit supporting documentation and assay validation records to the National Laboratory Certification Program (NLCP) for SAMHSA review and approval. When an oral fluid biomarker test is approved through this process, SAMHSA will authorize the individual HHS-certified laboratory to perform the biomarker test for federally regulated specimens only upon MRO request (*i.e.,* a blanket request for all specimens or a case-by-case request for a specific specimen). A certified laboratory may choose to begin the process by submitting supporting documentation for review prior to assay validation, or may send supporting documentation with completed validation records. The Department will include measurands and decision points for other specimen validity tests in the OFMG (*e.g.,* Section 11.17).

Once a biomarker test has been added to the authorized biomarker panel published in the FRN, HHS-certified laboratories may routinely conduct the test without requiring an MRO request, and only require a signed MRO request for case-by-case biomarker testing (in accordance with OFMG section 3.5). The Department will continue to require NLCP review of biomarker assay validation records before allowing a laboratory to use the test for federally regulated workplace specimens.

This process will facilitate the identification of donors who attempt to subvert their drug test, and ensure that biomarker tests used for federally regulated workplace programs are scientifically supportable and properly validated, and that all HHS-certified test facilities use the same analytes and cutoffs.

For consistency and to avoid misinterpretation of biomarker test results, the Department is requiring HHS-certified test facilities and Medical Review Officers (MROs) to report results using the nomenclature (*i.e.,* analyte names and abbreviations) published with the biomarker testing panel.

Medical Review Officer (MRO) Verification of Codeine and Morphine Test Results

The MRO has an essential role in federally regulated workplace drug testing programs, which includes performing the review of laboratory results and supporting documentation, interviewing the donor when necessary, and making a final determination regarding the result.

As described in Section 13.5(c)(2) of the current OFMG, when a donor has no legitimate medical explanation for a positive codeine or morphine result equal to or greater than 150 ng/mL, the MRO reports the specimen as positive to the agency. When a donor has no legitimate medical explanation for a positive codeine or morphine result less than 150 ng/mL, the MRO must determine that there is clinical evidence of illegal opioid use (in addition to the test results) to report such specimens as positive. If the MRO finds no clinical evidence of illegal opioid use, the MRO verifies the opiate results as negative. The Department is maintaining 150 ng/mL as a conservative decision point to rule out results that may have been due to poppy seed ingestion rather than illicit drug use. Because MROs routinely conduct donor interviews by telephone, rather than in-person, some MROs have expressed concern to the Department over the feasibility of the current requirement to make a clinical assessment (*i.e.,* physical examination) of the donor. In light of this information, the Department reviewed the verification procedures and determined that the additional requirement for clinical evidence of illegal opioid use is no longer practical or effective. The Department proposes to revise the procedures, now in renumbered Section 13.5(c)(3), to remove the requirement for the MRO to report specimens with morphine and/or codeine between the cutoff and 150 ng/mL as positive based on clinical evidence of illicit drug use. The MRO will verify such specimens as negative unless the donor admits to illegal opioid use that could have caused the positive result. The revised procedures will provide a reliable and objective basis for identifying illicit drug use, based on current scientific information and industry practice. Retaining the decision point may provide useful information on opioids, as the Department can use the semi-annual MRO reports (described below) to compare results of specimens with morphine and codeine concentrations between the cutoff and 150 ng/mL to results of other opioids, including 6-acetylmorphine.

Medical Review Officer (MRO) Semiannual Reports

The Department, through the NLCP, obtains information from HHS-certified laboratories that is reviewed to verify accurate reports and compliance with Guidelines requirements. The NLCP conducts statistical analysis and provides reports to the Department on federally regulated workplace testing, although the data are limited to laboratory-reported results and not the final, MRO-verified results. To obtain additional information needed to assess compliance with the Mandatory Guidelines, the Department proposes to require each MRO performing medical review services for Federal agencies to submit semiannual reports, in January and July of each year, of Federal agency specimens that were reported as positive for a drug or drug metabolite by the laboratory, and verified as negative by the MRO, along with the reason for the negative verification (*e.g.,* a valid prescription for a drug). The reports will not contain any personally identifiable information of the donors.

This revision to the Guidelines will enable Department oversight of MRO reporting practices and will enhance the Department's ability to verify the accuracy of MRO reports and address areas of confusion about Guidelines requirements. The information in the MRO reports will be matched to information submitted to the NLCP by HHS-certified laboratories for the same specimens. This additional information will improve statistical analyses and provide a clearer picture of illicit drug use by Federal job applicants and employees.

MROs may also experience some savings because the removal of the clinical evaluation requirement for some codeine and morphine positive results will simplify the MRO verification process.

Proposed Revisions to the Guidelines

This preamble describes the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG), and the rationale for the changes.

Subpart A—Applicability

Section 1.5 defines terms used in the OFMG. The Department has added terms and revised definitions in this section in accordance with proposed changes to these Guidelines, and to standardize terms and definitions, where possible, to apply to all authorized specimen types.

The Department proposes to revise the Substituted Specimen definition to include specimens tested for a biomarker, when the biomarker is absent or is present at a concentration inconsistent with that established for a human specimen. For clarity, the Department also added a reference to the oral fluid specimen reporting criteria for substitution in Section 3.7 of the UrMG. For clarity and for consistency with the revised Substituted Specimen definition, the Department proposes to edit the Adulterated Specimen definition to apply to specimens with ''an abnormal concentration of a normal constituent (*e.g.,* nitrite in urine''), rather than ''an abnormal concentration of an endogenous substance''; revise definitions for Cutoff and Initial Specimen Validity Test to remove the ''(for urine)'' specification for identifying a substituted specimen; and revise the Invalid Result definition to mention both ''adulterated'' and ''substituted'' as results that may be determined for an oral fluid specimen. The Department proposes to revise the Collection Container definition to apply to all authorized specimen types, by changing ''a urine specimen'' to ''a donor's drug test specimen.'' The Department has also added definitions for ''Biomarker Testing Panel'' and ''Drug Testing Panel'' consistent with the proposed publication of these testing panels in a separate FRN each year.

Section 1.7 describes what constitutes a donor's refusal to take a federally regulated drug test. Section 1.7(a) includes exceptions for a donor who fails to appear in a reasonable time for a pre-employment test and a donor who leaves the collection site before the collection process begins for a pre-employment test. The Department finds that there is no justification for altering a refusal to test based on whether the test is being conducted in the employment or pre-employment context and, therefore, proposes to remove these exceptions. The collector will report a refusal to test for any donor who fails to appear in a reasonable time or who leaves the collection site before the collection is complete, regardless of the reason for the test.

The Department also revised Section 1.7(a)(7) to include a donor's refusal to wash their hands when directed to do so by the collector as an example of a refusal to test by failing to cooperate with the testing process. See also Section 8.4(a).

Section 1.8(a) describes the potential consequences for a refusal to test. The Department has reworded this section to clarify potential actions for a Federal employee who refuses to take a drug

test, and the potential action for an applicant who refuses to take a pre-employment test.

Subpart C—Oral Fluid Specimen Tests

The Department proposes to edit Section 3.1 to reflect the proposed process for publishing drug and biomarker testing panels in an FRN each year containing a list of authorized drug analytes and biomarkers that can be tested. As described under *Authorized drug testing panel* and *Authorized biomarker testing panel* above, the time required to revise the Guidelines through the Federal review process has impeded the Department's ability to respond to drug use trends, and to make drug analyte or cutoff changes based on the state of the science (*e.g.,* new technologies, research including dosing studies). This new process is expected to improve the effectiveness of Federal agency drug testing programs in support of the Federal Drug-Free Workplace Program. See also Section 3.4.

The Department also revised item 3.1(c) to remove albumin or immunoglobulin G (IgG) tests as examples of biomarker tests, and to allow specimen validity tests that could be used to identify specimens that are not valid for testing. See also Sections 3.8 and 11.17(g).

For clarity, the Department also revised the header for Section 3.2 to refer to ''drugs other than those in the drug testing panel'' (see above) rather than ''additional drugs''.

The Department has revised Section 3.4 of the OFMG to describe the proposed publication of a final notification in the **Federal Register** each year that will include the authorized drugs, test analytes, and cutoffs; the authorized biomarkers, test analytes, and cutoffs; and the nomenclature required for laboratory and MRO reports. The annual notification will be posted on the SAMHSA website, *https://www.samhsa.gov/workplace.* The table in Section 3.4 of the final OFMG will remain in effect until the effective date of the new panels published in the separate FRN.

The Department proposes to add a new Section 3.7 and revise Section 3.8 to require specimens to be reported as substituted based on a biomarker concentration outside the range established for that biomarker in human oral fluid, rather than reporting such results as invalid. See also Section 1.5. Section 3.8 also addresses specimen validity tests that could be used to identify invalid specimens. See also Sections 3.1 and 11.17(g).

Subpart G—Oral Fluid Specimen Collection Devices

The Department proposes to revise Section 7.2(b) to clarify that, depending on the device type, a collection device may include one or two specimen tubes for a split specimen collection. The Department also proposes to add two new requirements for collection devices in this section.

In Section 7.2(b)(2), the Department added a requirement for oral fluid specimen tubes to be sufficiently transparent to enable a visual assessment of the contents without opening the tube. This will enable the collector to identify oral fluid specimens with abnormal physical characteristics and take action (*e.g.,* recollection) to obtain an acceptable specimen. See also Section 8.5(a)(3).

In Section 7.2(b)(3), the Department added a requirement for the collection device manufacturer to include the device lot expiration date on each specimen tube. The collector will check the expiration date of each device prior to use and document this action on the Federal Custody and Control Form (CCF), and the laboratory accessioner will check and document the expiration date on both A and B specimen tubes upon receipt. As described below regarding Section 15.1, laboratories must reject oral fluid specimens collected using an expired device.

Subpart H—Oral Fluid Specimen Collection Procedure

The Department is proposing revisions to the oral fluid collection procedures as described below, for clarity and for consistency with the 2020 Federal CCF and with the Oral Fluid Specimen Collection Handbook, which were both finalized following OFMG publication in 2019.

Proposed revisions to Section 8.3 include reordering collection steps (*e.g.,* item d, item h.4) and rewording for clarity (*e.g.,* items g and h). The Department also added steps similar to those for urine collections, to deter donor attempts to adulterate or substitute the specimen. The added requirement for the collector to inspect the contents of the donor's pockets applies only when the collector does not keep the donor under direct observation until the end of the collection, including the 10-minute wait period described in section 8.3(h). Unlike a urine collection, if the donor refuses to display the contents of their pockets, the collector will continue with the oral fluid collection, but will keep the donor under their direct observation. This is not a refusal to test. In Section 8.3(h)(4), the Department clarified that the collector must inform the donor that the donor's failure to remain at the collection site until the collection is complete will be reported as a refusal to test. This is consistent with Section 1.7.

The Department revised wording in Section 8.3(f) regarding how instructions for completing the Federal CCF are provided to the donor. This is consistent with changes made to the Federal CCF to enable its use with both urine and oral fluid specimens.

The Department also proposes to add steps in Section 8.4 to deter donor attempts to tamper with the specimen. Proposed revisions include a new item requiring the donor to wash their hands under the collector's observation, and to keep their hands within view and avoid touching items or surfaces after handwashing. A donor's refusal to wash their hands when instructed by the collector constitutes a refusal to test. In Section 8.4(b), the Department added a new item 1 specifying that the collector opens the package containing the specimen collection device, in the presence of the donor. In Section 8.4(d), the Department added ''an attempt to prevent the device from collecting sufficient oral fluid'' to the examples of donor attempts to tamper with a specimen. The Oral Fluid Specimen Collection Handbook includes additional examples of tampering attempts.

In Section 8.5, the Department added a new item a.3 requiring the collector to check each collected specimen for abnormal physical characteristics. See also Section 7.2.

The Department also revised the wording in Section 8.9(a)(3) for clarity.

Subpart I—HHS Certification of Laboratories

Section 9.5 describes the qualitative and quantitative specifications for oral fluid performance test (PT) samples. In item a.2, the Department added that a PT sample may contain an adulterant or may satisfy the criteria for a substituted specimen or invalid result.

Section 9.6 describes PT requirements for an applicant laboratory and Section 9.7 describes PT requirements for an HHS-certified laboratory. The Department has added requirements for specimen validity testing challenges in new items (a)(7) through (a)(10) in both sections. In addition, the Department is proposing to edit Section 9.7(a)(5) to state clearly that quantitative values reported for drug tests are evaluated based on reported results for each PT cycle, not on cumulative results reported over two consecutive PT cycles. An HHS-certified laboratory

must not obtain a quantitative value outside the specified range for a drug, based on the appropriate reference or peer group mean.

Subpart K—Laboratory

Section 11.17 describes the requirements for an HHS-certified laboratory to report primary (A) specimen test results to an MRO. The Department proposes to add the requirements for reporting an oral fluid specimen as adulterated in item 11.17(d) and as substituted in item 11.17(e). See also Section 1.5.

Section 11.17(g) addresses laboratory and MRO discussions to determine whether additional testing may be useful for specimens with certain invalid results. Because biomarker testing could be used to identify substitution, the Department has revised this section to indicate that additional testing may be useful in being able to report a substituted result, as well as positive or adulterated results. The Department has also reworded item 11.17(g) to allow laboratories to report specimens as invalid based on specimen validity tests. See also Sections 3.1 and 3.8.

Section 11.17(i) and 11.17(p) includes requirements for the laboratory to report ''non-negative'' results for a specimen to the MRO. The Department is adding ''substituted'' to the list of non-negative results in these sections.

The Department also proposes to add a new item 11.17(l) stating that the laboratory must use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports. This change is to ensure consistency in reporting and interpretation of test results, by requiring the results of each test performed to be reported using clear and correct nomenclature for test analytes, with the same terminology and units of measurement. See also Section 3.4.

Section 11.18 addresses how long specimens must be retained by the laboratory. The Department proposes to edit item a to require HHS-certified laboratories to retain specimens reported as substituted for at least one year (*i.e.,* the same as specimens reported as positive, adulterated, or invalid). The Department is also revising item b of this section to require laboratories to maintain oral fluid specimens in accordance with the collection device manufacturer's instructions (*i.e.,* frozen at −20 °C or less, or refrigerated).

Section 11.20 describes information that must be included on HHS-certified laboratories statistical summary reports for oral fluid testing. The Department proposes to require laboratories to include the number of substituted specimens.

Section 11.21 describes HHS-certified laboratory information that is available to a Federal agency. The Department proposes to add that an agency may request records of specimens reported as substituted.

Subpart M—Medical Review Officer (MRO)

Section 13.5(b)(2) describes MRO actions when a laboratory reports an invalid result in conjunction with a positive, adulterated, or substituted result. The Department has revised this section to include substituted as well as positive or adulterated results. The Department has added an item to this section to clarify that the MRO takes the required action for the invalid result (specified in item e of this section) only when the MRO has verified the other result(s) for the specimen (*i.e.,* positive, adulterated, or substituted) as negative or when the split (B) specimen was tested and reported as a failure to reconfirm.

Section 13.5(c) describes MRO actions to determine whether the donor has a legitimate medical explanation for a positive specimen test result. The Department added a new item Section 13.5(c)(1) to clarify that the MRO reports a positive result when the donor admits unauthorized use of the drug(s) that caused the positive test result, and documents the admission of unauthorized drug use in the MRO records and in the MRO's report to the Federal agency. A donor's admission of unauthorized drug use corroborates the positive test.

Currently, Section 13.5(c)(1) includes the policy of the Department that ingestion of food products containing marijuana is not an acceptable medical explanation for a positive drug test result. The Department proposes to reword this policy, now in item ii of Section 13.5(c)(2), to clarify that the policy applies to any positive oral fluid drug test results, not just marijuana, with the exception of positive codeine and morphine results less than 150 ng/mL as described in Section 13.5(d). The section now states that ingestion of food products containing a drug is not an acceptable medical explanation for a positive drug test, with ''products containing marijuana'' as an example. The Department also proposes to add a new item iii to this section stating that a physician's authorization or medical recommendation for a Schedule I substance is not an acceptable medical explanation for a positive drug test. Under the Controlled Substances Act CSA, a Schedule I substance is defined as a drug, chemical, or other substance with no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. (Ref. 1) The Drug Enforcement Administration (DEA) maintains the current listing of controlled substances on their website.

Section 13.5.(c)(3) describes MRO actions when the donor has no legitimate medical explanation for a positive drug test result, and includes exceptions for codeine and morphine results. As described above under *Medical Review Officer (MRO) verification of codeine and morphine test results,* the Department proposes to maintain the 150 ng/mL decision point used to rule out codeine and morphine results that may have been due to poppy seed ingestion rather than illicit drug use, and remove the additional requirement for clinical evidence of illegal opioid use. MROs will verify positive codeine and morphine results less than 150 ng/mL as negative, and will include the specimen in the required report of verified negative specimens described under Section 13.11 below. If the donor admits unauthorized drug use during their interview with the MRO that could have caused the positive result, the MRO verifies the result as positive.

The Department also proposes to revise Section 13.5(c)(3) to address substituted oral fluid specimens where appropriate.

Section 13.9 describes how an MRO reports primary (A) drug test results to an agency. The Department proposes to add a new item 13.9(e) stating that the MRO must use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports. See also Section 3.4.

The Department has included a new Section 13.11 describing the proposed requirement for an MRO to send semiannual reports to the Secretary or designated HHS representative for Federal agency specimens that were reported as positive by a laboratory and verified as negative by the MRO. As described under *Medical Review Officer (MRO) semiannual reports* above, this change will enable Department oversight of MRO practices and will enhance the Department's ability to verify the accuracy of MRO reports and address areas of confusion about Guidelines requirements. In addition, the information in the MRO reports will be matched to information submitted to the NLCP by HHS-certified laboratories for the same specimens, thereby improving statistical analyses and

providing a clearer picture of illicit drug use by Federal job applicants and employees. The reports must not include any personally identifiable information for the donor, and must be submitted within 14 working days after the end of the semiannual period (*i.e.,* in July and January). Section 13.11 lists the information that must be included on the reports. To facilitate report preparation and review, the Department will include a template for these MRO reports in the MRO Guidance Manual and will arrange a secure method for MROs to submit reports electronically.

The Department has included a new Section 13.12 describing the Federal agency's responsibilities for designating an MRO. These responsibilities include verifying and documenting that individuals meet the MRO requirements in these Guidelines before allowing them to serve as an MRO for the agency's drug testing program and on an ongoing basis, and ensuring that each MRO reports drug test results in accordance with the Guidelines. Further, the Federal agency must obtain documentation from the MRO to confirm that the MRO and any external service provider ensures the confidentiality integrity and availability of the data and limits the access to any data transmission, storage, and retrieval system.

Subpart N—Split Specimen Tests

The Department proposes to add a new Section 14.4 describing how an HHS-certified laboratory reports a split (B) oral fluid specimen when the primary (A) specimen was reported substituted. The Department proposes to revise this section to address primary (A) specimens reported as substituted based on biomarker test results. See also Section 1.5.

Section 14.5 states that the HHS-certified laboratory that tested a split (B) specimen must report the results to the MRO. The Department proposes to reword this section to require the laboratory to use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports for split (B) specimens. See also Section 3.4.

Section 14.6 describes the actions an MRO takes after receiving a split (B) oral fluid specimen result from an HHS-certified laboratory. The Department proposes to revise this section to address MRO verification of split (B) specimen results when the primary (A) specimen was reported as substituted, and when a B specimen was reported as substituted based on biomarker See also Section 1.5. The Department also proposes to add a new item 14.6(k) to address MRO verification of split (B) specimen results when the B specimen fails to reconfirm adulteration or substitution and is invalid.

Section 14.7 describes how an MRO reports split (B) specimen test results to an agency. The Department proposes to add a new item 14.7(e) stating that the MRO must use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports. See also Section 3.4.

Subpart O—Criteria for Rejecting a Specimen for Testing

The Department is proposing to add a new item c to Section 15.1, requiring the laboratory to reject oral fluid specimens collected using an expired device (*i.e.,* when the expiration date on the specimen tube precedes the collection date), unless the split (B) specimen can be redesignated as the primary (A) specimen. See also Section 7.2.

General Revisions

In addition to the proposed changes described by subpart and section above, the Department has edited the OFMG to address proposed changes (*e.g.,* removing ''for urine'' when referring to substituted specimens; referencing the proposed annual FRN with drug and biomarker testing panels) and has reworded some items for clarity and/or for consistency with the UrMG.

Impact of These Guidelines on Government Regulated Industries

The Department is aware that these proposed new Guidelines may impact the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) regulated industries depending on these agencies' decisions to incorporate the final OFMG revisions into their programs under their own authority.

Costs and Benefits

Costs

The proposed OFMG revision to publish the drug testing panel in a separate FRN each January (*e.g.,* Section 3.4) may result in a cost increase for HHS-certified laboratories and MROs (*e.g.,* costs for test supplies, assay validation, administrative changes) when a new drug is added to the panel or when analytes or cutoffs are changed for current drugs. The added costs will depend on the change. For example, implementation costs would be lower for laboratories that already offer the drug test or use the different analyte or cutoff for their non-regulated clients. MROs may experience increased costs when an agency chooses to test their Federal job applicants and employees for a new authorized drug with a high positivity rate or a Schedule II drug requiring the MRO to review medical explanations. Additional costs for testing and MRO review will be incorporated into the overall cost for the Federal agency submitting the specimen to the laboratory. Added costs to MROs would be expected to shift to Federal agencies over time, as existing contracts expire and new contract terms are negotiated. As noted earlier in this preamble, the Department will consider costs when deciding whether to make a change to the authorized drug tests. At this time, the Department will not require HHS-certified laboratories to implement authorized biomarker tests. Each laboratory should conduct their own cost analysis when deciding whether to offer biomarker testing to federally regulated clients. The Department will consider costs when deciding whether to require all certified laboratories to test for a specific biomarker.

There will be some administrative costs for MROs associated with the generation and submission of the semiannual reports of verified-negative results (see Section 13.11). The Department encourages the use of electronic recordkeeping to facilitate information retrieval and report generation, and will enable secure submission of electronic information to reduce MRO costs to provide these reports.

Benefits

The potential benefits of more timely changes to the drug testing panel will result in a healthier and more productive workforce, as well as avoid the issues associated with addiction and rehabilitation. Since the personnel tested under this program are in positions that are safety sensitive, potential benefits include decreased risk of transportation and workplace accidents, decreased risk of low-probability high consequence events, a more responsible workforce in positions of public trust, and potentially reducing individuals' dependence or addiction and the personal benefits associated with those conditions. Considering the potential health and performance costs of drug misuse, the benefits to the Federal workplace and the individuals within that workplace justify the more agile method of changing the drug testing panel for the Federal workplace drug testing programs.

The number of commercial substitution and adulteration products aimed at defeating a drug test continues to proliferate for both urine and oral fluid. Manufacturers alter their existing

products or develop new products to subvert drug and specimen validity tests in federally regulated workplace programs. (Ref. 2 and 3) When the Department added provisions for biomarker testing in the current OFMG, the intent was to identify non-human oral fluid samples that were submitted for testing in place of the donor's oral fluid. The proposed revision to report a specimen as substituted (not invalid) based on biomarker testing is consistent with this intention. This revision, as well as the Department review and approval of biomarker tests and the added flexibility for making changes to the drug and biomarker testing panels, will strengthen the Federal Government's ability to identify illicit drug use and donor attempts to subvert drug tests.

The proposed requirement for semiannual MRO reports on laboratory-positive/MRO- negative results will enable the Department to ensure accurate reports and MRO compliance with Guidelines requirements. The information in the MRO reports will be matched to information for the same specimens that was submitted to the NLCP by the HHS-certified laboratory, thereby improving statistical analyses and providing a clearer picture of illicit drug use by Federal job applicants and employees.

MROs may also experience some savings, as the removal of the clinical evaluation requirement for some codeine and morphine positive results will simplify the MRO verification process.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines, which establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in oral fluid drug testing for Federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form (Federal CCF) used to document the collection and chain of custody of urine and oral fluid specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination; the National Laboratory Certification Program (NLCP) application; the NLCP Laboratory Information Checklist; and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect.

In support of the Government Paperwork Reduction Act (PRA), the Department revised the Federal CCF to enable its use as an electronic form (78 FR 42091, July 15, 2013) and developed requirements and oversight procedures to ensure that HHS-certified test facilities and other service providers (*e.g.,* collection sites, MROs) using an electronic Federal CCF (ECCF) maintain the accuracy, security, and confidentiality of electronic drug test information. Before a Federal ECCF can be used for Federal agency specimens, HHS-certified test facilities must submit detailed information and proposed standard operating procedures (SOPs) to the NLCP for SAMHSA review and approval, and undergo an NLCP inspection focused on the proposed ECCF.

Since 2013, SAMHSA has encouraged the use of Federal ECCFs and other electronic processes in HHS-certified test facilities, when practicable, for federally regulated testing operations. In accordance with Section 8108(a) of the SUPPORT for Patients and Communities Act, SAMHSA has set a deadline of August 31, 2023, for all HHS-certified laboratories to submit a request for approval of an electronic (paperless) Federal CCF.

The title and description of the information collected and respondent description are shown in the following paragraphs with an estimate of the annual reporting, disclosure, and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid.

Description: The Mandatory Guidelines establish the scientific and technical guidelines for Federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions.

Description of Respondents: Individuals or households, businesses, or other-for-profit and not-for-profit institutions.

The burden estimates in the tables below are based on the following number of respondents: 10,500 donors who apply for employment or are employed in testing designated positions, 100 collectors, 10 oral fluid specimen testing laboratories, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory or IITF required to submit application for certification.	10	1	3	30
9.10(a)(3)	Materials to submit to become an HHS inspector.	10	1	2	20
11.3	Laboratory submits qualifications of responsible person (RP) to HHS.	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.20	Specifications for laboratory semiannual statistical report of test results to each Federal agency.	10	5	0.5	25
13.9 and 14.7	Specifies that MRO must report all verified primary and split specimen test results to the Federal agency.	100	14	0.05 (3 min)	70

ESTIMATE OF ANNUAL REPORTING BURDEN—Continued

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
13.11	Specifications for MRO semiannual report to the Secretary or designated representative for Federal agency specimen results that were laboratory-positive and MRO-verified negative.	100	2	0.5	100
16.1(b) & 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed.	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review.	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total		256			392

The following reporting requirements are also in the proposed Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or refusal to participate in the collection process on the Federal CCF (Sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (Section 10.3(a)); MRO notifies the Federal agency and HHS when an error occurs on a blind sample (Section 10.4(d)); and Sections 13.6 and 13.7 describe the actions an MRO takes for the medical evaluation of a donor who cannot provide an oral fluid specimen. SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3(a), 8.6(b)(2)	Collector must contact Federal agency point of contact.	100	1	0.05 (3 min)	5
11.21, 11.22	Information on drug test that laboratory must provide to Federal agency upon request or to donor through MRO.	25	10	3	750
13.8(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	14	3	4,200
Total		225			4,955

The following disclosure requirements are also included in the proposed Guidelines, but have not been addressed in the above disclosure burden table: the collector must explain the basic collection procedure to the donor and answer any questions (Section 8.3(h)). SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3, 8.4, 8.5, 8.8	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2,660
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	38,000	1	0.08 (5 min)	3,040
11.8(a) & 11.17	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	25	1,520	0.05 (3 min)	1,900
13.4(d)(4),13.9(c),14.7(c)	MRO completes Federal CCF before reporting the primary or split specimen result.	100	380	0.05 (3 min)	1,900

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN—Continued

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
14.1(b)	MRO documents donor's request to have split specimen tested.	100	2	0.05 (3 min)	10
Total		38,325			9,510

The proposed Guidelines contain several recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector (Section 4.3(a)(3)) and the documentation must be maintained in the collector's training file (Section 4.3(c)). SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a Federal agency specimen, the collector is required to provide a statement (Section 6.2(b)) explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H (Section 8.4(d)) requires collectors to enter any information on the Federal CCF of any unusual findings during the oral fluid specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subpart K describes a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.,* Sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.10(a); 11.13(a); 11.16; 11.19(a), (b), and (c); 11.20; 11.21(a); and 11.22). These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis.

Thus, the total annual response burden associated with the testing of oral fluid specimens by the laboratories and IITFs is estimated to be 14,857 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,809 hours currently approved by OMB under control number 0930–0158 for oral fluid testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of these proposed Guidelines to OMB for its review. Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

OMB is required to make a decision concerning the collection of information contained in these proposed Guidelines between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to HHS on the proposed Guidelines.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street NW, Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to 202–395–6974 (fax).

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3. Quest Diagnostics, 2018. Workforce drug positivity at highest rate in a decade, finds analysis of more than 10 million drug test results. *https://www.questdiagnostics.com/dms/Documents/Employer-Solutions/DTI-2018/2018-quest-diagnostics-drug-testing-index-2018-report/2018QuestDiagnosticsDrugTestingIndex.pdf.* Accessed October 19, 2018.

Summary

These proposed revisions are intended to simplify changes to the authorized drug testing panel for Federal workplace drug testing programs, facilitate the identification of substituted specimens using biomarker testing, improve detection of illicit codeine and/or morphine use, and provide the Department with information on Federal agency drug test specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified negative by the Medical Review Officer (MRO). There is no requirement for Federal agencies to use oral fluid as part of their drug testing program. A Federal agency may choose to use urine or oral fluid, or any combination of specimen types in accordance with the Mandatory Guidelines for each matrix in their program based on the agency's mission, its employees' duties, and the danger to the public health and safety or to national security that could result from an employee's failure to carry out the duties of his or her position. The Department believes that the proposed revisions to the Mandatory Guidelines save costs and improve the effectiveness of Federal workplace drug testing programs.

Dated: March 22, 2022

Miriam E. Delphin-Rittmon,

Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration.

Approved: March 22, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS USING ORAL FLUID SPECIMENS

Subpart A—Applicability

1.1 To whom do these Guidelines apply?
1.2 Who is responsible for developing and implementing these Guidelines?
1.3 How does a federal agency request a change from these Guidelines?
1.4 How are these Guidelines revised?
1.5 What do the terms used in these Guidelines mean?
1.6 What is an agency required to do to protect employee records?
1.7 What is a refusal to take a federally regulated drug test?
1.8 What are the potential consequences for refusing to take a federally regulated drug test?

Subpart B—Oral Fluid Specimens

2.1 What type of specimen may be collected?
2.2 Under what circumstances may an oral fluid specimen be collected?
2.3 How is each oral fluid specimen collected?
2.4 What volume of oral fluid is collected?
2.5 How is the split oral fluid specimen collected?
2.6 When may an entity or individual release an oral fluid specimen?

Subpart C—Oral Fluid Specimen Tests

3.1 Which tests are conducted on an oral fluid specimen?
3.2 May a specimen be tested for drugs other than those in the drug testing panel?
3.3 May any of the specimens be used for other purposes?
3.4 What are the drug and biomarker test analytes and cutoffs for undiluted (neat) oral fluid?
3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?
3.6 What criteria are used to report an oral fluid specimen as adulterated?
3.7 What criteria are used to report an oral fluid specimen as substituted?
3.8 What criteria are used to report an invalid result for an oral fluid specimen?

Subpart D—Collectors

4.1 Who may collect a specimen?
4.2 Who may not collect a specimen?
4.3 What are the requirements to be a collector?
4.4 What are the requirements to be a trainer for collectors?
4.5 What must a federal agency do before a collector is permitted to collect a specimen?

Subpart E—Collection Sites

5.1 Where can a collection for a drug test take place?
5.2 What are the requirements for a collection site?
5.3 Where must collection site records be stored?
5.4 How long must collection site records be stored?
5.5 How does the collector ensure the security and integrity of a specimen at the collection site?
5.6 What are the privacy requirements when collecting an oral fluid specimen?

Subpart F—Federal Drug Testing Custody and Control Form

6.1 What federal form is used to document custody and control?
6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

Subpart G—Oral Fluid Specimen Collection Devices

7.1 What is used to collect an oral fluid specimen?
7.2 What are the requirements for an oral fluid collection device?
7.3 What are the minimum performance requirements for a collection device?

Subpart H—Oral Fluid Specimen Collection Procedure

8.1 What privacy must the donor be given when providing an oral fluid specimen?
8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?
8.3 What are the preliminary steps in the oral fluid specimen collection procedure?
8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?
8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?
8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?
8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?
8.8 How does the collector prepare the oral fluid specimens?
8.9 How does the collector report a donor's refusal to test?
8.10 What are a federal agency's responsibilities for a collection site?

Subpart I—HHS Certification of Laboratories

9.1 Who has the authority to certify laboratories to test oral fluid specimens for federal agencies?
9.2 What is the process for a laboratory to become HHS-certified?
9.3 What is the process for a laboratory to maintain HHS certification?
9.4 What is the process when a laboratory does not maintain its HHS certification?
9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?
9.6 What are the PT requirements for an applicant laboratory?
9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?
9.8 What are the inspection requirements for an applicant laboratory?
9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?
9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?
9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?
9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?
9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?
9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?
9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?
9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?
9.17 Where is the list of HHS-certified laboratories published?

Subpart J—Blind Samples Submitted by an Agency

10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?
10.2 What are the requirements for blind samples?
10.3 How is a blind sample submitted to an HHS-certified laboratory?
10.4 What happens if an inconsistent result is reported for a blind sample?

Subpart K—Laboratory

11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?
11.2 What are the responsibilities of the responsible person (RP)?
11.3 What scientific qualifications must the RP have?
11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?
11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?
11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?
11.7 What security measures must an HHS-certified laboratory maintain?
11.8 What are the laboratory chain of custody requirements for specimens and aliquots?
11.9 What are the requirements for an initial drug test?
11.10 What must an HHS-certified laboratory do to validate an initial drug test?

11.11 What are the batch quality control requirements when conducting an initial drug test?
11.12 What are the requirements for a confirmatory drug test?
11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?
11.14 What are the batch quality control requirements when conducting a confirmatory drug test?
11.15 What are the analytical and quality control requirements for conducting specimen validity tests?
11.16 What must an HHS-certified laboratory do to validate a specimen validity test?
11.17 What are the requirements for an HHS-certified laboratory to report a test result?
11.18 How long must an HHS-certified laboratory retain specimens?
11.19 How long must an HHS-certified laboratory retain records?
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Subpart A—Applicability

Section 1.1 To whom do these Guidelines apply?

(a) These Guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3), but excluding the Armed Forces as defined in 5 U.S.C. 2101(2);

(3) Any other employing unit or authority of the federal government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

Section 1.2 Who is responsible for developing and implementing these Guidelines?

(a) Executive Order 12564 and Public Law 100–71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

Section 1.3 How does a federal agency request a change from these Guidelines?

(a) Each federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

Section 1.4 How are these Guidelines revised?

(a) To ensure the full reliability and accuracy of specimen tests, the accurate

reporting of test results, and the integrity and efficacy of federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) Revisions to these Guidelines will be published in final as a notice in the **Federal Register**.

Section 1.5 What do the terms used in these Guidelines mean?

The following definitions are adopted:

Accessioner. The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of a normal constituent (*e.g.,* nitrite in urine).

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Biomarker Testing Panel. The panel published in the **Federal Register** that includes the biomarkers authorized for testing, with analytes and cutoffs for initial and confirmatory biomarker tests, as described under Section 3.4.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Device. A product that is used to collect an oral fluid specimen and may include a buffer or diluent.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

Confirmatory Drug Test. A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The analytical value (*e.g.,* drug, drug metabolite, or biomarker concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

Donor. The individual from whom a specimen is collected.

Drug Testing Panel. The panel published in the **Federal Register** that includes the drugs authorized for testing, with analytes and cutoffs for initial and confirmatory drug tests, as described under Section 3.4.

External Service Provider. An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or (for urine) an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is adulterated, invalid, substituted, or (for urine) dilute.

Instrumented Initial Test Facility (IITF). A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.8 when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantification (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug

or drug metabolite) can be accurately established.

Lot. A number of units of an item (*e.g.,* reagents, quality control material, oral fluid collection device) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

Positive Result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmatory test cutoff.

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2).

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Oral Fluid). A collection in which two specimens (primary [A] and split [B]) are collected, concurrently or serially, and independently sealed in the presence of the donor; or a collection in which a single specimen is collected using a single collection device and is subdivided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

Standard. Reference material of known purity or a solution containing a reference material at a known concentration.

Substituted Specimen. A specimen that has been submitted in place of the donor's specimen, as evidenced by the absence of a biomarker or a biomarker concentration inconsistent with that established for a human specimen, as indicated in the biomarker testing panel, or (for urine) creatinine and specific gravity values that are outside the physiologically producible ranges of human urine, in accordance with the criteria to report a urine specimen as substituted in UrMG Section 3.7.

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: a collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101–24.104, all agency contracts with laboratories, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100–71. Each federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, subparts A and E, may be applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *https://www.hhs.gov/hipaa/index.html.*

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete;

(3) Fail to provide a specimen (*e.g.,* oral fluid or another authorized specimen type) for any drug test required by these Guidelines or federal agency regulations;

(4) Fail to provide a sufficient amount of oral fluid when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(5) Fail or decline to participate in an alternate specimen collection (*e.g.,* urine) as directed by the federal agency or collector (*i.e.,* as described in Section 8.6);

(6) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (*i.e.,* Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(7) Fail to cooperate with any part of the testing process (*e.g.,* disrupt the collection process, fail to rinse the mouth or wash hands after being directed to do so by the collector, refuse to provide a split specimen);

(8) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(9) Attempt to adulterate, substitute, or dilute the specimen; or

(10) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) A refusal to take a test may result in the initiation of disciplinary or adverse action for a federal employee, up to and including removal from federal employment. An applicant's refusal to take a pre-employment test may result in non-selection for federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test, the collector must terminate the collection process and take action as described in Section 8.9. Required action includes immediately notifying the federal agency's designated representative by any means (*e.g.,* telephone or secure facsimile [fax] machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal CCF, and sending all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

Subpart B—Oral Fluid Specimens

Section 2.1 What type of specimen may be collected?

A federal agency may collect oral fluid and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using oral fluid must follow these Guidelines.

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

A federal agency may collect an oral fluid specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post accident test;

(e) Return to duty test; or

(f) Follow-up test.

Section 2.3 How is each oral fluid specimen collected?

Each oral fluid specimen is collected as a split specimen (*i.e.,* collected either simultaneously or serially) as described in Sections 2.5 and 8.8.

Section 2.4 What volume of oral fluid is collected?

A volume of at least 1 mL of undiluted (neat) oral fluid for each oral fluid specimen (designated ''Tube A'' and ''Tube B'') is collected using a collection device. If the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen), the A and B tubes must have a volume marking clearly noting a level of 1 mL.

Section 2.5 How is the split oral fluid specimen collected?

The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''A'' (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''B'' (split) either simultaneously or serially (*i.e.,* using two devices or using one device and subdividing the specimen), as described in Section 8.8.

Section 2.6 When may an entity or individual release an oral fluid specimen?

Entities and individuals subject to these Guidelines under Section 1.1 may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

Subpart C—Oral Fluid Specimen Tests

Section 3.1 Which tests are conducted on an oral fluid specimen?

A federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine as provided in the drug testing panel described under Section 3.4;

(b) Is authorized to test each specimen for other Schedule I or II drugs as provided in the drug testing panel;

(c) Is authorized upon a Medical Review Officer's request to test an oral fluid specimen to determine specimen validity using, for example, a test for a specific adulterant;

(d) Is authorized to test each specimen for one or more biomarkers as provided in the biomarker testing panel described under Section 3.4; and

(e) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

Section 3.2 May a specimen be tested for drugs other than those in the drug testing panel?

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act. The federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in the drug testing panel described under Section 3.4. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

Section 3.3 May any of the specimens be used for other purposes?

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines must only be tested for drugs and to determine

their validity in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees, or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What are the drug and biomarker test analytes and cutoffs for undiluted (neat) oral fluid?

The Secretary will publish the drug and biomarker test analytes and cutoffs (*i.e.,* the ''drug testing panel'' and ''biomarker testing panel'') for initial and confirmatory drug and biomarker tests in the **Federal Register** each year. The drug and biomarker testing panels will also be available on the internet at *https://www.samhsa.gov/workplace/drug-testing.*

This drug testing panel will remain in effect until the effective date of a new drug testing panel published in the **Federal Register**:

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana (THC) [2]	4 ng/mL [3]	THC	2 ng/mL
Cocaine/Benzoylecgonine	15 ng/mL	Cocaine	8 ng/mL
		Benzoylecgonine	8 ng/mL
Codeine/Morphine	30 ng/mL	Codeine	15 ng/mL
		Morphine	15 ng/mL
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone	15 ng/mL
		Hydromorphone	15 ng/mL
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone	15 ng/mL
		Oxymorphone	15 ng/mL
6-Acetylmorphine	4 ng/mL [3]	6-Acetylmorphine	2 ng/mL
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine	25 ng/mL
		Methamphetamine	25 ng/mL
MDMA [4]/MDA [5]	50 ng/mL	MDMA	25 ng/mL
		MDA	25 ng/mL

[1] For grouped analytes (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.,* equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol (THC).
[3] *Alternate technology (THC and 6–AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.,* 2 ng/mL for THC, 2 ng/mL for 6–AM).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

(a) The drug testing panel will include drugs authorized for testing in federal workplace drug testing programs, with the required test analytes and cutoffs;

(b) The biomarker testing panel will include biomarkers authorized for testing in federal workplace drug testing programs, with the required test analytes and cutoffs; and

(c) HHS-certified laboratories and Medical Review Officers must use the nomenclature (*i.e.,* analyte names and abbreviations) published in the **Federal Register** with the drug and biomarker testing panels to report federal workplace drug test results.

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* specimen validity tests). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report an oral fluid specimen as adulterated?

An HHS-certified laboratory reports a primary (A) specimen as adulterated when the presence of an adulterant is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Section 3.7 What criteria are used to report an oral fluid specimen as substituted?

An HHS-certified laboratory reports a primary (A) specimen as substituted when a biomarker is not detected or is present at a concentration inconsistent with that established for human oral fluid for both the initial (first) test and the confirmatory (second) test on two separate aliquots (*i.e.,* using the test analytes and cutoffs listed in the biomarker testing panel).

Section 3.8 What criteria are used to report an invalid result for an oral fluid specimen?

An HHS-certified laboratory reports a primary (A) oral fluid specimen as an invalid result when:

(a) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid immunoassay or alternate technology initial drug test results cannot be obtained);

(b) Interference with the drug confirmatory assay occurs on two separate aliquots of the specimen and

the laboratory is unable to identify the interfering substance;

(c) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments;

(d) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(e) A specimen validity test on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

Subpart D—Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or personal friend (*e.g.,* fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to the collection procedure described in these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must include the following:

(i) All steps necessary to complete an oral fluid collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen tube tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are error-free.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of their training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer's training and provide that documentation to a federal agency when requested.

Section 4.5 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

Subpart E—Collection Sites

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, providing the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies; and

(f) The ability to store records securely.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during, and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory.

Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory or MRO discovers that the collector used an incorrect form, the laboratory or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G—Oral Fluid Specimen Collection Devices

Section 7.1 What is used to collect an oral fluid specimen?

An FDA-cleared single-use collection device intended to collect an oral fluid specimen must be used. This collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.

Section 7.2 What are the requirements for an oral fluid collection device?

An oral fluid specimen collection device must provide:

(a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;

(b) One or two sealable, non-leaking tubes [depending on the device type, as described in Section 8.8(a)] that:

(1) Maintain the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites,

(2) are sufficiently transparent to enable a visual assessment of the contents (*i.e.,* oral fluid, buffer/diluent, collection pad) for identification of abnormal physical characteristics without opening the tube, and

(3) include the device lot expiration date on each specimen tube (*i.e.,* the expiration date of the buffer/diluent or, for devices without a buffer/diluent, the earliest expiration date of any device component);

(c) Components that ensure pre-analytical drug and drug metabolite stability; and

(d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

Section 7.3 What are the minimum performance requirements for a collection device?

An oral fluid collection device must meet the following minimum performance requirements.

(a) Reliable collection of a minimum of 1 mL of undiluted (neat) oral fluid;

(b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):

(1) The volume of oral fluid collected should be at least 1.0 mL ±10 percent, and

(2) The volume of diluent in the device should be within ±2.5 percent of the diluent target volume;

(c) Stability (recoverable concentrations ≥80 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for five days at room temperature (64–77 °F/18–25 °C) and under the manufacturer's intended shipping and storage conditions; and

(d) Recover ≥80 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff listed in the drug testing panel.

Subpart H—Oral Fluid Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?

The following privacy requirements apply when a donor is providing an oral fluid specimen:

(a) Only authorized personnel and the donor may be present in the restricted

access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor.

Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

The collector must deter the adulteration or substitution of an oral fluid specimen at the collection site.

Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

The collector must take the following steps before beginning an oral fluid specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(e) The collector asks the donor to remove any unnecessary outer garments (*e.g.,* coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the oral fluid specimen. The collector must ensure that all personal belongings (*e.g.,* purse or briefcase) remain with the outer garments. The donor may retain the donor's wallet.

(f) If the donor will remain under the collector's direct observation until the end of the collection, including the 10-minute wait period described in Section 8.3(h), the collector proceeds to Section 8.3(g). If the collector will not keep the donor under direct observation from this point until the end of the collection, the collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(1) If no items are present that can be used to adulterate or substitute the specimen, the collector instructs the donor to return the items to their pockets and continues the collection procedure.

(2) If an item is present whose purpose is to adulterate or substitute the specimen (*e.g.,* a commercial drug culture product or other substance for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(3) If an item that could be used to adulterate or substitute the specimen (*e.g.,* common personal care products such as mouthwash, lozenges, capsules) appears to have been inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) If the donor refuses to show the collector the items in their pockets, the collector must keep the donor under direct observation until the end of the oral fluid collection.

(g) The collector requests that the donor open the donor's mouth, and the collector inspects the oral cavity to ensure that it is free of any items (*e.g.,* candy, gum, food, tobacco) that could impede or interfere with the collection of an oral fluid specimen or items that could be used to adulterate, substitute, or dilute the specimen.

(1) If an item is present that whose purpose is to adulterate or substitute the specimen (*e.g.,* a commercial drug culture product or other item for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(2) If an item is present that could impede or interfere with the collection of an oral fluid specimen (including abnormally colored saliva), or the donor claims to have ''dry mouth,'' the collector gives the donor water (*e.g.,* up to 4 oz.) to rinse their mouth. The donor may drink the water. If the donor refuses to remove the item or refuses to rinse, this is a refusal to test.

(3) If the donor claims that they have a medical condition that prevents opening their mouth for inspection, the collector follows the procedure in Section 8.6(b)(2).

(h) The collector must initiate a 10-minute wait period prior to collecting the specimen. During these 10 minutes, the collector must:

(1) Explain the basic collection procedure to the donor;

(2) Provide the instructions for completing the Federal CCF for the donor's review, and informs the donor that these instructions and the collection device-specific instructions are available upon request.

(3) Answer any reasonable and appropriate questions the donor may have regarding the collection procedure; and

(4) Inform the donor that they must remain at the collection site (*i.e.,* in the area designated by the collector) during the wait period, and that failure to follow these instructions will be reported as a refusal to test.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

(a) The collector shall instruct the donor to wash and dry the donor's hands under the collector's observation, and to keep their hands within view and avoid touching items or surfaces after handwashing. If the donor refuses to wash their hands when instructed by the collector, this is a refusal to test.

(b) The collector will provide or the donor may select the specimen collection device(s) to be used for the collection. The device(s) must be clean, unused, and wrapped/sealed in original packaging. See Section 8.8(a) for types of specimen collection devices used for oral fluid split specimen collections.

(1) The collector will open the package in view of the donor.

(2) Both the collector and the donor must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(c) The collector reviews with the donor the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(d) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to prevent the device from collecting sufficient oral fluid; an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must report a refusal to test in accordance with Section 8.9.

Section 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the oral fluid specimen:

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(1) Under the observation of the collector, the donor is responsible for positioning the specimen collection device for collection. The collector must ensure the collection is performed correctly and that the collection device is working properly. If there is a failure to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and notes the failed collection attempt on the Federal CCF. If the donor states that they are unable to provide an oral fluid specimen during the collection process or after multiple failures to collect the specimen, the collector follows the procedure in Section 8.6.

(2) The donor and the collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(3) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid oral fluid specimen (*e.g.,* unusual color, presence of foreign objects or material), documents any unusual findings on the Federal CCF, and takes action (*e.g.,* recollection) to obtain an acceptable specimen.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to begin the collection process after a failure to collect the specimen as required in step (a)(1) above, refuses to provide a split specimen as instructed by the collector, or refuses to provide an alternate specimen as authorized in Section 8.6, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.

Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

(a) If the donor states that they are unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and attempt to provide an oral fluid specimen.

(b) The donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor may choose not to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (*i.e.,* in an area designated by the collector) during the wait period.

(2) If the donor states that they are unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the oral fluid specimens?

(a) All federal agency collections are to be split specimen collections. An oral fluid split specimen collection may be:

(1) Two specimens collected simultaneously with two separate collection devices;

(2) Two specimens collected serially with two separate collection devices. The donor is not allowed to drink or rinse their mouth between the two collections. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF;

(3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or

(4) A single specimen collected using a single collection device, that is subsequently subdivided into two specimens.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube A'' and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube B''.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen tube. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Tube A and Tube B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the Tube A oral fluid specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

Section 8.9 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any oral fluid specimen collected and reports the refusal to test by:

(a) Notifying the federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the federal agency's designated representative.

Section 8.10 What are a federal agency's responsibilities for a collection site?

(a) A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I—HHS Certification of Laboratories

Section 9.1 Who has the authority to certify laboratories to test oral fluid specimens for federal agencies?

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory, including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory is prohibited from stating or implying that it is certified by HHS under these Guidelines to test oral fluid specimens for federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory to become HHS-certified?

(a) A laboratory seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

Section 9.3 What is the process for a laboratory to maintain HHS certification?

(a) To maintain HHS certification, a laboratory must:

(1) Successfully participate in both the maintenance PT and inspection programs (*i.e.,* successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory does not maintain its HHS certification?

(a) A laboratory that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.18, 11.19, and 14.8;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.21 and 11.22 and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in the drug testing panel and may be sent to the laboratory as undiluted (neat) oral fluid. The PT samples must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance, an adulterant, or other substances for special purposes, or may satisfy the criteria for a substituted specimen or invalid result.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) The laboratory must (to the greatest extent possible) handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

Section 9.6 What are the PT requirements for an applicant laboratory?

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the specified criteria; and

(10) Do not report any PT sample as adulterated with a compound that is not present in the sample or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the specified criteria; and

(10) Do not report any PT sample as adulterated with a compound that is not present in the sample or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the inspection requirements for an applicant laboratory?

(a) An applicant laboratory is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's testing procedures and facilities using an inspection checklist.

Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?

(a) An HHS-certified laboratory must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in Subpart K;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory.

(b) The Secretary or a federal agency may conduct an inspection at any time.

Section 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the laboratory must start the certification process from the beginning.

Section 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

(a) If an HHS-certified laboratory fails to satisfy the minimum requirements for certification, the laboratory is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's certification is revoked or suspended in

accordance with the process described in Subpart P, the laboratory is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory has successfully completed the certification requirements as a new applicant laboratory.

Section 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory by a federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing.

Section 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?

(a) When a laboratory's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory with written notice of the suspension or proposed revocation by fax, mail, personal service, or registered or certified mail, return receipt requested. This notification shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) The written notification shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notification, or if expedited review is requested, within 3 days of the date the laboratory received the notification. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notification is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notification provided to a laboratory that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of Subpart P.

Section 9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notification of revocation under Section 9.15 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory which has had its certification revoked may reapply for HHS certification as an applicant laboratory.

Section 9.17 Where is the list of HHS-certified laboratories published?

(a) The list of HHS-certified laboratories is published monthly in the **Federal Register**. This notification is also available on the internet at *https://www.samhsa.gov/workplace.*

(b) An applicant laboratory is not included on the list.

Subpart J—Blind Samples Submitted by an Agency

Section 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative and 25 percent must be positive for one or more drugs.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer's collection device as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in the drug testing panel.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with the expected result (*e.g.,* a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K—Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: Quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology. Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an

alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 11.7 What security measures must an HHS-certified laboratory maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.,* for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.11.

Section 11.10 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff, using samples at several concentrations between 0 and 150 percent of the cutoff;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.12 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification (*e.g.,* gas chromatography-mass spectrometry [GC–MS], liquid chromatography-mass spectrometry [LC–MS], GC–MS/MS, LC–MS/MS) or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of an oral fluid specimen when identifying and quantifying drugs or their metabolites.

Section 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff;

(5) The accuracy (bias) and precision at 40 percent of the cutoff;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff;

(2) At least one control certified to contain no drug or drug metabolite;

(3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each invalid, adulterated, or substituted specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results; and

(c) Controls must be analyzed concurrently with specimens.

Section 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.17 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (g)(1) through (g)(5) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with the cutoffs listed in the drug testing panel.

(d) A primary (A) oral fluid specimen is reported adulterated when the presence of an adulterant is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(e) A primary (A) oral fluid specimen is reported substituted when a biomarker is not present or is present at a concentration inconsistent with that established for human oral fluid.

(f) For a specimen that has an invalid result for one of the reasons stated in items (g)(1) through (g)(5) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive, adulterated, or substituted result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(g) A primary (A) oral fluid specimen is reported as an invalid result when:

(1) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid initial drug test results cannot be obtained);

(2) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(3) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments;

(4) The physical appearances of the A and B specimens are clearly different (note: A is tested); or

(5) A specimen validity test on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

(h) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(i) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for an oral fluid specimen. For example, a specimen can be positive for a specific drug and adulterated.

(j) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(k) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(l) An HHS-certified laboratory must report results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

(m) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(n) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(o) HHS-certified laboratories must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(p) For positive, adulterated, substituted, invalid, and rejected specimens, laboratories must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.18 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured storage in accordance with the collection device manufacturer's specifications (*i.e.,* frozen at −20 °C or less, or refrigerated), to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

Section 11.19 How long must an HHS-certified laboratory retain records?

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.21) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.20 What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period. The summary report must not include any personally identifiable information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) Number of specimen results reported;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test;

(10) Number of specimens reported positive;

(11) Number of specimens reported positive for each drug and drug metabolite;

(12) Number of specimens reported adulterated;

(13) Number of specimens reported substituted; and

(14) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.21 What HHS-certified laboratory information is available to a federal agency?

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all

internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.22 What HHS-certified laboratory information is available to a federal employee?

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and/or the federal agency requesting copies of any records relating to the employee's drug test results or a documentation package as described in Section 11.21(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

Section 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

No, only HHS-certified laboratories are authorized to test oral fluid specimens for federal agency workplace drug testing programs in accordance with these Guidelines.

Subpart M—Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A currently licensed physician who has:

(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notification in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notification is also available on the internet at *https://www.samhsa.gov/workplace/drug-testing.*

Section 13.3 What training is required before a physician may serve as an MRO?

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any federal agency for which the individual may serve as an MRO;

(b) Certified MROs must complete training on any revisions to these Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.17(f) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of two years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after six months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen and an alternate specimen was not collected, as addressed in Sections 8.6 and 13.6.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

(a) When the HHS-certified laboratory reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports multiple results for the primary (A) specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (f) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, do not report the verified invalid result to the federal agency at this time. The MRO takes the action described in Section 13.5(e) for the verified invalid result(s) for the primary (A) specimen only when:

(i) The MRO verifies the laboratory-reported positive, adulterated, or substituted result as negative based on a legitimate medical explanation as described in 13.5(c)(2) and 13.5(d)(1), or based on codeine and/or morphine concentrations less than 150 ng/mL as described in 13.5(c)(3)(i); or

(ii) The split (B) specimen is tested and reported as a failure to reconfirm as described in Section 14.6(m).

(c) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor admits unauthorized use of the drug(s) that caused the positive result, the MRO reports the test result as positive to the agency. The MRO must document the donor's admission of unauthorized drug use in the MRO records and in the MRO's report to the agency.

(2) If the donor provides documentation (*e.g.,* a valid prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency.

(i) Passive exposure to a drug (*e.g.,* exposure to secondhand marijuana smoke) is not a legitimate medical explanation for a positive drug test result.

(ii) Ingestion of food products containing a drug (*e.g.,* products containing marijuana) is not a legitimate medical explanation for a positive drug test result. See exceptions for positive codeine and morphine results in item 3 below.

(iii) A physician's authorization or medical recommendation for a Schedule 1 controlled substance is not a legitimate medical explanation for a positive drug test result.

(3) If the donor is unable to provide a legitimate medical explanation for the positive result, the MRO reports the positive result to the agency, for all drugs except codeine and/or morphine as follows:

(i) For codeine and/or morphine less than 150 ng/mL, the MRO must report the result as negative to the agency, unless the donor admits unauthorized use of the drug(s) that caused the positive result as described in item (c)(1) above.

(ii) For codeine and/or morphine equal to or greater than 150 ng/mL and no legitimate medical explanation, the MRO shall report a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(d) When the HHS-certified laboratory reports an adulterated or substituted result for the primary (A) oral fluid specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated or substituted result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the federal agency because the oral fluid specimen was adulterated or substituted.

(e) When the HHS-certified laboratory reports an invalid result for the primary (A) oral fluid specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result.

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medication), the MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a test cancelled result with the reason for the invalid result and directs the federal agency to immediately collect another specimen from the donor.

(i) If the second specimen collected provides a valid result, the MRO follows the procedures in 13.5(a) through (d).

(ii) If the second specimen collected provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* urine).

(f) When the HHS-certified laboratory reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor.

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

(a) When another specimen type (*e.g.,* urine) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of oral fluid to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid and is highly likely to prevent the employee from providing a sufficient amount of oral fluid for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has or, with a high degree of probability, could have precluded the employee from providing a sufficient amount of oral fluid. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient oral fluid specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] exists, making provision of a sufficient oral fluid specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the federal agency is not authorized to allow the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

Section 13.8 Who may request a test of a split (B) specimen?

(a) For a positive, adulterated, or substituted result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or substituted result is being reported to the federal agency on the primary (A) specimen.

Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory, or have any agreement with the HHS-certified laboratory that may be construed as a potential conflict of interest.

Section 13.11 What reports must an MRO provide to the Secretary for oral fluid testing?

(a) An MRO must send to the Secretary or designated HHS representative a semiannual report of federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. The report must not include any personally identifiable information for the donor and must be submitted by mail, fax, or other secure electronic transmission method within 14 working days after the end of the semiannual period (*i.e.,* in January and July). The semiannual report must contain the following information:

(1) Reporting period (inclusive dates);

(2) MRO name, company name, and address;

(3) Federal agency name; and

(4) For each laboratory-reported positive drug test result that was verified as negative by the MRO:

(i) Specimen identification number;

(ii) Laboratory name and address;

(iii) Positive drug(s) or drug metabolite(s) verified as negative;

(iv) MRO reason for verifying as negative (*e.g.,* a donor prescription [the MRO must specify the prescribed drug]);

(v) All results reported to the federal agency by the MRO for the specimen; and

(vi) Date of the MRO report to the federal agency.

(b) An MRO must provide copies of the drug test reports that the MRO sent to a federal agency available when requested to do so by the Secretary.

(c) If an MRO did not verify any positive laboratory results as negative during the reporting period, the MRO should file a report that states that the MRO has no reportable results during the applicable reporting period.

Section 13.12 What are a federal agency's responsibilities for designating an MRO?

(a) Before allowing an individual to serve as an MRO for the agency, a federal agency must verify and document the following:

(1) That the individual satisfies all requirements in Section 13.1, including certification by an MRO certification organization that has been approved by the Secretary, as described in Section 13.2; and

(2) that the individual is not an employee, agent of, or have any financial interest in an HHS-certified laboratory that tests the agency's specimens, as described in Section 13.10.

(b) The federal agency must verify and document that each MRO reviewing and reporting results for the agency:

(1) Completes training on any revisions to these Guidelines prior to their effective date;

(2) at least every five years, maintains their certification by completing requalification training and passing a requalification examination; and

(3) provides biannual reports to the Secretary or designated HHS representative as required in Section 13.11;

(c) The federal agency must ensure that each MRO reports drug test results to the agency in accordance with Sections 13.9 and 14.7.

(1) Before allowing an MRO to report results electronically, the agency must obtain documentation from the MRO to confirm that the MRO and any external service providers ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

Subpart N—Split Specimen Tests

Section 14.1 When may a split (B) specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) specimen be tested at a different (*i.e.,* second) HHS-certified oral fluid laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) oral fluid specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another oral fluid specimen from the donor, with no notification given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified oral fluid laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoffs established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

Section 14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?

(a) The HHS-certified laboratory must use its confirmatory specimen validity test at an established LOQ to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported substituted?

(a) The HHS-certified laboratory must test for the biomarker using its confirmatory test (*i.e.,* using the confirmatory test analytes and cutoffs listed in the biomarker testing panel).

(b) The second HHS-certified laboratory may only conduct the confirmatory biomarker test(s) needed to reconfirm the substituted result reported by the first HHS-certified laboratory.

Section 14.5 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.6 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) oral fluid specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and the specimen was adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test to the agency and indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and the specimen was substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request that Laboratory A test the primary (A) specimen using its confirmatory test for the biomarker.

(1) If the primary (A) specimen's test results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency.

(2) If the primary (A) specimen's results fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *Failed to reconfirm a single or all drug positive results and the specimen was not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s]), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm a single or all drug positive results and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s]) and the reason for the invalid result, cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure and notifies the HHS office responsible for coordination of the drug-free workplace program.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was adulterated.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was not adulterated or substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen had an invalid result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (not adulterated: Specifying the adulterant or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm substitution or adulteration and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: Specifying the adulterant or not substituted, and the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure and notifies the HHS office responsible for coordination of the drug-free workplace program.

(l) Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result. The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(m) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s] and not adulterated: Specifying the adulterant or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(n) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s] and adulterated) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may

take action based on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(o) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s] and not adulterated: Specifying the adulterant). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(p) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: Specifying the adulterant, and not substituted), and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(q) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (not adulterated: Specifying the adulterant). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(r) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

Section 14.7 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.8 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

Subpart O—Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory to report an oral fluid specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the primary (A) or split (B) specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken, or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The primary (A) specimen was collected using an expired device (*i.e.,* the device expiration date precedes the collection date) and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(d) The collector's printed name and signature are omitted on the Federal CCF;

(e) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen;

(f) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(g) The specimen was received at the HHS-certified laboratory without a CCF;

(h) The CCF was received at the HHS-certified laboratory without a specimen;

(i) The collector performed two separate collections using one CCF; or

(j) The HHS-certified laboratory identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the HHS-certified laboratory may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-federal form or an expired Federal CCF, the HHS-certified laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory should not cause an HHS-certified laboratory to reject an oral fluid specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's Social Security Number or employee identification number;

(6) A telephone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A ''reason for test'' box is not marked;

(9) A ''drug tests to be performed'' box is not marked;

(10) The specimen type box (Oral Fluid) is not marked (*i.e.,* by the collector or laboratory);

(11) A ''collection'' box is not marked;

(12) The ''each device within expiration date'' box is not marked;

(13) The collection site address is missing;

(14) The collector's printed name is missing but the collector's signature is properly recorded;

(15) The time of collection is not indicated;

(16) The date of collection is not indicated;

(17) Incorrect name of delivery service;

(18) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(19) The donor's name inadvertently appears on the HHS-certified laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory should not cause an MRO to cancel a test:

(1) The testing laboratory fails to indicate the correct name and address in the results section when a different laboratory name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 What discrepancies may require an MRO to cancel a test?

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or substituted; or

(3) The electronic report provided by the HHS-certified laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported drug positive, adulterated, invalid result, or substituted.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that they inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory. If, after at least 5 business days, the laboratory does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P—Laboratory Suspension/Revocation Procedures

Section 16.1 When may the HHS certification of a laboratory be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of the official's employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 16.3 Are there any limitations on issues subject to review?

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

Section 16.4 Who represents the parties?

The appellant's request for review shall specify the name, address, and telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notification of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notification of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 16.7 What procedures are used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 16.8 When is there an opportunity for oral presentation?

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at their discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of the official's employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including

argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At their discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory received notification of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by fax, secured electronic transmissions, or overnight mail.

Section 16.10 Are any types of communications prohibited?

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notification to the other party.

Section 16.11 How are communications transmitted by the reviewing official?

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by fax, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and federal holidays. However, if a due date falls on a Saturday, Sunday, or federal holiday, then the due date is the next federal working day.

Section 16.12 What are the authority and responsibilities of the reviewing official?

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notification to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 16.13 What administrative records are maintained?

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 16.14 What are the requirements for a written decision?

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue their decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notification.* If the suspension and proposed revocation are

upheld, the revocation will become effective immediately and the public will be notified by publication of a notification in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notification will be given by publication in the **Federal Register**.

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

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Part III

Department of Health and Human Services

42 CFR Chapter I

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter I

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Notification of mandatory guidelines.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') is proposing to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG), which published in the **Federal Register** of January 23, 2017.

DATES: Submit comments on or before June 6, 2022.

ADDRESSES: In commenting, please refer to file code SAMHSA 2022–0001. Because of staff and resource limitations, SAMHSA cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this document to *https://www.regulations.gov.* Follow ''Submit a comment'' instructions.
- *By regular mail.* You may mail written comments to the following address: SAMHSA, Center for Substance Abuse Prevention (CSAP), Division of Workplace Programs (DWP), 5600 Fishers Lane, Room 16N02, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the following address: SAMHSA, CSAP, DWP, 5600 Fishers Lane, Room 16N02, Rockville, MD 20857.
- *By hand or courier.* You may deliver your written comments by hand or courier to the following address prior to the close of the comment period: SAMHSA, CSAP, DWP, 5600 Fishers Lane, Room 16N02, Rockville, MD 20857. If you intend to deliver your comments to the Rockville address, please call (240) 276–2600 in advance to schedule your arrival with one of our staff members. Because access to the SAMHSA building is secure, persons without Federal Government identification are encouraged to schedule their delivery or to leave comments with the security guard at the front desk located in the main lobby of the building.

All comments received before the close of the comment period will be available for viewing by the public. Please note that all comments are posted in their entirety, including personal or confidential business information that is included in the comment. SAMHSA will post all comments before the close of the comment period on the following website: *https://www.regulations.gov.* Use the website's search function to view the associated comments.

Comments received before the close of the comment period will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at SAMHSA, CSAP, DWP, 5600 Fishers Lane, Rockville, MD 20857, Monday through Friday of each week, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, please call (240) 276–2600.

FOR FURTHER INFORMATION CONTACT: Eugene D. Hayes, Ph.D., MBA, SAMHSA, CSAP, DWP; 5600 Fishers Lane, Room 16N02, Rockville, MD 20857, by telephone (240) 276–1459 or by email at *Eugene.Hayes@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

This notification of proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) includes revisions that will: Establish a process whereby the Department annually publishes the authorized drug testing panel (*i.e.,* drugs, analytes, and cutoffs) to be used for Federal workplace drug testing programs; revise the definition of a substituted specimen to include specimens with a biomarker concentration inconsistent with that established for a human specimen; establish a process whereby the Department publishes an authorized biomarker testing panel (*i.e.,* biomarkers, analytes, and cutoffs) for Federal workplace drug testing programs; revise the confirmatory test cutoff for morphine; revise the Medical Review Officer (MRO) verification process for positive codeine and morphine specimens; and require MROs to submit semiannual reports to the Secretary or designated HHS representative on Federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. In addition, some wording changes have been made for clarity and for consistency with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG), 84 FR 57554 (October 25, 2019), or to apply to any authorized specimen type.

The Department is publishing a separate Federal Register Notification (FRN) elsewhere in this issue of the **Federal Register** proposing revisions to the OFMG, including the same or similar revisions proposed for the UrMG, where appropriate.

Background

The Department of Health and Human Services, pursuant to the Department's authority under Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order 12564, establishes the scientific and technical guidelines for Federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for Federal agencies. Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates that 275,000 urine specimens are tested annually by Federal agencies.

As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** (FR) on April 11, 1988 (53 FR 11979). The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 (59 FR 29908), September 30, 1997 (62 FR 51118), November 13, 1998 (63 FR 63483), April 13, 2004 (69 FR 19644), and November 25, 2008 (73 FR 71858). SAMHSA published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) on January 23, 2017 (82 FR 7920), and HHS published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) on October 25, 2019 (84 FR 57554).

Proposed Revisions to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs

Authorized Drug Testing Panel

The Guidelines pertain to a matter of Federal agency personnel and, therefore, are not subject to the notice and comment procedures under the Administrative Procedures Act. In light of the potential impact on entities outside of the Federal Government, the Department has chosen to submit the Guidelines to notice and comment, and will continue to do so. In this revision, the Department is proposing to change the way a specific part of the Guidelines

(*i.e.,* the drug testing panel) is published and the frequency with which it is published.

Since the original Guidelines were published in 1988, several recommendations have been made for drugs to be added to or removed from Federal workplace drug testing programs. The Department has revised the Guidelines in the past to add or remove drugs from the authorized drug testing panel and to revise test cutoffs (*i.e.,* Section 3.4 of the UrMG). The time required to revise the Guidelines through the Federal review process has impeded the Department's ability to respond to drug use trends. Individuals may change their drug use, and illicit drug manufacturers may change their manufacturing methods, to avoid testing positive for drugs included in proposed Guidelines, especially as the number of new drugs and drug analogues increases. A less flexible drug testing panel may delay needed drug analyte or cutoff changes based on the state of the science (*e.g.,* new technologies, research including dosing studies). Therefore, the Department proposes to publish the drug testing panel in the **Federal Register** on at least an annual basis, including any revisions to the panel, without the need (perceived or otherwise) to undergo notice and comment. Should the Department remove a drug from the drug testing panel, a Federal agency may test specimens for that drug in accordance with Section 3.2 (*i.e.,* on a case-by-case basis for reasonable suspicion or post accident testing, or routinely with a waiver from the Secretary). This process is expected to improve the effectiveness of Federal agency drug testing programs in support of the Federal Drug-Free Workplace Program. The drug testing panel in Section 3.4 of the final UrMG will remain in effect until the Department publishes a separate FRN with the drug testing panel.

The Department will continue to monitor drug use trends and review information on new drugs of abuse from sources such as Federal regulators, researchers, the drug testing industry (including HHS-certified laboratories), and public and private sector employers, to determine whether drugs should be added or removed from the panel. Any changes to analytes and cutoffs made in accordance with the newly established drug testing panel publishing process will be based on a thorough review of relevant information, including the current state of the science, laboratory capabilities, cost associated with the change, and benefits of the change to Federal agencies. The Department will set a date for the panel changes to take effect and include the effective date in the annual drug testing panel FRN in order to allow time for drug testing service providers (*e.g.,* immunoassay kit manufacturers) to develop or revise their products, and for HHS-certified laboratories to develop or revise assays, complete validation studies, and revise procedures. The prior version of the panel will remain in effect until the effective date of a newly published annual panel.

For consistency and to avoid misinterpretation of drug test results, the Department is requiring HHS-certified laboratories and HHS-certified instrumented initial test facilities (collectively referred to hereafter as ''HHS-certified test facilities'') and Medical Review Officers (MROs) to report results using the nomenclature (*i.e.,* analyte names and abbreviations) published with the drug testing panel.

Authorized Biomarker Testing Panel

A biomarker is an endogenous substance used to validate a biological specimen. The purpose of a biomarker test is to determine whether a submitted specimen is a human specimen. The current UrMG (effective October 1, 2017) allow additional specimen validity testing using biomarkers upon MRO request, to provide information to assist the MRO in the verification process. The current UrMG also require HHS-certified laboratories to report a specimen as invalid when the biomarker is not present or when its concentration is not consistent with that established for human urine but does not allow these specimens to be reported as substituted. The Department proposes to revise the UrMG to define such specimens as substituted, and to allow only biomarker tests that have been authorized by SAMHSA for use in Federal agency workplace drug testing programs.

To ensure that scientifically valid biomarker tests, analytes, and cutoffs are standardized for Federal workplace drug testing, the Department will institute an approval process for biomarker tests, based on review of data from the scientific and/or medical literature, before authorizing the use of the biomarker test. This process is equivalent to the approval process currently in use for testing additional Schedule 1 and 2 drugs or adding new tests for a specific adulterant. The Department will accept scientific information submitted for review from various sources (*e.g.,* HHS-certified test facilities, drug testing industry stakeholders, researchers). The Department will include the authorized biomarker testing panel (*i.e.,* a table of biomarkers authorized for testing, with test analytes and cutoffs), in the FRN to be published annually (as described earlier in this preamble). Federal agencies may choose to test some or all of their workplace specimens for one or more authorized biomarkers.

An HHS-certified laboratory, or (for urine only) an HHS-certified instrumented initial test facility (IITF), may request authorization from SAMHSA to conduct a biomarker test that has not been included on the list of authorized biomarkers. The test facility must submit supporting documentation and assay validation records to the National Laboratory Certification Program (NLCP) for SAMHSA review and approval. When a urine biomarker test is approved through this process, SAMHSA will authorize the individual HHS-certified test facility to perform the biomarker test for federally regulated specimens only upon MRO request (*i.e.,* a blanket request for all specimens or a case-by-case request for a specific specimen). A certified laboratory or IITF may choose to begin the process by submitting supporting documentation for review prior to assay validation, or may send supporting documentation with completed validation records. The Department will continue to include measurands and decision points for other specimen validity tests in the UrMG (*e.g.,* Sections 11.19 and 12.15).

Once a biomarker test has been added to the authorized biomarker panel published in the FRN, any HHS-certified laboratory or IITF may routinely conduct the test without requiring an MRO request, and only require a signed MRO request for case-by-case biomarker testing (in accordance with UrMG section 3.5). The Department will continue to require NLCP review of biomarker assay validation records before allowing an IITF or laboratory to use the test for federally regulated workplace specimens.

This process will facilitate the identification of donors who attempt to subvert their drug test, and ensure that biomarker tests used for federally regulated workplace programs are scientifically supportable and properly validated, and that all HHS-certified test facilities use the same analytes and cutoffs.

For consistency and to avoid misinterpretation of biomarker test results, the Department is requiring HHS-certified test facilities and Medical Review Officers (MROs) to report results using the nomenclature (*i.e.,* analyte names and abbreviations) published with the biomarker testing panel.

Medical Review Officer (MRO) Verification of Codeine and Morphine Test Results

The MRO has an essential role in federally regulated workplace drug testing programs that includes performing the review of laboratory results and supporting documentation, interviewing the donor when necessary, and making a final determination regarding the result. As described in Section 13.5d(2) of the current UrMG, when a donor has no legitimate medical explanation for a positive codeine or morphine result equal to or greater than 15,000 ng/mL, the MRO reports the specimen as positive to the agency. When a donor has no legitimate medical explanation for a positive codeine or morphine result less than 15,000 ng/mL, the MRO must determine that there is clinical evidence of illegal opioid use (in addition to the test results) to report such specimens as positive. If the MRO finds no clinical evidence of illegal opioid use, the MRO verifies the opiate results as negative. These requirements were included in the UrMG to address positive codeine and/or morphine results that may be due to poppy seed ingestion. The Department proposes to remove the additional decision point for codeine and morphine, to adjust the confirmatory test cutoff for morphine from 2,000 to 4,000 ng/mL, and to remove the additional requirement for clinical evidence of illegal opioid use, as described above. The confirmatory test cutoff for codeine will remain at 2,000 ng/mL. The basis for the Department's proposed changes is described in the following paragraphs.

A review of the scientific literature, as cited below, regarding the role of poppy seed food products in producing positive urine drug tests for the opiates, codeine and morphine, was undertaken to ascertain whether the current decision point should be maintained or changed. The Department focused on studies using analytical techniques acceptable to modern forensic toxicology laboratories, for which the researchers included information on poppy seed doses and adequately described the analytical techniques. Because most common poppy variants produce morphine in great excess to codeine, morphine concentrations significantly exceeded codeine concentrations in all reviewed studies.

Studies of patients being tested for abstention from heroin use suggest that urine concentrations of morphine are often below 15,000 ng/mL and the heroin metabolite, 6-acetylmorphine (6-AM) is absent, indicating the heroin use was not within the short detection limit for 6-AM. A study by Colby et al. examined morphine concentrations in urine specimens from chronic pain patients being monitored for medication compliance. Patients with positive 6-AM results had morphine concentrations averaging 85,000 ng/mL (±154,000 ng/mL), with 25% at or below 10,000 ng/mL and an additional 15% falling between 10,000 ng/mL and 20,000 ng/mL. (Ref. 1) However, it is well known that 6-AM is generally positive in only the first few urine specimens following heroin dosing, making it the limiting factor in unequivocal detection of heroin use. (Ref. 2 and 3) Further, in a study by Wang et al., heroin metabolites including morphine were measured in subjects seeking in-patient addiction treatment for heroin use. In 20 subjects without 6-AM positive urine specimens, the total morphine concentration ranged from 87 to 34,896 ng/mL and averaged 9,960 ng/mL. Only 30% of the subjects had specimens above the 15,000 ng/mL decision point specified by the current UrMG. Lowering the morphine cutoff to 4,000 ng/mL would identify another 30% of the heroin users in this type of cohort. (Ref. 4)

In regard to poppy seed food products, the literature is consistent in the conclusion that regular ingestion of poppy seed-containing foods (bagels, cakes, curries, etc.) rarely results in urine opiate concentrations above the 2,000 ng/mL cutoff specified in the current UrMG, and that proper handling by pre-washing and cooking the poppy seeds into food products causes loss of both morphine and codeine. Studies attempting to characterize morphine and codeine results after reasonable consumption of poppy seed food products on an acute and chronic basis reported maximum morphine concentrations ranging between 160 and 3,000 ng/mL with codeine ranging between 11 and 390 ng/mL. (Ref. 3 and 5–8) There is only one study in which the urine concentration of morphine exceeded 4,000 ng/mL after ingestion of regular prepared food containing poppy seeds, and the researchers reported that some subjects became ill due to the large amount of poppy seeds in the food product. (Ref. 9) The results of this study have not been duplicated in subsequent studies involving prepared food products.

Other studies used extreme exposure protocols involving intolerable or near intolerable amounts of raw and/or unwashed poppy seeds, which are known to contain much more codeine and morphine than their washed and cooked counterparts. In one such extreme study in 2015, the researchers reported that participants felt that 15 g of raw, unwashed poppy seeds was close to the bearable limit for ingestion, and the maximum urine concentration was 4,200 ng/mL for morphine and 664 ng/mL for codiene. (Ref. 7) Of note, this study also included the same dose of poppy seeds baked in a roll and maximum morphine and codeine concentrations were considerably lower at 1,400 and 194 ng/ml, respectively. This research confirms the results of extreme ingestion by three volunteers in a 2003 study by Rohrig and Moore, and the experience in a 2014 study by Smith et al. in which only 19 of 22 participants could tolerate ingestion of all planned doses. (Ref. 10 and 11) Further, in the 2014 study, seven of the 19 subjects did not produce a positive morphine result (*i.e.,* ≥2,000 ng/mL) until after the second extreme dose of poppy seeds, approximately eight hours after the first dose. At all times in this study, codeine results were below the 2,000 ng/mL cutoff. The Department finds these studies relevant to setting the cutoff limit of 4,000 ng/mL for morphine and sufficient for eliminating positives due to poppy seeds because they confirm that urine morphine concentrations exceeding 4,000 ng/mL would be very rare, transient, and a consequence of unrealistic and extreme poppy seed exposure (*i.e.,* ingesting barely tolerable amounts of raw and/or unwashed poppy seeds).

The Department also reviewed information on other sources of poppy seed exposure. In reaction to at least 12 deaths reported in the scientific literature associated with the use of tea prepared with unwashed poppy seeds and the availability of unwashed poppy seeds from online retailers, the Drug Enforcement Administration (DEA) issued a warning in 2019 restating that unwashed poppy seeds are a danger to the user, and their use and misuse may result in unpredictable outcomes including death when used alone or in combination with other drugs. DEA reiterated that the morphine and codeine, if present as contaminants on poppy seed material, are not exempted from the Controlled Substances Act (CSA) control. (Ref. 12)

In summary, the Department is not aware of any evidence that reasonable or realistic consumption of poppy seed-containing food products would cause a positive drug test using the codeine and morphine cutoffs specified by these Guidelines. Only purposeful consumption of large amounts (*e.g.,* 15 g or more) of raw and/or unwashed poppy seeds has been shown to result in codeine at or above 600 ng/mL or in morphine exceeding 4,000 ng/mL, and

the extreme amounts of poppy seeds in these studies, described by subjects as intolerable or barely tolerable, do not represent a real-world situation for donors in a Federal agency testing program.

Based on this information, the Department has decided that no additional decision point is needed for MRO verification of codeine and morphine results. Further, the Department has concluded that continued use of the current 15,000 ng/mL decision point diminishes the deterrent effect of the program by attributing codeine and morphine results between the cutoff and 15,000 ng/mL to poppy seed ingestion in the absence of a legitimate medical explanation. The Department proposes to raise the confirmatory test cutoff for morphine to 4,000 ng/mL to rule out any donor claims that consumption of poppy seed food products (on an acute or chronic basis) was the reason for a positive morphine test result. This cutoff change makes the Federal drug testing program cutoffs for codeine and morphine the same as the Department of Defense (DoD) program cutoffs, which were previously raised to these concentrations to eliminate positive tests due to poppy seeds. (Ref. 14)

Medical Review Officer (MRO) Semiannual Reports

The Department, through the NLCP, obtains information from HHS-certified laboratories that is reviewed to verify accurate reports and compliance with Guidelines requirements. The NLCP conducts statistical analysis and provides reports to the Department on federally regulated workplace testing, although the data are limited to laboratory-reported results and not the final, MRO-verified results. To obtain additional information needed to assess compliance with the Mandatory Guidelines, the Department proposes to require each MRO performing medical review services for Federal agencies to submit semiannual reports, in January and July of each year, of Federal agency specimens that were reported as positive for a drug or drug metabolite by the laboratory, and verified as negative by the MRO, along with the reason for the negative verification (*e.g.,* a valid prescription for a drug). The reports will not contain any personally identifiable information of the donors.

This revision to the Guidelines will enable Department oversight of MRO reporting practices and will enhance the Department's ability to verify the accuracy of MRO reports and address areas of confusion about Guidelines requirements. The information in the MRO reports will be matched to information submitted to the NLCP by HHS-certified laboratories for the same specimens. This additional information will improve statistical analyses and provide a clearer picture of illicit drug use by Federal job applicants and employees.

Proposed Revisions to the Guidelines

This preamble describes the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG), and the rationale for the changes.

Subpart A—Applicability

Section 1.5 defines terms used in the UrMG. The Department has added terms and revised definitions in this section in accordance with proposed changes to these Guidelines, and to standardize terms and definitions, where possible, to apply to all authorized specimen types.

The Department proposes to revise the Substituted Specimen definition to include specimens tested for a biomarker, when the biomarker is absent or is present at a concentration inconsistent with that established for a human specimen. For clarity, the Department also added a reference to the reporting criteria for substitution in Section 3.7 of these Guidelines. For clarity and consistency with the revised Substituted Specimen definition, the Department proposes to edit the Adulterated Specimen definition to apply to specimens with ''an abnormal concentration of a normal constituent (*e.g.,* nitrite in urine),'' rather than ''an abnormal concentration of an endogenous substance,'' and to revise definitions for Cutoff and Initial Specimen Validity Test to remove the ''(for urine)'' specification for identifying a substituted specimen. The Department proposes to revise the Collection Container definition to apply to all authorized specimen types, by changing ''a urine specimen'' to ''a donor's drug test specimen.'' The Department has also added definitions for ''Biomarker Testing Panel'' and ''Drug Testing Panel'' consistent with the proposed publication of these testing panels in a separate FRN each year.

Section 1.7 describes what constitutes a donor's refusal to take a federally regulated drug test. Section 1.7(a) includes exceptions for a donor who fails to appear in a reasonable time for a pre-employment test and a donor who leaves the collection site before the collection process begins for a pre-employment test. The Department finds that there is no justification for altering a refusal to test based on whether the test is being conducted in the employment or pre-employment context and, therefore, proposes to remove these exceptions. The collector will report a refusal to test for any donor who fails to appear in a reasonable time or who leaves the collection site before the collection is complete, regardless of the reason for the test.

Section 1.8(a) describes the potential consequences for a refusal to test. The Department has reworded this section to clarify potential actions for a Federal employee who refuses to take a drug test, and the potential action for an applicant who refuses to take a pre-employment test.

Subpart C—Urine Specimen Tests

The Department proposes to edit Section 3.1 to reflect the proposed process for publishing drug and biomarker testing panels in an FRN each year containing a list of authorized drug analytes and biomarkers that can be tested. As described under *Authorized drug testing panel* and *Authorized biomarker testing panel* above, the time required to revise the Guidelines through the Federal review process has impeded the Department's ability to respond to drug use trends, and to make drug analyte or cutoff changes based on the state of the science (*e.g.,* new technologies, research including dosing studies). This new process is expected to improve the effectiveness of Federal agency drug testing programs in support of the Federal Drug-Free Workplace Program. See also Section 3.4.

For clarity, the Department also revised the header for Section 3.2 to refer to ''drugs other than those in the drug testing panel'' (see above) rather than ''additional drugs''.

The Department has revised the analytes and cutoffs table in Section 3.4 of the UrMG to reflect the proposed change to the confirmatory cutoff for morphine, and revised the section to describe the publication of a final notification in the **Federal Register** each year that will include the authorized drugs, test analytes, and cutoffs; the authorized biomarkers, test analytes, and cutoffs; and the nomenclature required for IITF, laboratory, and MRO reports. The annual notification will be posted on the SAMHSA website, *https://www.samhsa.gov/workplace.* The table in Section 3.4 of the final UrMG will remain in effect until the effective date of the new panels published in the separate FRN.

Section 3.7 describes the criteria used to report a specimen as substituted and Section 3.9 describes the criteria used to report an invalid result for a urine

specimen. The current sections require laboratories to report a specimen as invalid when a biomarker is not present or its concentration is outside the range established for that biomarker in human urine. As described under *Authorized biomarker testing panel* above, the purpose of a biomarker test is to determine whether a submitted specimen is a human specimen. Therefore, the Department proposes to revise these sections to require specimens to be reported as substituted, rather than invalid, based on biomarker testing. See also Section 1.5.

Subpart H—Urine Specimen Collection Procedure

The Department proposes to revise the wording in Section 8.3(f) regarding how instructions for completing the Federal Custody and Control Form (CCF) are provided to the donor. This is consistent with changes made to the Federal CCF to enable its use with both urine and oral fluid specimens.

The Department moved items under Section 8.3(h) into a new item 8.3(i) addressing the collector's request for the donor to display the contents of their pockets and subsequent collector actions. The required actions remain the same, but the Department revised wording in new items 8.3(i)(1) through 8.3(i)(4) for clarity.

In Section 8.5(a), the Department clarified that the collector must inform the donor that the donor's failure to remain at the collection site until the collection is complete will be reported as a refusal to test. This is consistent with Section 1.7.

The Department also revised wording in Section 8.9(a)(3) for clarity.

Subpart I—HHS Certification of Laboratories and IITFs

Section 9.7 describes performance test (PT) requirements for an HHS-certified laboratory and Section 9.9 describes PT requirements for an HHS-certified IITF. PT error criteria will remain the same; however, the Department is proposing to edit some items for clarity. Specifically, the Department proposes to revise Sections 9.7(a)(5), 9.7(a)(10), and 9.9(a)(6) to state clearly that quantitative values reported for drug and specimen validity tests are evaluated based on reported results for each PT cycle, not on cumulative results reported over two consecutive PT cycles. An HHS-certified test facility must not obtain a quantitative value outside the specified range for a drug or specimen validity test result, based on the appropriate reference or peer group mean.

The Department also revised Section 9.6(a)(11) for an applicant laboratory and Section 9.7(a)(10) for an HHS-certified laboratory to address requirements for PT samples reported as substituted based on biomarker test results, in addition to those reported as substituted based on creatinine and specific gravity test results.

Subpart K—Laboratory

Section 11.19 describes the requirements for an HHS-certified laboratory to report primary (A) specimen test results to an MRO. The Department proposes to revise the requirements for reporting a specimen as substituted in item 11.19(e) to include specimens with a biomarker concentration inconsistent with that established for human urine, in addition to those reported as substituted based on creatinine and specific gravity test results (see also Sections 1.5, 3.7, and 3.9).

Section 11.19(g) addresses laboratory and MRO discussions to determine whether additional testing may be useful for specimens with certain invalid results. Because biomarker testing could be used to identify substitution, the Department has revised this section to indicate that additional testing may be useful in being able to report a substituted result, as well as positive or adulterated results.

Section 11.19(g) describes the requirements for a laboratory to report a specimen as invalid. The Department has added an item 13 addressing tests used to determine specimen validity, other than those specifically listed in this section.

The Department also proposes to add a new item 11.19(m) stating that the laboratory must use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports. This change is to ensure consistency in reporting and interpretation of test results, by requiring the results of each test performed to be reported using clear and correct nomenclature for test analytes, with the same terminology and units of measurement. See also Section 3.4.

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.15 describes the requirements for an HHS-certified IITF to report primary (A) specimen test results to an MRO. The Department proposes to add a new item 12.15(e) stating that the IITF must use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports. See also Section 3.4.

Subpart M—Medical Review Officer (MRO)

Section 13.4(f) describes when an MRO must conduct a medical examination or review an examining physician's findings when the collector reported that the donor was unable to provide a specimen. The Department has clarified that a medical examination is not required when an alternate specimen was collected.

Section 13.5(c)(2) describes MRO actions when a laboratory reports an invalid result in conjunction with a positive, adulterated, or substituted result. The Department has added an item to this section to clarify that the MRO takes the required action for the invalid result (specified in item f of this section) only when the MRO has verified the other result(s) for the specimen (*i.e.,* positive, adulterated, or substituted) as negative or when the split (B) specimen was tested and reported as a failure to reconfirm.

Section 13.5(d) describes MRO actions to determine whether the donor has a legitimate medical explanation for a positive specimen test result. The Department added a new item Section 13.5(d)(1) to clarify that the MRO reports a positive result when the donor admits unauthorized use of the drug(s) that caused the positive test result, and documents the admission of unauthorized use in the MRO records and in the MRO's report to the Federal agency. A donor's admission of unauthorized use corroborates the positive test.

Currently, Section 13.5(d)(2) includes the policies of the Department that passive exposure to marijuana smoke and ingestion of food products containing marijuana are not acceptable medical explanations for a positive marijuana test result. The Department proposes to reword this section to clarify that these policies apply to any positive urine drug test results, not only positive marijuana results. Item i of this section now states that passive exposure to any drug is not an acceptable medical explanation for a positive drug test, with ''exposure to secondhand marijuana smoke'' as an example of passive exposure. Item ii of this section now states that ingestion of food products containing a drug is not an acceptable medical explanation for a positive drug test, with ''products containing marijuana'' and ''poppy seeds containing codeine and/or morphine'' as examples. The Department also proposes to add a new item iii to this section stating that a physician's authorization or medical recommendation for a Schedule I

substance is not an acceptable medical explanation for a positive drug test. Under the CSA, a Schedule I substance is defined as a drug, chemical, or other substance with no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. (Ref. 13) The DEA maintains the current listing of controlled substances on their website.

Section 13.5(d)(3) describes MRO actions when the donor has no legitimate medical explanation for a positive drug test result. The Department has revised this section to remove the exceptions for codeine and morphine. As described above under *MRO verification of codeine and morphine test results,* the Department has removed the additional 15,000 ng/mL decision point for codeine and morphine, as well as the requirement for the MRO to report such specimens as positive based on clinical evidence of illicit drug use (in addition to the drug test results). The MRO will follow the same verification procedures for all specimens with positive test results.

Section 13.9 describes how an MRO reports primary (A) drug test results to an agency. The Department proposes to add a new item 13.9(e) stating that the MRO must use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports. See also Section 3.4.

The Department has included a new Section 13.11 describing the proposed requirement for an MRO to send semiannual reports to the Secretary or designated HHS representative for Federal agency specimens that were reported as positive by a laboratory and verified as negative by the MRO. As described under *Medical Review Officer (MRO) semiannual reports* above, this change will enable Department oversight of MRO practices and will enhance the Department's ability to verify the accuracy of MRO reports and address areas of confusion about Guidelines requirements. In addition, the information in the MRO reports will be matched to information submitted to the NLCP by HHS-certified laboratories for the same specimens, thereby improving statistical analyses and providing a clearer picture of illicit drug use by Federal job applicants and employees. The reports must not include any personally identifiable information for the donor, and must be submitted within 14 working days after the end of the semiannual period (*i.e.,* in July and January). Section 13.11 lists the information that must be included on the reports. To facilitate report preparation and review, the Department will include a template for these MRO reports in the MRO Guidance Manual and will arrange a secure method for MROs to submit reports electronically.

The Department has included a new Section 13.12 describing the Federal agency's responsibilities for designating an MRO. These responsibilities include verifying and documenting that individuals meet the MRO requirements in these Guidelines before allowing them to serve as an MRO for the agency's drug testing program and on an ongoing basis, and ensuring that each MRO reports drug test results in accordance with the Guidelines. Further, the Federal agency must obtain documentation from the MRO to confirm that the MRO and any external service provider ensures the confidentiality integrity and availability of the data and limits the access to any data transmission, storage, and retrieval system.

Subpart N—Split Specimen Tests

Section 14.4 describes how an HHS-certified laboratory reports a split (B) urine specimen when the primary (A) specimen was reported substituted. The Department proposes to revise this section to address primary (A) specimens reported as substituted based on biomarker test results, in addition to those reported as substituted based on creatinine and specific gravity test results. See also Section 1.5.

Section 14.5 states that the HHS-certified laboratory that tested a split (B) specimen must report the results to the MRO. The Department proposes to reword this section to require the laboratory to use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports for split (B) specimens. See also Section 3.4.

Section 14.6 describes the actions an MRO takes after receiving a split (B) urine specimen result from an HHS-certified laboratory. Section 14.6(c) specifies MRO actions when the laboratory failed to reconfirm one or more positive results and reported the split specimen as substituted. The Department proposes to revise this item to address actions when the B specimen was reported as substituted based on biomarker test results, in addition to those reported as substituted based on creatinine and specific gravity test results. See also Section 1.5. The Department also proposes to add a new item 14.6(k) to address MRO verification of split (B) specimen results when the B specimen fails to reconfirm adulteration or substitution and is invalid.

Section 14.7 describes how an MRO reports split (B) specimen test results to an agency. The Department proposes to add a new item 14.7(e) stating that the MRO must use the HHS-specified nomenclature published with the drug and biomarker testing panels on reports. See also Section 3.4.

General Revisions

In addition to the proposed changes described by subpart and section above, the Department has edited the UrMG to address proposed changes (*e.g.,* removing ''for urine'' when referring to substituted specimens; referencing the proposed annual FRN with drug and biomarker testing panels) and has reworded some items for clarity and/or for consistency with the OFMG.

Impact of These Guidelines on Government Regulated Industries

The proposed revised Guidelines may impact the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) regulated industries depending on these agencies' decisions to incorporate the final UrMG revisions into their programs under their own authority.

Costs and Benefits

Costs

The proposed UrMG revision to publish the drug testing panel in a separate FRN each year (*e.g.,* Section 3.4) may result in a cost increase for HHS-certified test facilities and MROs (*e.g.,* costs for test supplies, assay validation, administrative changes) when a new drug is added to the panel or when analytes or cutoffs are changed for current drugs. The added costs will depend on the change. For example, implementation costs would be lower for laboratories that already offer the drug test or use the different analyte or cutoff for their non-regulated clients. MROs may experience increased costs when an agency chooses to test their Federal job applicants and employees for a new authorized drug with a high positivity rate or a Schedule II drug requiring the MRO to review medical explanations. Additional costs for testing and MRO review will be incorporated into the overall cost for the Federal agency submitting the specimen to the laboratory. Added costs to MROs would be expected to shift to Federal agencies over time, as existing contracts expire and new contract terms are negotiated. As noted earlier in this preamble, the Department will consider costs when deciding whether to make a change to the authorized drug tests. At this time, the Department will not

require HHS-certified test facilities to implement authorized biomarker tests. Each laboratory and IITF should conduct their own cost analysis when deciding whether to offer biomarker testing to federally regulated clients. The Department will consider costs when deciding whether to require all certified test facilities to test for a specific biomarker.

The proposed change to the morphine confirmatory test cutoff from 2,000 ng/mL to 4,000 ng/mL will result in some initial costs for HHS-certified laboratories (*e.g.,* to revalidate their opiate confirmatory assays, revise opiate calibrators and controls, and revise review and reporting procedures). However, there should also be some cost savings as described below under *Benefits.*

There will be some administrative costs for MROs associated with the generation and submission of the semiannual reports of verified-negative results (see Section 13.11). The Department encourages the use of electronic recordkeeping to facilitate information retrieval and report generation, and will enable secure submission of electronic information to reduce MRO costs to provide these reports.

Benefits

The potential benefits of more timely changes to the drug testing panel will result in a healthier and more productive workforce, as well as avoid the issues associated with addiction and rehabilitation. Since the personnel tested under this program are in positions that are safety sensitive, potential benefits include decreased risk of transportation and workplace accidents, decreased risk of low-probability high consequence events, a more responsible workforce in positions of public trust, and potentially reducing individuals' dependence or addiction and the personal benefits associated with those conditions. Considering the potential health and performance costs of drug misuse, the benefits to the Federal workplace and the individuals within that workplace justify the more agile method of changing the drug testing panel for the Federal workplace drug testing programs.

The number of commercial substitution and adulteration products aimed at defeating a drug test continues to proliferate for both urine and oral fluid. Manufacturers alter their existing products or develop new products to subvert drug and specimen validity tests in federally regulated workplace programs. (Ref. 15 and 16) When the Department added provisions for biomarker testing in the current UrMG, the intent was to identify non-human urine samples that were submitted for testing in place of the donor's urine. The proposed revision to report a specimen as substituted (not invalid) based on biomarker testing is consistent with this intention. This revision, as well as the Department review and approval of biomarker tests and the added flexibility for making changes to the drug and biomarker testing panels, will strengthen the Federal Government's ability to identify illicit drug use and donor attempts to subvert drug tests.

The proposed requirement for semiannual MRO reports on laboratory-positive/MRO-negative results will enable the Department to ensure accurate reports and MRO compliance with Guidelines requirements. The information in the MRO reports will be matched to information for the same specimens that was submitted to the NLCP by the HHS-certified laboratory, thereby improving statistical analyses and providing a clearer picture of illicit drug use by Federal job applicants and employees.

As noted above under *Costs,* HHS-certified laboratories will incur some initial costs for changing the morphine confirmatory test cutoff; however, laboratories will also experience some benefits in that the removal of the 15,000 ng/mL decision points for codeine and morphine will simplify codeine and morphine review and reporting procedures. MROs may also experience some savings, as the removal of the decision points and clinical evaluation requirement for some codeine and morphine positive results will simplify the MRO verification process. That is, codeine and morphine positive results will be reviewed and verified using the same procedures as positive results for other drugs.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines, which establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for Federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form (Federal CCF) used to document the collection and chain of custody of urine and oral fluid specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination; the National Laboratory Certification Program (NLCP) application; the NLCP Laboratory Information Checklist; and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect.

In support of the Government Paperwork Reduction Act (PRA), the Department revised the Federal CCF to enable its use as an electronic form (78 FR 42091, July 15, 2013) and developed requirements and oversight procedures to ensure that HHS-certified test facilities and other service providers (*e.g.,* collection sites, MROs) using an electronic version of the Federal CCF (ECCF) maintain the accuracy, security, and confidentiality of electronic drug test information. Before a Federal ECCF can be used for Federal agency specimens, HHS-certified test facilities must submit detailed information and proposed standard operating procedures (SOPs) to the NLCP for SAMHSA review and approval, and undergo an NLCP inspection focused on the proposed ECCF.

Since 2013, SAMHSA has encouraged the use of Federal ECCFs and other electronic processes in HHS-certified test facilities, when practicable, for federally regulated testing operations. In accordance with Section 8108(a) of the SUPPORT for Patients and Communities Act, SAMHSA has set a deadline of August 31, 2023, for all HHS-certified laboratories to submit a request for approval of an electronic (paperless) Federal CCF.

The title and description of the information collected and respondent description are shown in the following paragraphs with an estimate of the annual reporting, disclosure, and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: The Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine.

Description: The Mandatory Guidelines establish the scientific and technical guidelines for Federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents,

individuals for cause, and random testing of persons in sensitive positions.

Description of Respondents: Individuals or households, businesses, or other-for-profit and not-for-profit institutions.

The burden estimates in the tables below are based on the following number of respondents: 38,000 donors who apply for employment or are employed in testing designated positions, 100 collectors, 25 urine specimen testing laboratories, 1 IITF, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory or IITF required to submit application for certification.	10	1	3	30
9.12(a)(3)	Materials to submit to become an HHS inspector.	10	1	2	20
11.3	Laboratory submits qualifications of responsible person (RP) to HHS.	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.22	Specifications for laboratory semiannual statistical report of test results to each Federal agency.	10	5	0.5	25
12.3(a)	IITF [1] submits qualifications of RT to HHS	1	1	1	1
12.4(c)	IITF [1] submits information to HHS on new RT or alternate RT.	1	1	1	1
12.19	Specifications for IITF [1] semiannual statistical report of test results to each Federal agency.	1	1	1	1
13.9 and 14.7	Specifies that MRO must report all verified primary and split specimen test results to the Federal agency.	100	14	0.05 (3 min)	70
13.11	Specifications for MRO semiannual report to the Secretary or designated representative for Federal agency specimen results that were laboratory-positive and MRO-verified negative.	100	2	0.5	100
16.1(b) & 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed.	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review.	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total		259			395

[1] Although IITFs are allowed under the UrMG, SAMHSA has not received any IITF application for certification to test federally regulated specimens. IITF numbers are provided in this analysis as placeholders for administrative purposes.

The following reporting requirements are also in the proposed Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or refusal to participate in the collection process on the Federal CCF (Sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (Section 10.3(a)); MRO notifies the Federal agency and HHS when an error occurs on a blind sample (Section 10.4(d)); and Sections 13.6 and 13.7 describe the actions an MRO takes for the medical evaluation of a donor who cannot provide a urine specimen. SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3(a), 8.5(f)(2)(iii), 8.6(b)(2).	Collector must contact Federal agency point of contact.	100	1	0.05 (3 min)	5
11.23, 11.24	Information on drug test that laboratory must provide to Federal agency upon request or to donor through MRO.	25	10	3	750

ESTIMATE OF ANNUAL DISCLOSURE BURDEN—Continued

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
12.20, 12.21	Information on drug test that IITF must provide to Federal agency upon request or to donor through MRO.	1	1	1	1
13.8(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	14	3	4,200
Total		226			4956

The following disclosure requirements are also included in the proposed Guidelines, but have not been addressed in the above disclosure burden table: The collector must explain the basic collection procedure to the donor and answer any questions (Section 8.3(e) and (g)). SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3, 8.5, 8.8	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2,660
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	38,000	1	0.08 (5 min)	3,040
11.8(a) & 11.19	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	25	1,520	0.05 (3 min)	1,900
12.8(a) & 12.15	IITF completes Federal CCF upon receipt of specimen and before reporting result.	1	1	1	1
13.4(d)(4),13.9(c),14.7(c)	MRO completes Federal CCF before reporting the primary or split specimen result.	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested.	100	2	0.05 (3 min)	10
Total		38,326			9,511

The proposed Guidelines contain several recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector (Section 4.3(a)(3)) and the documentation must be maintained in the collector's training file (Section 4.3(c)). SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a Federal agency specimen, the collector is required to provide a statement (Section 6.2(b)) explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H (Sections 8.4(c), 8.5(d)(2), 8.5(e)(1) and (2)) requires collectors to enter any information on the Federal CCF of any unusual findings during the urine specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subpart K describes a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.,* Sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.11(a); 11.14(a); 11.17; 11.21(a), (b), and (c); 11.22; 11.23(a); and 11.24). These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis.

Thus, the total annual response burden associated with the testing of urine specimens by the laboratories and IITFs is estimated to be 14,862 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of these proposed Guidelines to OMB for its review. Comments on the information collection requirements are specifically solicited in order to:
(1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility;
(2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and
(4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology.

OMB is required to make a decision concerning the collection of information contained in these proposed Guidelines between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to HHS on the proposed Guidelines.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street NW, Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to 202–395–6974 (fax).

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Summary

These proposed revisions are intended to simplify changes to the authorized drug testing panel for Federal workplace drug testing programs, facilitate the identification of substituted specimens using biomarker testing, improve detection of illicit codeine and/or morphine use, and provide the Department with information on Federal agency drug test specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified negative by the Medical Review Officer (MRO). The Department believes that the proposed revisions to the Mandatory Guidelines save costs and improve the effectiveness of Federal workplace drug testing programs.

Dated: March 22, 2022.

Miriam E. Delphin-Rittmon,

Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration.

Approved: March 22, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens

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Subpart A—Applicability

Section 1.1 To whom do these Guidelines apply?

(a) These Guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3), but excluding the Armed Forces as defined in 5 U.S.C. 2101(2);

(3) Any other employing unit or authority of the federal government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories and instrumented initial test facilities (IITFs) that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

Section 1.2 Who is responsible for developing and implementing these Guidelines?

(a) Executive Order 12564 and Public Law 100–71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

Section 1.3 How does a federal agency request a change from these Guidelines?

(a) Each federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a federal agency must submit a written request to

the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

Section 1.4 How are these Guidelines revised?

(a) To ensure the full reliability and accuracy of specimen tests, the accurate reporting of test results, and the integrity and efficacy of federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) Revisions to these Guidelines will be published in final as a notice in the **Federal Register**.

Section 1.5 What do the terms used in these Guidelines mean?

The following definitions are adopted:

Accessioner. The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of a normal constituent (*e.g.,* nitrite in urine).

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Responsible Technician. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF when the responsible technician is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Biomarker Testing Panel. The panel published in the **Federal Register** that includes the biomarkers authorized for testing, with analytes and cutoffs for initial and confirmatory biomarker tests, as described under Section 3.4.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Container. A receptacle used to collect a donor's drug test specimen.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

Confirmatory Drug Test. A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The analytical value (*e.g.,* drug, drug metabolite, or biomarker concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

Dilute Specimen. A urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

Donor. The individual from whom a specimen is collected.

Drug Testing Panel. The panel published in the **Federal Register** that includes the drugs authorized for testing, with analytes and cutoffs for initial and confirmatory drug tests, as described under Section 3.4.

External Service Provider. An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or (for urine) an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

Gender Identity. Gender identity means an individual's internal sense of being male or female, which may be different from an individual's sex assigned at birth.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is adulterated, invalid, substituted, or (for urine) dilute.

Instrumented Initial Test Facility (IITF). A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.9 when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantification (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (*e.g.,* reagents, quality control material) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

Positive Result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmatory test cutoff.

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2).

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

Responsible Technician (RT). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified IITF.

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Urine). A collection in which the specimen collected is divided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

Standard. Reference material of known purity or a solution containing a reference material at a known concentration.

Substituted Specimen. A specimen that has been submitted in place of the donor's specimen, as evidenced by the absence of a biomarker or a biomarker concentration inconsistent with that established for a human specimen, as indicated in the biomarker testing panel, or (for urine) creatinine and specific gravity values that are outside the physiologically producible ranges of human urine, in accordance with the criteria to report a specimen as substituted in UrMG Section 3.7.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101–24.104, all agency contracts with laboratories, IITFs, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100–71. Each federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, subparts A and E, may be applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *https://www.hhs.gov/hipaa/index.html.*

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete;

(3) Fail to provide a specimen (*e.g.,* urine or another authorized specimen type) for any drug test required by these Guidelines or federal agency regulations;

(4) In the case of a direct observed or monitored collection, fail to permit the observation or monitoring of your provision of a specimen when required as described in Sections 8.9 and 8.10;

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(6) Fail or decline to participate in an alternate specimen collection (*e.g.,* oral fluid) as directed by the federal agency or collector (*i.e.,* as described in Section 8.6);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification

process (*i.e.,* Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(8) Fail to cooperate with any part of the testing process (*e.g.,* refuse to empty pockets when directed by the collector, disrupt the collection process, fail to wash hands after being directed to do so by the collector);

(9) For an observed collection, fail to follow the observer's instructions related to the collection process;

(10) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(11) Attempt to adulterate, substitute, or dilute the specimen;

(12) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(13) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) A refusal to take a test may result in the initiation of disciplinary or adverse action for a federal employee, up to and including removal from federal employment. An applicant's refusal to take a pre-employment test may result in non-selection for federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test, the collector must terminate the collection process and take action as described in Section 8.13. Required action includes immediately notifying the federal agency's designated representative by any means (*e.g.,* telephone or secure facsimile [fax] machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal CCF, and sending all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

Subpart B—Urine Specimens

Section 2.1 What type of specimen may be collected?

A federal agency may collect urine and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using urine must follow these Guidelines.

Section 2.2 Under what circumstances may a urine specimen be collected?

A federal agency may collect a urine specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post accident test;

(e) Return to duty test; or

(f) Follow-up test.

Section 2.3 How is each urine specimen collected?

Each urine specimen is collected as a split specimen as described in Section 2.5.

Section 2.4 What volume of urine is collected?

A donor is expected to provide at least 45 mL of urine for a specimen.

Section 2.5 How does the collector split the urine specimen?

The collector pours at least 30 mL into a specimen bottle that is designated as A (primary) and then pours at least 15 mL into a specimen bottle that is designated as B (split).

Section 2.6 When may an entity or individual release a urine specimen?

Entities and individuals subject to these Guidelines under Section 1.1 may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

Subpart C—Urine Specimen Tests

Section 3.1 Which tests are conducted on a urine specimen?

A federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine metabolites as provided in the drug testing panel described under Section 3.4;

(b) Is authorized to test each specimen for other Schedule I or II drugs as provided in the drug testing panel;

(c) Must ensure that the following specimen validity tests are conducted on each urine specimen:

(1) Determine the creatinine concentration on every specimen;

(2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH on every specimen; and

(4) Perform one or more specimen validity tests for oxidizing adulterants on every specimen.

(d) Is authorized to test each specimen for one or more biomarkers as provided in the biomarker testing panel; and

(e) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

Section 3.2 May a specimen be tested for drugs other than those in the drug testing panel?

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act. The federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in the drug testing panel described under Section 3.4. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

Section 3.3 May any of the specimens be used for other purposes?

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees, or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What are the drug and biomarker test analytes and cutoffs for urine?

The Secretary will publish the drug and biomarker test analytes and cutoffs (*i.e.,* the ''drug testing panel'' and ''biomarker testing panel'') for initial and confirmatory drug and biomarker tests in the **Federal Register** each year. The drug and biomarker testing panels will also be available on the internet at *http://www.samhsa.gov/workplace/drug-testing.*

This drug testing panel will remain in effect until the effective date of a new drug testing panel published in the **Federal Register**:

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolite (THCA) [2]	50 ng/mL [3]	THCA	15 ng/mL
Cocaine metabolite (Benzoylecgonine)	150 ng/mL [3]	Benzoylecgonine	100 ng/mL
Codeine/Morphine	2,000 ng/mL	Codeine	2,000 ng/mL
		Morphine	4,000 ng/mL
Hydrocodone/Hydromorphone	300 ng/mL	Hydrocodone	100 ng/mL
		Hydromorphone	100 ng/mL
Oxycodone/Oxymorphone	100 ng/mL	Oxycodone	100 ng/mL
		Oxymorphone	100 ng/mL
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL
Amphetamine/Methamphetamine	500 ng/mL	Amphetamine	250 ng/mL
		Methamphetamine	250 ng/mL
MDMA [4]/MDA [5]	500 ng/mL	MDMA	250 ng/mL
		MDA	250 ng/mL

[1] *For grouped analytes* (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.,* equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).
[3] *Alternate technology (THCA and benzoylecgonine):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.,* 15 ng/mL for THCA, 100 ng/mL for benzoylecgonine).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

(a) The drug testing panel will include drugs authorized for testing in federal workplace drug testing programs, with the required test analytes and cutoffs;

(b) The biomarker testing panel will include biomarkers authorized for testing in federal workplace drug testing programs, with the required test analytes and cutoffs; and

(c) HHS-certified IITFs, HHS-certified laboratories, and Medical Review Officers must use the nomenclature (*i.e.,* analyte names and abbreviations) published in the **Federal Register** with the drug and biomarker testing panels to report federal workplace drug test results.

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* tetrahydrocannabivarin, specimen validity tests). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report a urine specimen as adulterated?

An HHS-certified laboratory reports a primary (A) specimen as adulterated when:

(a) The pH is less than 4 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(b) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion

chromatography, capillary electrophoresis) on the second aliquot;

(c) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(d) The presence of a halogen (*e.g.,* chlorine from bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or great than 200 mcg/mL nitrite-equivalent cutoff or an equal to or great than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(e) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory test (*e.g.,* GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(f) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(g) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(h) The presence of any other adulterant not specified in paragraphs (b) through (g) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Section 3.7 What criteria are used to report a urine specimen as substituted?

An HHS-certified laboratory reports a primary (A) specimen as substituted when:

(a) The creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests on two separate aliquots (*i.e.,* the same colorimetric test may be used to test both aliquots) and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory specific gravity tests on two separate aliquots (*i.e.,* a refractometer is used to test both aliquots), or

(b) A biomarker is not detected or is present at a concentration inconsistent with that established for human urine for both the initial (first) test and the confirmatory (second) test on two separate aliquots (*i.e.,* using the test analytes and cutoffs in the biomarker testing panel).

Section 3.8 What criteria are used to report a urine specimen as dilute?

A dilute result may be reported only in conjunction with the positive or negative drug test results for a specimen.

(a) An HHS-certified laboratory or an HHS-certified IITF reports a primary (A) specimen as dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003 on a single aliquot.

(b) In addition, an HHS-certified laboratory reports a primary (A) specimen as dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030.

Section 3.9 What criteria are used to report an invalid result for a urine specimen?

An HHS-certified laboratory reports a primary (A) specimen as an invalid result when:

(a) Inconsistent creatinine concentration and specific gravity results are obtained (*i.e.,* the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(b) The pH is equal to or greater than 4 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(c) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(d) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(e) The possible presence of a halogen (*e.g.,* chlorine from bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on two separate aliquots or relying on the odor of the specimen as the initial test;

(f) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

(g) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff, an equal to or greater than 50 mcg/mL chromium (VI)-

equivalent cutoff, or a halogen concentration is equal to or greater than the LOQ) for both the initial (first) test and the second test on two separate aliquots;

(h) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

(i) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid immunoassay or alternate technology initial drug test results cannot be obtained);

(j) Interference with the drug confirmatory assay occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(k) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments;

(l) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(m) A specimen validity test (*i.e.,* other than the tests listed above) on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

Subpart D—Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect urine specimens in accordance with these Guidelines.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory or IITF must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or personal friend (*e.g.,* fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to the collection procedure described in these Guidelines;

(3) Is trained and qualified to collect a urine specimen. Training must include the following:

(i) All steps necessary to complete a urine collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include one uneventful collection scenario, one insufficient specimen quantity scenario, one temperature out of range scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen bottle tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are error-free.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of their training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be an observer for a direct observed collection?

(a) An individual may serve as an observer for a direct observed collection when the individual has satisfied the requirements:

(1) Is knowledgeable about the direct observed collection procedure described in Section 8.9 of these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program or additional information provided by the Secretary relating to the direct observed collection procedure described in these Guidelines;

(3) Has received training on the following subjects:

(i) All steps necessary to perform a direct observed collection; and

(ii) The observer's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring that the observation is done in a professional manner that minimizes the discomfort to the employee so observed, ensuring the security of the specimen by maintaining visual contact with the collection container until it is delivered to the collector, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(b) The gender of the observer must be the same as the donor's gender, which is determined by the donor's gender identity. The observer selection process is described in Section 8.10(b).

(c) The observer is not required to be a trained collector.

Section 4.5 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors and may train others to collect urine specimens when they have completed the following:

(1) Qualified as a trained collector and regularly conducted urine drug test collections for a period of at least one year; or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer's training and provide that

documentation to a federal agency when requested.

Section 4.6 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

Subpart E—Collection Sites

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect a urine specimen (*e.g.,* an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.12.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory or IITF;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies;

(f) The ability to store records securely; and

(g) The ability to restrict the donor access to potential diluents in accordance with Section 8.2.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during, and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory or IITF are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory or IITF.

Section 5.6 What are the privacy requirements when collecting a urine specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory or IITF to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory or IITF must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory, HHS-certified IITF, or MRO discovers that the collector used an incorrect form, the laboratory, IITF, or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory or IITF reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory or IITF must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G—Urine Specimen Collection Containers and Bottles

Section 7.1 What is used to collect a urine specimen?

A single-use collection container with a means (*i.e.,* thermometer) to measure urine temperature and two specimen bottles must be used.

Section 7.2 What are the requirements for a urine collection container and specimen bottles?

(a) The collection container, the thermometer, and the specimen bottles must not substantially affect the composition of drugs and/or metabolites in the urine specimen.

(b) The two specimen bottles must be sealable and non-leaking, and must maintain the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory or IITF for the presence of drugs or their metabolites.

(c) The two specimen bottles must be sufficiently transparent to enable an objective assessment of specimen appearance and identification of abnormal physical characteristics without opening the bottle.

Section 7.3 What are the minimum performance requirements for a urine collection container and specimen bottles?

(a) The collection container must be capable of holding at least 55 mL and have a volume marking clearly noting a level of 45 mL.

(b) One of the two specimen bottles must be capable of holding at least 35 mL and the other at least 20 mL, and each must have a volume marking clearly noting the appropriate level (30 mL for the primary specimen and 15 mL for the split specimen).

(c) The thermometer may be affixed to or built into the collection container and must provide graduated temperature readings from 32–38 °C/90–100 °F. Alternatively, the collector may use another technology to measure specimen temperature (*e.g.,* thermal radiation scanning), providing the thermometer does not come into contact with the specimen.

Subpart H—Urine Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing a urine specimen?

The following privacy requirements apply when a donor is providing a urine specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor. The gender of the observer for purposes of a direct observed collection (*i.e.,* as described in Section 8.10) must be the same as the donor's gender, which is determined by the donor's gender identity. The gender of the monitor for a monitored collection (*i.e.,* as described in Section 8.12) must be the same as the donor's gender, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place).

(c) The collector must give the donor visual privacy while providing the specimen. The donor is allowed to provide a urine specimen in an enclosed stall within a multi-stall restroom or in a single person restroom during a monitored collection.

Section 8.2 What must the collector ensure at the collection site before starting a urine specimen collection?

The collector must deter the dilution or substitution of a specimen at the collection site by:

(a) Placing a toilet bluing agent in a toilet bowl or toilet tank, so the reservoir of water in the toilet bowl always remains blue. If no bluing agent is available or if the toilet has an automatic flushing system, the collector shall turn the water supply off to the toilet and flush the toilet to remove the water in the toilet when possible.

(b) Secure other sources of water (*e.g.,* shower or sink) in the enclosure where urination occurs. If the enclosure has a source of water that cannot be disabled or secured, a monitored collection must be conducted in accordance with Section 8.11.

Section 8.3 What are the preliminary steps in the urine specimen collection procedure?

The collector must take the following steps before beginning a urine specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because the donor states that they are unable to urinate or an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(e) The collector explains the basic collection procedure to the donor.

(f) The collector provides the instructions for completing the Federal CCF for the donor's review, and informs the donor that the instructions are available upon request.

(g) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

(h) The collector asks the donor to remove any unnecessary outer garments (*e.g.,* coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the urine specimen. The collector must ensure that all personal belongings (*e.g.,* purse or briefcase) remain with the outer garments. The donor may retain the donor's wallet.

(i) The collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(1) If no items are present that can be used to adulterate, substitute, or dilute the specimen, the collector instructs the donor to return the items to their pockets and continues the collection procedure.

(2) If an item is present whose purpose is to adulterate, substitute, or dilute the specimen (*e.g.,* a commercial drug culture product or other substance for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13.

(3) If an item that could be used to adulterate, substitute, or dilute the specimen (*e.g.,* common personal care products such as eyedrops, mouthwash, or hand sanitizer) appears to have been inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) If the donor refuses to show the collector the items in their pockets, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13.

(j) The collector shall instruct the donor to wash and dry the donor's hands prior to urination. After washing the donor's hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate or substitute the specimen.

(k) If the donor refuses to wash their hands when instructed by the collector, this is considered a ''refusal to test.'' The collector must stop the collection and report the refusal to test as described in Section 8.13.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?

(a) The collector will provide or the donor may select a specimen collection container that is clean, unused, wrapped/sealed in original packaging and compliant with Subpart G. The

specimen collection container package will be opened in view of the donor.

(b) The collector instructs the donor to provide the specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collector directs the donor to provide a specimen of at least 45 mL, to not flush the toilet, and to return with the specimen as soon as the donor has completed the void.

(1) Except in the case of a direct observed collection (*i.e.,* as described in Section 8.10) or a monitored collection (*i.e.,* as described in Section 8.12), neither the collector nor anyone else may go into the room with the donor.

(2) The collector may set a reasonable time limit for specimen collection.

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute), the collector must report a refusal to test in accordance with Section 8.13.

Section 8.5 What steps does the collector take during and after the urine specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the urine specimen:

(a) The collector must inform the donor that, once the collection procedure has begun, the donor must remain at the collection site (*i.e.,* in an area designated by the collector) until the collection is complete and that failure to follow these instructions will be reported as a refusal to test. This includes the wait period (*i.e.,* up to 3 hours) if needed to provide a sufficient specimen as described in step (f)(2) below and in Section 8.6.

(b) After providing the specimen, the donor gives the specimen collection container to the collector. Both the donor and the collector must keep the specimen container in view at all times until the collector seals the specimen bottles as described in Section 8.8.

(c) After the donor has given the specimen to the collector, whenever practical, the donor shall be allowed to wash the donor's hands and the donor may flush the toilet.

(d) The collector must measure the temperature of the specimen within 4 minutes of receiving the specimen from the donor. The collector records on the Federal CCF whether or not the temperature is in the acceptable range of 32°–38 °C/90°–100 °F.

(1) The temperature measuring device must accurately reflect the temperature of the specimen and not contaminate the specimen.

(2) If the temperature of the specimen is outside the range of 32°–38 °C/90°–100 °F, that is a reason to believe that the donor may have adulterated or substituted the specimen. Another specimen must be collected under direct observation in accordance with Section 8.9. The collector must forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(e) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid urine specimen (*e.g.,* unusual color, presence of foreign objects or material, unusual odor).

(1) The collector notes any unusual finding on the Federal CCF. A specimen suspected of not being a valid urine specimen must be forwarded to an HHS-certified laboratory for testing.

(2) When there is any reason to believe that a donor may have adulterated or substituted the specimen, another specimen must be obtained as soon as possible under direct observation in accordance with Section 8.10. The collector must forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(f) The collector must determine the volume of urine in the specimen container. The collector must never combine urine collected from separate voids to create a specimen.

(1) If the volume is at least 45 mL, the collector will proceed with steps described in Section 8.8.

(2) If the volume is less than 45 mL, the collector discards the specimen and immediately collects a second specimen using the same procedures as for the first specimen (including steps in paragraphs c and d of this section).

(i) The collector may give the donor a reasonable amount of liquid to drink for this purpose (*e.g.,* an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). However, the donor is not required to drink any fluids during this waiting time.

(ii) If the donor provides a sufficient urine specimen (*i.e.,* at least 45 mL), the collector proceeds with steps described in Section 8.8.

(iii) If the employee has not provided a sufficient specimen (*i.e.,* at least 45 mL) within three hours of the first unsuccessful attempt to provide the specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(g) If the donor fails to remain present through the completion of the collection, declines to have a direct observed collection as required in steps (d)(2) or (e)(2) above, refuses to provide a second specimen as required in step (f)(2) above, or refuses to provide an alternate specimen as authorized in step (f)(2)(iii) above, the collector stops the collection and reports the refusal to test in accordance with Section 8.13.

Section 8.6 What procedure is used when the donor states that they are unable to provide a urine specimen?

(a) If the donor states that they are unable to provide a urine specimen during the collection process, the collector requests that the donor enter the restroom (stall) and attempt to provide a urine specimen.

(b) The donor demonstrates their inability to provide a specimen when he or she comes out of the stall with an empty collection container.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a reasonable amount of liquid to drink for this purpose (*e.g.,* an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). If the donor simply needs more time before attempting to provide a urine specimen, the donor may choose not to drink any fluids during the 3 hour wait time.

(2) If the donor states that they are unable to provide a urine specimen, the collector records the reason for not collecting a urine specimen on the

Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the urine specimens?

(a) All federal agency collections are to be split specimen collections.

(b) The collector, in the presence of the donor, pours the urine from the collection container into two specimen bottles to be labeled ''A'' and ''B''. The collector pours at least 30 mL of urine into Bottle A and at least 15 mL into Bottle B, and caps each bottle.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over each specimen bottle cap. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen bottle. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Bottle A and Bottle B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory or IITF that will be testing the Bottle A urine specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory or IITF, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

(j) The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: The collector may use excess urine to conduct clinical tests (*e.g.,* protein, glucose) if the collection was conducted in conjunction with a physical examination required by federal agency regulation. Neither the collector nor anyone else may conduct further testing (such as specimen validity testing) on the excess urine.

Section 8.9 When is a direct observed collection conducted?

A direct observed collection procedure must be conducted when:

(a) The agency has authorized a direct observed collection because:

(1) The donor's previous drug test result was reported by an MRO as positive, adulterated, or substituted; or

(2) The HHS-certified laboratory reports to the MRO that a specimen is invalid, and the MRO reported to the agency that there was not a legitimate medical explanation for the result; or

(3) The MRO reported to the agency that the primary (A) specimen was positive, adulterated, or substituted but the test was cancelled because the split (B) specimen could not be tested or the split specimen failed to reconfirm the primary specimen result; or

(b) At the collection site, an immediate collection of a second urine specimen is required because:

(1) The temperature of the specimen collected during a routine collection is outside the acceptable temperature range; or

(2) The collector suspects that the donor has tampered with the specimen during a routine collection (*e.g.,* abnormal physical characteristic such as unusual color and/or odor, and/or excessive foaming when shaken).

(c) The collector must contact a collection site supervisor to review and concur in advance with any decision by the collector to obtain a specimen under direct observation.

(d) If the donor declines to have a direct observed collection, the collector reports a refusal to test (*i.e.,* as described in Section 8.13).

Section 8.10 How is a direct observed collection conducted?

(a) A direct observed collection procedure is the same as that for a routine collection, except an observer watches the donor urinate into the collection container. The observer's gender must be the same as the donor's gender, which is determined by the donor's gender identity, with no exception to this requirement.

(b) Before an observer is selected, the collector informs the donor that the gender of the observer will match the donor's gender, which is determined by the donor's gender identity (as defined in Section 1.5). The collector then selects the observer to conduct the observation:

(i) The collector asks the donor to identify the donor's gender on the Federal CCF and initial it.

(ii) The donor will then be provided an observer whose gender matches the donor's gender.

(iii) The collector documents the observer's name and gender on the Federal CCF.

(c) If there is no collector available of the same gender as the donor's gender, the collector or collection site supervisor shall select an observer trained in direct observed specimen collection as described in Section 4.4. The observer may be an individual that is not a trained collector.

(d) At the point in a routine collection where the donor enters the restroom with the collection container, a direct observed collection includes the following additional steps:

(1) The observer enters the restroom with the donor;

(2) The observer must directly watch the urine go from the donor's body into the collection container (the use of mirrors or video cameras is not permitted);

(3) The observer must not touch or handle the collection container unless the observer is also serving as the collector;

(4) After the donor has completed urinating into the collection container:

(i) If the same person serves as the observer and collector, that person may receive the collection container from the donor while they are both in the restroom;

(ii) If the observer is not serving as the collector, the donor and observer leave the restroom and the donor hands the collection container directly to the collector. The observer must maintain visual contact of the collection

container until the donor hands the container to the collector.

(5) The collector checks the box for an observed collection on the Federal CCF and writes the name of the observer and the reason for an observed collection on the Federal CCF; and

(6) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.11 When is a monitored collection conducted?

(a) In the event that an agency-designated collection site is not available and there is an immediate requirement to collect a specimen (*e.g.,* an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.12.

(b) If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted.

(c) If the donor declines to permit a collection to be monitored when required, the collector reports a refusal to test (*i.e.,* as described in Section 8.13).

Section 8.12 How is a monitored collection conducted?

A monitored collection is the same as that for a routine collection, except that a monitor accompanies the donor into the restroom to check for signs that the donor may be tampering with the specimen. The monitor remains in the restroom, but outside the stall, while the donor is providing the specimen. A person of the same gender as the donor shall serve as the monitor, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The same procedures used for selecting an observer of the appropriate gender in Section 8.10(b) must be used to select the monitor for the purposes of Section 8.12, unless the monitor is a medical professional as described above. The monitor may be an individual other than the collector and need not be a qualified collector.

(a) The collector secures the restroom being used for the monitored collection so that no one except the employee and the monitor can enter the restroom until after the collection has been completed.

(b) The monitor enters the restroom with the donor.

(c) The monitor must not watch the employee urinate into the collection container. If the monitor hears sounds or makes other observations indicating an attempt by the donor to tamper with a specimen, there must be an additional collection under direct observation in accordance with Section 8.9.

(d) The monitor must not touch or handle the collection container unless the monitor is also the collector.

(e) After the donor has completed urinating into the collection container:

(1) If the same person serves as the monitor and collector, that person may receive the collection container from the donor while they are both in the restroom;

(2) If the monitor is not serving as the collector, the donor and monitor leave the restroom and the donor hands the collection container directly to the collector. The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) If the monitor is not serving as the collector, the collector writes the name of the monitor on the Federal CCF.

(g) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.13 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any urine collected and reports the refusal to test by:

(a) Notifying the federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the federal agency's designated representative.

Section 8.14 What are a federal agency's responsibilities for a collection site?

(a) A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory or IITF) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I—HHS Certification of Laboratories and IITFs

Section 9.1 Who has the authority to certify laboratories and IITFs to test urine specimens for federal agencies?

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory or IITF including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory or IITF to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory or IITF to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory or IITF is prohibited from stating or implying that it is certified by HHS under these Guidelines to test urine specimens for federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory or IITF to become HHS-certified?

(a) A laboratory or IITF seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory or IITF provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

Section 9.3 What is the process for a laboratory or IITF to maintain HHS certification?

(a) To maintain HHS certification, a laboratory or IITF must:

(1) Successfully participate in both the maintenance PT and inspection programs (*i.e.,* successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory or IITF does not maintain its HHS certification?

(a) A laboratory or IITF that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.20, 11.21, 12.18, and 14.8;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.23, 11.24, 12.20, 12.21, and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in the drug testing panel and must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance, an adulterant, or other substances for special purposes, or may satisfy the criteria for a substituted specimen, dilute specimen, or invalid result.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) PT samples used to evaluate specimen validity tests shall satisfy, but are not limited to, one of the following criteria:

(1) The nitrite concentration will be at least 20 percent above the cutoff;

(2) The pH will be between 1.5 and 5.0 or between 8.5 and 12.5;

(3) The concentration of an oxidant will be at a level sufficient to challenge a laboratory's ability to identify and confirm the oxidant;

(4) The creatinine concentration will be between 0 and 20 mg/dL; or

(5) The specific gravity will be less than or equal to 1.0050 or between 1.0170 and 1.0230.

(c) For each PT cycle, the set of PT samples going to each HHS-certified laboratory or IITF will vary but, within each calendar year, each HHS-certified laboratory or IITF will analyze essentially the same total set of samples.

(d) The laboratory or IITF must (to the greatest extent possible) handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

Section 9.6 What are the PT requirements for an applicant laboratory?

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean; and

(ii) pH values are no more than ±0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than ±0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than ±0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Do not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Do not report any sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, substituted when the appropriate reference or peer group

means for both creatinine and specific gravity are within the acceptable range, or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.7 What are the PT requirements for an HHS-certified urine laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean;

(ii) pH values are no more than ±0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than ±0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than ±0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Do not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Do not report any PT sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range, or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the PT requirements for an applicant IITF?

(a) An applicant IITF that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Correctly identify at least 90 percent of the total drug challenges over the three sets of PT samples;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over the three sets of PT samples;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over the three sets of PT samples that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for creatinine concentration or ±0.002 specific gravity units for specific gravity.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.9 What are the PT requirements for an HHS-certified IITF?

(a) An IITF certified under these Guidelines must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Correctly identify at least 90 percent of the total drug challenges over two consecutive PT cycles;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for creatinine concentration, or ±0.002 specific gravity units for specific gravity.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified IITF's certification.

Section 9.10 What are the inspection requirements for an applicant laboratory or IITF?

(a) An applicant laboratory or IITF is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's or IITF's testing procedures and facilities using an inspection checklist.

Section 9.11 What are the maintenance inspection requirements for an HHS-certified laboratory or IITF?

(a) An HHS-certified laboratory or IITF must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory or IITF is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's or IITF's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory or IITF must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.12 Who can inspect an HHS-certified laboratory or IITF and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in Subpart K or as a responsible technician for an HHS-certified IITF as described in Subpart L;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory or IITF.

(b) The Secretary or a federal agency may conduct an inspection at any time.

Section 9.13 What happens if an applicant laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory or IITF fails to satisfy the requirements established for the initial certification process, the laboratory or IITF must start the certification process from the beginning.

Section 9.14 What happens if an HHS-certified laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?

(a) If an HHS-certified laboratory or IITF fails to satisfy the minimum requirements for certification, the laboratory or IITF is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's or IITF's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory or IITF may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's or IITF's certification is revoked or suspended in accordance with the process described in Subpart P, the laboratory or IITF is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory or IITF has successfully completed the certification requirements as a new applicant laboratory or IITF.

Section 9.15 What factors are considered in determining whether revocation of a laboratory's or IITF's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory or IITF in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug and specimen validity test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug and specimen validity tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory or IITF by a federal agency using the laboratory's or IITF's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory or IITF; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory or IITF to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing.

Section 9.16 What factors are considered in determining whether to suspend a laboratory's or IITF's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's or IITF's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.17 How does the Secretary notify an HHS-certified laboratory or IITF that action is being taken against the laboratory or IITF?

(a) When laboratory's or IITF's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory or IITF with written notice of the suspension or proposed revocation by fax, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory or IITF will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory or IITF received the notice, or if expedited review is requested, within 3 days of the date the laboratory or IITF received the notice. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation

must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory or IITF that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory or IITF that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory or IITF that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of Subpart P.

Section 9.18 May a laboratory or IITF that had its HHS certification revoked be recertified to test federal agency specimens?

Following revocation, a laboratory or IITF may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.17 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory or IITF which has had its certification revoked may reapply for HHS certification as an applicant laboratory or IITF.

Section 9.19 Where is the list of HHS-certified laboratories and IITFs published?

(a) The list of HHS-certified laboratories and IITFs is published monthly in the **Federal Register**. This notification is also available on the internet at *http://www.samhsa.gov/workplace.*

(b) An applicant laboratory or IITF is not included on the list.

Subpart J—Blind Samples Submitted by an Agency

Section 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories or IITFs?

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory or IITF that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative, 15 percent must be positive for one or more drugs, and 10 percent must either be adulterated or substituted.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in the drug testing panel.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier as negative using appropriate initial and confirmatory tests.

(c) A blind sample that is adulterated must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is an adulterated sample at the time of validation.

(d) A blind sample that is substituted must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is a substituted sample at the time of validation.

(e) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory or IITF, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory or IITF?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory or IITF uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory or IITF reports a result for a blind sample that is inconsistent with the expected result (*e.g.,* a laboratory or IITF reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory or IITF and attempt to determine if the laboratory or IITF made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory or IITF;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K—Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: Quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic

procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 11.7 What security measures must an HHS-certified laboratory maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.,* for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What test(s) does an HHS-certified laboratory conduct on a urine specimen received from an IITF?

An HHS-certified laboratory must test the specimen in the same manner as a specimen that had not been previously tested.

Section 11.10 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay; or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.12.

Section 11.11 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff, using samples at several concentrations between 0 and 150 percent of the cutoff;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.12 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.13 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification (*e.g.,* gas chromatography/mass spectrometry [GC–MS], liquid chromatography-mass spectrometry [LC–MS], GC–MS/MS, LC–MS/MS) or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of a urine specimen when identifying and quantifying drugs or their metabolites.

Section 11.14 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff;

(5) The accuracy (bias) and precision at 40 percent of the cutoff;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.15 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff;

(2) At least one control certified to contain no drug or drug metabolite;

(3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.16 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each invalid, adulterated, or substituted specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results (required specimen validity tests are addressed in Section 11.18); and

(c) Controls must be analyzed concurrently with specimens.

Section 11.17 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.18 What are the requirements for conducting each specimen validity test?

(a) The requirements for measuring creatinine concentration are as follows:

(1) The creatinine concentration must be measured to one decimal place on both the initial creatinine test and the confirmatory creatinine test;

(2) The initial creatinine test must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;

(iii) A control in the range of 3 mg/dL to 20 mg/dL; and

(iv) A control in the range of 21 mg/dL to 25 mg/dL.

(3) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL; and

(iii) A control in the range of 3 mg/dL to 4 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with initial creatinine test results greater than 5 mg/dL and less than 20 mg/dL, laboratories may perform a screening test using a refractometer that measures urine specific gravity to at least three decimal places to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be subjected to an initial specific gravity test using a four decimal place refractometer when the initial creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result using a three decimal place refractometer is less than 1.002.

(2) The screening specific gravity test must have the following calibrators and controls:

(i) A calibrator or control at 1.000;

(ii) One control targeted at 1.002;

(iii) One control in the range of 1.004 to 1.018.

(3) For the initial and confirmatory specific gravity tests, the refractometer must report and display specific gravity to four decimal places. The refractometer must be interfaced with a laboratory information management system (LIMS), computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the specific gravity test results;

(4) The initial and confirmatory specific gravity tests must have the following calibrators and controls:

(i) A calibrator or control at 1.0000;

(ii) One control targeted at 1.0020;

(iii) One control in the range of 1.0040 to 1.0180; and

(iv) One control equal to or greater than 1.0200 but not greater than 1.0250.

(c) Requirements for measuring pH are as follows:

(1) Colorimetric pH tests that have the dynamic range of 3 to 12 to support the 4 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper (*i.e.,* screening tests) that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH specimen validity test must be performed;

(2) For the initial and confirmatory pH tests, the pH meter must report and display pH to at least one decimal place. The pH meter must be interfaced with a LIMS, computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the pH test results;

(3) pH screening tests must have, at a minimum, the following controls:

(i) One control below the lower decision point in use;

(ii) One control between the decision points in use; and

(iii) One control above the upper decision point in use;

(4) An initial colorimetric pH test must have the following calibrators and controls:

(i) One calibrator at 4;

(ii) One calibrator at 11;

(iii) One control in the range of 3 to 3.8;

(iv) One control in the range 4.2 to 5;

(v) One control in the range of 5 to 9;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(5) An initial pH meter test, if a pH screening test is not used, must have the following calibrators and controls:

(i) One calibrator at 3;

(ii) One calibrator at 7;

(iii) One calibrator at 10;

(iv) One control in the range of 3 to 3.8;

(v) One control in the range 4.2 to 5;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(6) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test indicates that the pH is below the lower decision point in use:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One control in the range of 3 to 3.8; and

(iv) One control in the range 4.2 to 5; and

(7) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test indicates that the pH is above the upper decision point in use:

(i) One calibrator at 7;

(ii) One calibrator at 10;

(iii) One control in the range of 10 to 10.8; and

(iv) One control in the range of 11.2 to 12.

(d) Requirements for performing oxidizing adulterant tests are as follows:

(1) The initial test must include an appropriate calibrator at the cutoff

specified in Sections 11.19(d)(2), (3), or (4) for the compound of interest, a control without the compound of interest (*i.e.,* a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and

(2) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory test batch must include an appropriate calibrator, a control without the compound of interest (*i.e.,* a certified negative control), and a control with the compound of interest at a measurable concentration.

(e) The requirements for measuring the nitrite concentration are that the initial and confirmatory nitrite tests must have a calibrator at the cutoff, a control without nitrite (*i.e.,* certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

Section 11.19 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (h)(1) through (h)(12) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with the cutoffs listed in the drug testing panel.

(d) A primary (A) urine specimen is reported adulterated when:

(1) The pH is less than 4 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(4) The presence of halogen (*e.g.,* chlorine from bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory method (*e.g.,* GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory method (*e.g.,* GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(8) The presence of any other adulterant not specified in paragraphs (d)(2) through (d)(7) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(e) A primary (A) urine specimen is reported substituted when:

(1) The creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory creatinine tests (*i.e.,* the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (*i.e.,* a refractometer is used to test both aliquots) on two separate aliquots; or

(2) A biomarker is not present or is present at a concentration inconsistent with that established for human urine.

(f) A primary (A) urine specimen is reported dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(g) For a specimen that has an invalid result for one of the reasons stated in items (h)(4) through (h)(13) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive, adulterated, or substituted result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(h) A primary (A) urine specimen is reported as an invalid result when:

(1) Inconsistent creatinine concentration and specific gravity results are obtained (*i.e.,* the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 4 and less than 4.5 or equal to or greater than 9 and less than 11 using either a

colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(5) The possible presence of a halogen (*e.g.,* chlorine from bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

(7) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff, an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is equal to or greater than the LOQ) for both the initial (first) test and the second test on two separate aliquots;

(8) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

(9) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid initial drug test results cannot be obtained);

(10) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(11) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments;

(12) The physical appearances of the A and B specimens are clearly different (note: A is tested); or

(13) A specimen validity test (*i.e.,* other than the tests listed above) on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

(i) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(j) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for a urine specimen. For example, a specimen can be positive for a specific drug and adulterated.

(k) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(l) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(m) An HHS-certified laboratory must report results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

(n) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(o) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(p) HHS-certified laboratories must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(q) For positive, adulterated, substituted, invalid, and rejected specimens, laboratories must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.20 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured frozen storage (−20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

Section 11.21 How long must an HHS-certified laboratory retain records?

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.23) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.22 What statistical summary reports must an HHS-certified laboratory provide for urine testing?

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period. The summary report must not include any personally identifiable information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) Number of specimen results reported;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test;

(10) Number of specimens reported positive;

(11) Number of specimens reported positive for each drug and drug metabolite;

(12) Number of specimens reported adulterated;

(13) Number of specimens reported substituted; and

(14) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.23 What HHS-certified laboratory information is available to a federal agency?

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.24 What HHS-certified laboratory information is available to a federal employee?

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and/or the federal agency requesting copies of any records relating to the employee's drug test results or a documentation package as described in Section 11.23(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

Section 11.25 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Section 11.26 What type of relationship can exist between an HHS-certified laboratory and an HHS-certified IITF?

An HHS-certified laboratory can enter into any relationship with an HHS-certified IITF.

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.1 What must be included in the HHS-certified IITF's standard operating procedure manual?

(a) An HHS-certified IITF must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified IITF operations. When followed, the SOP manual ensures that all specimens are tested consistently using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for two years.

Section 12.2 What are the responsibilities of the responsible technician (RT)?

(a) Manage the day-to-day operations of the HHS-certified IITF even if another

individual has overall responsibility for alternate areas of a multi-specialty facility.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified IITF. The RT must ensure the continued competency of IITF personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified IITF, and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RT when procedures are first placed into use or changed or when a new individual assumes responsibility for the management of the HHS-certified IITF. The SOP must be reviewed and documented by the RT annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified IITF in response to the following: Quality control systems not within performance specifications, errors in result reporting or in analysis of performance testing samples, and inspection deficiencies. The RT must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 12.3 What qualifications must the RT have?

An RT must:

(a) Have at least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(b) Have training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF;

(c) Have training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise;

(d) Be found to fulfill RT responsibilities and qualifications, as demonstrated by the HHS-certified IITF's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying technician.

Section 12.4 What happens when the RT is absent or leaves an HHS-certified IITF?

(a) HHS-certified IITFs must have an RT and an alternate RT. When an RT is absent, an alternate RT must be present and qualified to fulfill the responsibilities of the RT.

(1) If an HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, business trip), the HHS-certified IITF may continue operations and testing of federal agency specimens under the direction of a certifying technician.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all specimens if the IITF does not have an RT or alternate RT for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RT or alternate RT.

(b) If the RT leaves an HHS-certified IITF:

(1) The HHS-certified IITF may maintain certification and continue testing federally regulated specimens under the direction of an alternate RT for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RT's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all federally regulated specimens if the IITF does not have a permanent RT within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RT.

(c) To nominate an individual as the RT or alternate RT, the HHS-certified IITF must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RT qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified IITF.

(d) The HHS-certified IITF must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RT.

Section 12.5 What qualifications must an individual have to certify a result reported by an HHS-certified IITF?

A certifying technician must have:

(a) Training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF relevant to the results that the individual certifies; and

(b) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 12.6 What qualifications and training must other personnel of an HHS-certified IITF have?

(a) All HHS-certified IITF staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified IITF must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 12.7 What security measures must an HHS-certified IITF maintain?

(a) An HHS-certified IITF must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times except for individuals conducting inspections (*i.e.,* for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified IITF must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for the access to the secured area.

Section 12.8 What are the IITF chain of custody requirements for specimens and aliquots?

(a) HHS-certified IITFs must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the IITF through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified IITFs must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 12.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay; or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified IITF must validate an initial drug test before testing specimens;

(c) Initial drug tests must be accurate and reliable for the testing of urine specimens when identifying drugs or their metabolites.

(d) An HHS-certified IITF may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 12.11.

Section 12.10 What must an HHS-certified IITF do to validate an initial drug test?

(a) An HHS-certified IITF must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff, using samples at several concentrations between 0 and 150 percent of the cutoff;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 12.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following calibrators and controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 12.12 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each specimen validity test result must be based on performing a single test on one aliquot;

(b) The HHS-certified IITF must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results in accordance with Section 12.14; and

(c) Controls must be analyzed concurrently with specimens.

Section 12.13 What must an HHS-certified IITF do to validate a specimen validity test?

An HHS-certified IITF must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 12.14 What are the requirements for conducting each specimen validity test?

(a) The requirements for measuring creatinine concentration are as follows:

(1) The creatinine concentration must be measured to one decimal place on the test;

(2) The creatinine test must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;

(iii) A control in the range of 3 mg/dL to 20 mg/dL; and

(iv) A control in the range of 21 mg/dL to 25 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with creatinine test results greater than 5 mg/dL and less than 20 mg/dL, an IITF must perform a screening test using a refractometer to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be forwarded to an HHS-certified laboratory when the creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result is less than 1.002.

(2) The screening specific gravity test must have the following calibrators and controls:

(i) A calibrator or control at 1.000;

(ii) One control targeted at 1.002; and

(iii) One control in the range of 1.004 to 1.018.

(c) The requirements for measuring pH are as follows:

(1) The IITF may perform the pH test using a pH meter, colorimetric pH test, dipsticks, or pH paper. Specimens must be forwarded to an HHS-certified laboratory when the pH is less than 4.5 or equal to or greater than 9.0.

(2) The pH test must have, at a minimum, the following calibrators and controls:

(i) One control below 4.5;

(ii) One control between 4.5 and 9.0;

(iii) One control above 9.0; and

(iv) One or more calibrators as appropriate for the test. For a pH meter: Calibrators at 4, 7, and 10.

(d) The requirements for measuring the nitrite concentration are that the nitrite test must have a calibrator at 200 mcg/mL nitrite, a control without nitrite (*i.e.,* certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL. Specimens with a nitrite concentration equal to or greater than 200 mcg/mL must be forwarded to an HHS-certified laboratory; and,

(e) Requirements for performing oxidizing adulterant tests are that the test must include an appropriate calibrator at the cutoff specified in Sections 11.19(d)(3), (4), or (6) for the compound of interest, a control without the compound of interest (*i.e.,* a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration. Specimens with an oxidizing adulterant result equal to or greater than the cutoff must be forwarded to an HHS-certified laboratory.

Section 12.15 What are the requirements for an HHS-certified IITF to report a test result?

(a) An HHS-certified IITF must report a test result to the agency's MRO within an average of 3 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying technician.

(b) A primary (A) specimen is reported negative when each drug test is negative and each specimen validity test result indicates that the specimen is a valid urine specimen.

(c) A primary (A) urine specimen is reported dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003.

(d) An HHS-certified IITF shall reject a urine specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified IITF will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(e) An HHS-certified IITF must report results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

(f) HHS-certified IITFs may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. IITFs and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(g) HHS-certified IITFs must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(h) For rejected specimens, IITFs must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 12.16 How does an HHS-certified IITF handle a specimen that tested positive, adulterated, substituted, or invalid at the IITF?

(a) The remaining specimen is resealed using a tamper-evident label/seal;

(b) The individual resealing the remaining specimen initials and dates the tamper-evident label/seal; and

(c) The resealed specimen and split specimen and the Federal CCF are sealed in a leak-proof plastic bag, and are sent to an HHS-certified laboratory under chain of custody within one day after completing the drug and specimen validity tests.

Section 12.17 How long must an HHS-certified IITF retain a specimen?

A specimen that is negative, negative/dilute, or rejected for testing is discarded.

Section 12.18 How long must an HHS-certified IITF retain records?

(a) An HHS-certified IITF must retain all records generated to support test results for at least 2 years. The IITF may convert hardcopy records to electronic records for storage and then discard the hardcopy records after six months.

(b) A federal agency may request the HHS-certified IITF to maintain a documentation package (as described in Section 12.20) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the IITF must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified IITF may retain records other than those included in the documentation package beyond the normal two-year period of time.

Section 12.19 What statistical summary reports must an HHS-certified IITF provide?

(a) HHS-certified IITFs must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period. The summary report must not include any personally identifiable information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified IITF name and address;

(3) Federal agency name;

(4) Total number of specimens tested;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test; and

(10) Number of specimens forwarded to an HHS-certified laboratory for testing.

(b) An HHS-certified IITF must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the IITF is performing drug-testing services.

(c) An HHS-certified IITF must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the IITF.

Section 12.20 What HHS-certified IITF information is available to a federal agency?

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report from a laboratory, the federal agency may submit a written request for copies of the IITF records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified IITF must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified IITF, and a copy of the electronic report (if any) generated by the HHS-certified IITF;

(4) A brief description of the HHS-certified IITF's drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of all test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the tests; and

(6) Copies of the résumé or curriculum vitae for the RT and for the certifying technician of record.

Section 12.21 What HHS-certified IITF information is available to a federal employee?

A federal employee who is the subject of a drug test may provide a written request through the MRO and/or the federal agency requesting access to any records relating to the employee's drug test results or a documentation package (as described in Section 12.20) and any relevant certification, review, or revocation of certification records.

Section 12.22 What types of relationships are prohibited between an HHS-certified IITF and an MRO?

An HHS-certified IITF must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified IITF for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified IITF or have any agreement with an HHS-certified IITF that may be construed as a potential conflict of interest.

Section 12.23 What type of relationship can exist between an HHS-certified IITF and an HHS-certified laboratory?

An HHS-certified IITF can enter into any relationship with an HHS-certified laboratory.

Subpart M—Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A currently licensed physician who has:

(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notification in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notification is also available on the internet at *http://www.samhsa.gov/workplace/drug-testing.*

Section 13.3 What training is required before a physician may serve as an MRO?

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any federal agency for which the individual may serve as an MRO;

(b) Certified MROs must complete training on any revisions to these Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.19(g) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of two years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after six months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, and an alternate specimen was not collected, as addressed in Sections 8.6 and 13.6.

Section 13.5 What must an MRO do when reviewing a urine specimen's test results?

(a) When the HHS-certified laboratory or HHS-certified IITF reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory or HHS-certified IITF reports a negative/dilute result for the primary (A) urine specimen, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor.

(1) If the recollected specimen provides a negative or negative/dilute result, the MRO reports a negative result to the agency, with no further action required.

(2) If the recollected specimen provides a result other than negative or negative/dilute, the MRO follows the procedures in 13.5(c) through (f) for the recollected specimen.

(c) When the HHS-certified laboratory reports multiple results for the primary

(A) urine specimen, as the MRO, you must follow the verification procedures described in 13.5(d) through (f) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, do not report the verified invalid result to the federal agency at this time. The MRO takes the action described in 13.5(f) for the verified invalid result(s) for the primary (A) specimen only when:

(i) The MRO verifies the laboratory-reported positive, adulterated, or substituted result as negative based on a legitimate medical explanation as described in 13.5(d)(2) and 13.5(e)(1); or

(ii) The split (B) specimen is tested and reported as a failure to reconfirm as described in Section 14.6(m).

(d) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor admits unauthorized use of the drug(s) that caused the positive result, the MRO reports the test result as positive to the agency. The MRO must document the donor's admission of unauthorized drug use in the MRO records and in the report to the agency.

(2) If the donor provides documentation (*e.g.,* a valid prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency. If the laboratory also reports that the urine specimen is dilute, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor. The MRO follows the procedures in 13.5(b)(1) or (2) for the recollected specimen.

(i) Passive exposure to a drug (*e.g.,* exposure to secondhand marijuana smoke) is not a legitimate medical explanation for a positive drug test result.

(ii) Ingestion of food products containing a drug (*e.g.,* products containing marijuana, poppy seeds containing codeine and/or morphine) is not a legitimate medical explanation for a positive urine drug test result.

(iii) A physician's authorization or medical recommendation for a Schedule 1 controlled substance is not a legitimate medical explanation for a positive drug test result.

(3) If the donor is unable to provide a legitimate medical explanation for the positive result, the MRO reports the positive result to the agency. If the laboratory also reports that the urine specimen is dilute, the MRO may choose not to report the dilute result.

(e) When the HHS-certified laboratory reports an adulterated or substituted result for the primary (A) urine specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated or substituted result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a refusal to test to the federal agency because the urine specimen was adulterated or substituted.

(f) When the HHS-certified laboratory reports an invalid result for the primary (A) urine specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result. In the case of an invalid result based on pH of 9.0 to 9.5, when an employee has no other medical explanation for the pH in this range, the MRO must consider whether there is evidence of elapsed time and high temperature that could account for the pH value. The MRO may contact the collection site, HHS-certified IITF, and/or HHS-certified laboratory to discuss time and temperature issues (*e.g.,* time elapsed from collection to receipt at the testing facility, likely temperature conditions between the time of the collection and transportation to the testing facility, specimen storage conditions).

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medication) or if the MRO determines that time and temperature account for the pH in the 9.0 to 9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation or if the MRO determines that time and temperature fail to account for the pH in the 9.0–9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and directs the federal agency to immediately collect another urine specimen from the donor using a direct observed collection.

(i) If the specimen collected under direct observation provides a valid result, the MRO follows the procedures in 13.5(a) through (e).

(ii) If the specimen collected under direct observation provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* oral fluid).

(g) When two separate specimens collected during the same testing event were sent to the HHS-certified laboratory for testing (*e.g.,* the collector sent a urine specimen out of temperature range and the subsequently collected specimen—urine or another authorized specimen type), as the MRO, you must follow the verification procedures described in Sections 13.4, 13.5, and 13.6, and:

(1) If both specimens were verified negative, report the result as negative.

(2) If one specimen was verified negative and the other was not (*i.e.,* the specimen was verified as negative/dilute or as positive, adulterated, substituted, and/or invalid), report only the verified result(s) other than negative. For example, if you verified one specimen as negative and the other as a refusal to test because the specimen was substituted, report only the refusal to the federal agency.

(3) If both specimens were verified as positive, adulterated, and/or substituted, report all results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, report the positive and the refusal results to the federal agency.

(4) If one specimen has been verified and the HHS-certified laboratory has not reported the result(s) of the other specimen,

(i) Report verified result(s) of positive, adulterated, or substituted immediately and do not wait to receive the result(s) of the other specimen.

(ii) Do not report a verified result of negative, negative/dilute, or invalid for the first specimen to the federal agency. Hold the report until results of both specimens have been received and verified.

(5) When the HHS-certified laboratory reports an invalid result for one or both specimens, follow the procedures in paragraph (c) above.

(h) When the HHS-certified laboratory or HHS-certified IITF reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor. The recollected specimen must be the same type (*i.e.,* urine).

Section 13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of urine for a drug test?

(a) When another specimen type (*e.g.,* oral fluid) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition (*e.g.,* a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time. Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genitourinary matters. Acute or temporary medical conditions, such as cystitis, urethritis, or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in the previous sentence.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of urine to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine and is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (*e.g.,* oral fluid) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

13.7 What happens when an individual is unable to provide a sufficient amount of urine for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of illicit drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* oral fluid) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition (as defined in Section 13.6(b)(1)) exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the federal agency is not authorized to allow

the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

Section 13.8 Who may request a test of a split (B) specimen?

(a) For a positive, adulterated, or substituted result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or substituted result is being reported to the federal agency on the primary (A) specimen.

Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory or an HHS-certified IITF for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or HHS-certified IITF, or have any agreement with the HHS-certified laboratory or the HHS-certified IITF that may be construed as a potential conflict of interest.

Section 13.11 What reports must an MRO provide to the Secretary for urine testing?

(a) An MRO must send to the Secretary or designated HHS representative a semiannual report of federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. The report must not include any personally identifiable information for the donor and must be submitted by mail, fax, or other secure electronic transmission method within 14 working days after the end of the semiannual period (*i.e.,* in January and July). The semiannual report must contain the following information:

(1) Reporting period (inclusive dates);

(2) MRO name, company name, and address;

(3) Federal agency name; and

(4) For each laboratory-reported positive drug test result that was verified as negative by the MRO:

(i) Specimen identification number;

(ii) Laboratory name and address;

(iii) Positive drug(s) or drug metabolite(s) the MRO verified as negative;

(iv) MRO reason for verifying the positive drug(s) or drug metabolite(s) as negative (*e.g.,* a donor prescription [the MRO must specify the prescribed drug]);

(v) All results reported to the federal agency by the MRO for the specimen; and

(vi) Date of the MRO report to the federal agency.

(b) An MRO must provide copies of the drug test reports that the MRO has sent to a federal agency when requested to do so by the Secretary.

(c) If an MRO did not verify any positive laboratory results as negative during the reporting period, the MRO should file a report that states that the MRO has no reportable results during the applicable reporting period.

Section 13.12 What are a federal agency's responsibilities for designating an MRO?

(a) Before allowing an individual to serve as an MRO for the agency, a federal agency must verify and document the following:

(1) that the individual satisfies all requirements in Section 13.1, including certification by an MRO certification organization that has been approved by the Secretary, as described in Section 13.2; and

(2) that the individual is not an employee, agent of, or have any financial interest in an HHS-certified laboratory or an HHS-certified IITF that tests the agency's specimens, as described in Section 13.10.

(b) The federal agency must verify and document that each MRO reviewing and reporting results for the agency:

(1) Completes training on any revisions to these Guidelines prior to their effective date;

(2) at least every five years, maintains their certification by completing requalification training and passing a requalification examination; and

(3) provides biannual reports to the Secretary or designated HHS representative as required in Section 13.11;

(c) The federal agency must ensure that each MRO reports drug test results to the agency in accordance with Sections 13.9 and 14.7.

(1) Before allowing an MRO to report results electronically, the agency must obtain documentation from the MRO to confirm that the MRO and any external service providers ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

Subpart N—Split Specimen Tests

Section 14.1 When may a split (B) specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) specimen be tested at a different (*i.e.,* second) HHS-certified laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) urine specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another urine specimen from the donor under direct observation, with no notice given to the

donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoffs established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

(c) For a split (B) urine specimen, if the second HHS-certified laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first HHS-certified laboratory, the second laboratory must conduct specimen validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory should conduct the same specimen validity tests as it would conduct on a primary (A) urine specimen and reports those results to the MRO.

Section 14.3 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported adulterated?

(a) An HHS-certified laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (B) urine specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (*i.e.,* either less than 4 or equal to or greater than 11);

(2) Nitrite must be measured using the laboratory's confirmatory nitrite test with a cutoff of equal to or greater than 500 mcg/mL;

(3) Surfactant must be measured using the laboratory's confirmatory surfactant test with a cutoff of equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff; or

(4) For adulterants without a specified cutoff (*e.g.,* glutaraldehyde, chromium (VI), pyridine, halogens (such as, chlorine from bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory must use its confirmatory specimen validity test at an established LOQ to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported substituted?

(a) An HHS-certified laboratory must use the following criteria to reconfirm a substituted result when testing a split (B) urine specimen:

(1) *For substitution based on creatinine and specific gravity testing:* The creatinine must be measured using the laboratory's confirmatory creatinine test with a cutoff of less than 2 mg/dL, and the specific gravity must be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than or equal to 1.0010 or equal to or greater than 1.0200.

(2) *For substitution based on biomarker testing:* The laboratory must test for the biomarker using its confirmatory test (*i.e.,* using the confirmatory test analytes and cutoffs in the biomarker testing panel).

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the substituted result reported by the first HHS-certified laboratory.

Section 14.5 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.6 What action(s) does an MRO take after receiving the split (B) urine specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) urine specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and the specimen was adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test to the agency and indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and the specimen was substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request additional review or testing as follows:

(1) *For substitution based on creatinine and specific gravity:* Request that Laboratory A review the creatinine and specific gravity results for the primary (A) specimen.

(2) *For substitution based on biomarker testing:* Request that Laboratory A test the primary (A) specimen using its confirmatory test for the biomarker.

(i) If the primary (A) specimen's test results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency.

(ii) If the primary (A) specimen's results fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *Failed to reconfirm a single or all drug positive results and the specimen was not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s]), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm a single or all drug positive results and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s] and the reason

for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was adulterated.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was not adulterated or substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen had an invalid result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (not adulterated: Specifying the adulterant/pH or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm substitution or adulteration and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: Specifying the adulterant/pH or not substituted, and the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure and notifies the HHS office responsible for coordination of the drug-free workplace program.

(l) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result.* The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(m) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s] and not adulterated: Specifying the adulterant/pH or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(n) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s] and adulterated) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(o) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s] and not adulterated: Specifying the adulterant/pH). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(p) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: Specifying the adulterant/pH, and not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(q) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (not adulterated: Specifying the adulterant/pH). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(r) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

Section 14.7 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.8 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

Subpart O—Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a urine specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory or IITF must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the primary (A) or split (B) specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken, or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF;

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen;

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(f) The specimen was received at the HHS-certified laboratory or IITF without a CCF;

(g) The CCF was received at the HHS-certified laboratory or IITF without a specimen;

(h) The collector performed two separate collections using one CCF; or

(i) The HHS-certified laboratory or IITF identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory or IITF must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the HHS-certified laboratory or IITF may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory or IITF cannot recover the collector's signature, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-federal form or an expired Federal CCF, the HHS-certified laboratory or IITF must test the specimen and also attempt to obtain a memorandum for record explaining why a non-federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory or IITF cannot obtain a memorandum for record from the collector, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory or IITF should not cause an HHS-certified laboratory or IITF to reject a urine specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's Social Security Number or employee identification number;

(6) A telephone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A ''reason for test'' box is not marked;

(9) A ''drug tests to be performed'' box is not marked;

(10) A ''collection'' box is not marked;

(11) The ''observed'' box is not marked (if applicable);

(12) The collection site address is missing;

(13) The collector's printed name is missing but the collector's signature is properly recorded;

(14) The time of collection is not indicated;

(15) The date of collection is not indicated;

(16) Incorrect name of delivery service;

(17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the HHS-certified laboratory or IITF copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(19) The collector failed to check the specimen temperature box and the ''Remarks'' line did not have a comment regarding the temperature being out of range. If, after at least 5 business days, the collector cannot provide a memorandum for record to attest to the fact that the collector did measure the specimen temperature, the HHS-certified laboratory or IITF may report the test result for the specimen but indicates that the collector could not provide a memorandum to recover the omission.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory or IITF should not cause an MRO to cancel a test:

(1) The testing laboratory or IITF fails to indicate the correct name and address in the results section when a different laboratory or IITF name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory or IITF will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an

error occurs more than once a month, the MRO must direct the collector, HHS-certified laboratory, or HHS-certified IITF (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 What discrepancies may require an MRO to cancel a test?

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or substituted; or

(3) The electronic report provided by the HHS-certified laboratory or HHS-certified IITF does not contain all the data elements required for the HHS standard laboratory or IITF electronic report for a specimen being reported drug positive, adulterated, invalid result, or substituted.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that they inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory or HHS-certified IITF. If, after at least 5 business days, the laboratory or IITF does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P—Laboratory or IITF Suspension/Revocation Procedures

Section 16.1 When may the HHS certification of a laboratory or IITF be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory or IITF in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory or IITF has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory or IITF which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of the official's employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 16.3 Are there any limitations on issues subject to review?

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

Section 16.4 Who represents the parties?

The appellant's request for review shall specify the name, address, and telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory or IITF attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 16.7 What procedures are used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the

request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 16.8 When is there an opportunity for oral presentation?

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at their discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of the official's employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At their discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory or IITF in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory or IITF received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the

suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by fax, secured electronic transmissions, or overnight mail.

Section 16.10 Are any types of communications prohibited?

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 16.11 How are communications transmitted by the reviewing official?

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by fax, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and federal holidays. However, if a due date falls on a Saturday, Sunday, or federal holiday, then the due date is the next federal working day.

Section 16.12 What are the authority and responsibilities of the reviewing official?

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 16.13 What administrative records are maintained?

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 16.14 What are the requirements for a written decision?

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue their decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notification.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notification in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notification will be given by publication in the **Federal Register**.

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

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Part IV

Department of Energy

10 CFR Parts 429 and 430

Energy Conservation Program: Energy Conservation Standards for Room Air Conditioners; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[EERE–2014–BT–STD–0059]

RIN 1904–AD97

Energy Conservation Program: Energy Conservation Standards for Room Air Conditioners

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking and announcement of a webinar.

SUMMARY: The Energy Policy and Conservation Act, as amended (''EPCA''), prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including room air conditioners. EPCA also requires the U.S. Department of Energy (''DOE'') to periodically determine whether more-stringent standards would be technologically feasible and economically justified, and would result in significant energy savings. In this notice of proposed rulemaking (''NOPR''), DOE proposes amended energy conservation standards for room air conditioners, and also announces a webinar to receive comment on these proposed standards and associated analyses and results.

DATES: DOE will hold a webinar on Tuesday, May 3, 2022, from 12:30 p.m. to 4:30 p.m. See section VIII, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

Comments: DOE will accept comments, data, and information regarding this NOPR no later than June 6, 2022.

Comments regarding the likely competitive impact of the proposed standard should be sent to the Department of Justice contact listed in the **ADDRESSES** section on or before May 9, 2022.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2014–BT–STD–0059, by any of the following methods:

(1) *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

(2) *Email: RoomAC2014STD0059@ee.doe.gov.* Include the docket number EERE–2014–BT–STD–0059 in the subject line of the message.

No telefacsimilies (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section IV of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing Covid–19 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket?D=EERE-2014-BT-STD-0059.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section VIII of this document for information on how to submit comments through *www.regulations.gov.*

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to Office of Energy Efficiency and Renewable Energy following the instructions at *RegInfo.gov.*

EPCA requires the Attorney General to provide DOE a written determination of whether the proposed standard is likely to lessen competition. The U.S. Department of Justice Antitrust Division invites input from market participants and other interested persons with views on the likely competitive impact of the proposed standard. Interested persons may contact the Division at *energy.standards@usdoj.gov* on or before the date specified in the **DATES** section. Please indicate in the ''Subject'' line of your email the title and *Docket* number of this proposed rulemaking.

FOR FURTHER INFORMATION CONTACT:

Mr. Bryan Berringer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–0371. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–1777. Email: *Sarah.Butler@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the webinar, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

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I. Synopsis of the Proposed Rule

Title III, Part B [1] of EPCA,[2] established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) These products include room air conditioners (''room ACs''), the subject of this proposed rulemaking.

Pursuant to EPCA, any new or amended energy conservation standard must be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in a significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) EPCA also provides that not later than 6 years after issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a notice of proposed rulemaking including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m))

In accordance with these and other statutory provisions discussed in this document, DOE proposes amended energy conservation standards for room ACs. The proposed standards, which are expressed in the amount of cooling provided per amount of energy consumed, measured in British thermal units per watt-hour (Btu/Wh) are shown in Table I.1. These proposed standards, if adopted, would apply to all room ACs listed in Table I.1 manufactured in, or imported into, the United States starting on the date 3 years after the publication of the final rule for this proposed rulemaking.

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[1] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[2] All references to EPCA in this document refer to the statute as amended through the Infrastructure Investment and Jobs Act, Public Law 117–58 (Nov. 15, 2021).

Table I.1 Proposed Energy Conservation Standards for Room Air Conditioners

Equipment Class	CEER (*Btu/Wh*)
1. Without reverse cycle, with louvered sides, and less than 6,000 Btu/h	13.1
2. Without reverse cycle, with louvered sides and 6,000 to 7,900 Btu/h	13.7
3. Without reverse cycle, with louvered sides and 8,000 to 13,900 Btu/h	16.0
4. Without reverse cycle, with louvered sides and 14,000 to 19,900 Btu/h	16.0
5a. Without reverse cycle, with louvered sides and 20,000 to 27,900 Btu/h	13.8
5b. Without reverse cycle, with louvered sides and 28,000 Btu/h or more	13.2
6. Without reverse cycle, without louvered sides, and less than 6,000 Btu/h	12.8
7. Without reverse cycle, without louvered sides and 6,000 to 7,900 Btu/h	12.8
8a. Without reverse cycle, without louvered sides and 8,000 to 10,900 Btu/h	14.1
8b. Without reverse cycle, without louvered sides and 11,000 to 13,900 Btu/h	13.9
9. Without reverse cycle, without louvered sides and 14,000 to 19,900 Btu/h	13.7
10. Without reverse cycle, without louvered sides and 20,000 Btu/h or more	13.8
11. With reverse cycle, with louvered sides, and less than 20,000 Btu/h	14.4
12. With reverse cycle, without louvered sides, and less than 14,000 Btu/h	13.7
13. With reverse cycle, with louvered sides, and 20,000 Btu/h or more	13.7
14. With reverse cycle, without louvered sides, and 14,000 Btu/h or more	12.8
15. Casement-Only	13.9
16. Casement-Slider	15.3

A. Benefits and Costs to Consumers

Table I.2 presents DOE's evaluation of the economic impacts of the proposed standards on consumers of room ACs, as measured by the average life-cycle cost (''LCC'') savings and the simple payback period (''PBP'').[3] The average LCC savings are positive for all product classes, and the PBP is less than the average lifetime of a room AC, which is estimated to be 9 years (see section IV.F.6 of this document).

[3] The average LCC savings refer to consumers that are affected by a standard and are measured relative to the efficiency distribution in the no-new-standards case, which depicts the market in the compliance year in the absence of new or amended standards (see section IV.F.8 of this document). The simple PBP, which is designed to compare specific efficiency levels, is measured relative to the baseline product (see section IV.F.9 of this document).

Table I.2 Impacts of Proposed Energy Conservation Standards on Consumers of Room Air Conditioners for Representative Product Classes (TSL 3)

Room AC Product Class	Average LCC Savings (*2020$*)	Simple Payback Period (*years*)
1. Without reverse cycle, with louvered sides, and less than 6,000 Btu/h	$63.49	0.7
2. Without reverse cycle, with louvered sides and 6,000 to 7,900 Btu/h	$80.02	0.9
3. Without reverse cycle, with louvered sides and 8,000 to 13,900 Btu/h	$99.14	2.8
4. Without reverse cycle, with louvered sides and 14,000 to 19,900 Btu/h	$97.49	2.9
5a. Without reverse cycle, with louvered sides and 20,000 Btu/h to 27,900 Btu/h	$152.52	2.6
5b. Without reverse cycle, with louvered sides and 28,000 Btu/h or more	$275.19	2.3
8a. Without reverse cycle, without louvered sides and 8,000 to 10,900 Btu/h	$74.28	3.3
8b. Without reverse cycle, without louvered sides and 11,000 to 13,900 Btu/h	$116.89	2.4
9. Without reverse cycle, without louvered sides and 14,000 to 19,900 Btu/h	$162.64	2.8
11. With reverse cycle, with louvered sides, and less than 20,000 Btu/h	$131.12	3.2
12. With reverse cycle, without louvered sides, and less than 14,000 Btu/h	$122.74	2.5
16. Casement-Slider	$81.33	4.0

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DOE's analysis of the impacts of the proposed standards on consumers is described in section IV.F of this document.

B. Impact on Manufacturers

The industry net present value (''INPV'') is the sum of the discounted cash flows to the industry from the base year through the end of the analysis period (2021–2055). Using a real discount rate of 7.2 percent, DOE estimates that the INPV for manufacturers of room ACs in the case without amended standards is $1.08 billion in 2020$. Under the proposed standards, the change in INPV is estimated to range from −6.0 percent to 7.8 percent, which is approximately −$64.5 million to $84.1 million. In order to bring products into compliance with amended standards, DOE estimated that the industry would incur total conversion costs of $22.8 million.

DOE's analysis of the impacts of the proposed standards on manufacturers is described in section IV.J of this document. The analytic results of the manufacturer impact analysis (''MIA'') are presented in section V.B.2 of this document.

C. National Benefits and Costs [4]

DOE's analyses indicate that the proposed energy conservation standards for room ACs would save a significant amount of energy. Relative to the case without amended standards, the lifetime energy savings for room ACs purchased in the 30-year period that begins in the anticipated year of compliance with the amended standards (2026–2055) amount to 1.40 quadrillion British thermal units (''Btu''), or quads.[5] This represents a savings of 12 percent relative to the energy use of these products in the case without amended standards (referred to as the ''no-new-standards case'').

The cumulative net present value (''NPV'') of total consumer benefits of the proposed standards for room ACs are $4.83 billion (at a 7-percent discount rate) and $10.56 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating-cost savings minus the estimated increased product costs for room ACs purchased in 2026–2055.

In addition, the proposed standards for room ACs are projected to yield significant environmental benefits. DOE estimates that the proposed standards would result in cumulative emission reductions (over the same period as for energy savings) of 49.5 million metric tons (''Mt'') [6] of carbon dioxide (''CO_2''), 19.1 thousand tons of sulfur dioxide (''SO_2''), 69.4 thousand tons of nitrogen oxides (''NO_X''), 339.3 thousand tons of methane (''CH_4''), 0.5 thousand tons of nitrous oxide (''N_2O''), and 0.1 tons of mercury (''Hg'').[7]

DOE estimates the value of climate benefits from a reduction in greenhouse gases using four different estimates of the social cost of CO_2 (''SC–CO_2''), the social cost of methane (''SC–CH_4''), and the social cost of nitrous oxide (''SC–N_2O''). Together these represent the

[4] All monetary values in this document are expressed in 2020 dollars.

[5] The quantity refers to full-fuel-cycle (''FFC'') energy savings. FFC energy savings includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and, thus, presents a more complete picture of the impacts of energy efficiency standards. For more information on the FFC metric, see section IV.H.2 of this document.

[6] A metric ton is equivalent to 1.1 short tons. Results for emissions other than CO_2 are presented in short tons.

[7] DOE calculated emissions reductions relative to the no-new-standards case, which reflects key assumptions in the *Annual Energy Outlook 2021* (''*AEO 2021*''). *AEO 2021* represents current Federal and State legislation and final implementation of regulations as of the time of its preparation. See section IV.K of this document for further discussion of *AEO 2021* assumptions that effect air pollutant emissions.

social cost of greenhouse gases (''SC–GHG''). DOE used interim SC–GHG values developed by an Interagency Working Group on the Social Cost of Greenhouse Gases (''IWG'').[8] The derivation of these values is discussed in section IV.L of this document. For presentational purposes, the climate benefits associated with the average SC–GHG at a 3-percent discount rate is $2.39 billion. DOE does not have a single central SC–GHG point estimate and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates.

DOE also estimates health benefits from SO_2 and NO_X emissions reductions.[9] DOE estimates the present value of the health benefits would be $1.82 billion using a 7-percent discount rate, and $4.14 billion using a 3-percent discount rate.[10] DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions.[11]

Table I.3 summarizes the economic benefits and costs expected to result from the proposed standards for room ACs. In the table, total benefits for both the 3-percent and 7-percent cases are presented using the average GHG social costs with 3-percent discount rate. DOE does not have a single central SC–GHG point estimate and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates. The estimated total net benefits using each of the four SC–GHG estimates are presented in section V.B.8 of this document.

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[8] *See* Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021, *available at www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrous Oxide.pdf?source=email.*

[9] DOE estimated the monetized value of NO_X and SO_2 emissions reductions associated with electricity savings using benefit per ton estimates from the scientific literature. See section IV.L.2 of this document for further discussion.

[10] DOE estimates the economic value of these emissions reductions resulting from the considered TSLs for the purpose of complying with the requirements of Executive Order 12866.

[11] On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

Table I.3 Summary of Monetized Economic Benefits and Costs of Proposed Energy Conservation Standards for Room Air Conditioners for TSL 3

	Billion 2020$
3% discount rate	
Consumer Operating Cost Savings	13.87
Climate Benefits*	2.39
Health Benefits**	4.14
Total Benefits†	20.41
Consumer Incremental Product Costs‡	3.31
Net Benefits	17.10
7% discount rate	
Consumer Operating Cost Savings	6.89
Climate Benefits*	2.39
Health Benefits**	1.82
Total Benefits†	11.10
Consumer Incremental Product Costs‡	2.05
Net Benefits	9.05

Note: This table presents the costs and benefits associated with consumer room ACs shipped in 2026−2055. These results include benefits to consumers which accrue after 2055 from the products shipped in 2026−2055.
*Climate benefits are calculated using four different estimates of the social cost of carbon (SC-CO_2), methane (SC-CH_4), and nitrous oxide (SC-N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate), as shown in Table V.50 through Table V.52. Together these represent the global social cost of greenhouse gases (SC-GHG). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC-GHG point estimate. See section IV.L of this document for more details.
** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.L of this document for more details.
† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate, but the Department does not have a single central SC-GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates. See Table V.55 for net benefits using all four SC-GHG estimates. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22-30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana v. Biden*, No. 21-cv-1074-JDC-KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from "adopting, employing, treating as binding, or relying upon" the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.
‡ Costs include incremental equipment costs as well as installation costs.

The benefits and costs of the proposed standards, for room ACs sold in 2026–2055, can also be expressed in terms of annualized values. The monetary values for the total annualized net benefits are (1) the reduced consumer operating costs, minus (2) the increase in product purchase prices and installation costs, plus (3) the value of the benefits of GHG, NO_X, and SO_2 emission reductions, all annualized.[12]

The national operating savings are domestic private U.S. consumer monetary savings that occur as a result of purchasing the covered products and are measured for the lifetime of room ACs shipped in 2026–2055. The climate benefits associated with reduced GHG emissions achieved as a result of the proposed standards are also calculated based on the lifetime of room ACs shipped in 2026–2055.

Estimates of annualized benefits and costs of the proposed standards are shown in Table I.4 of this document. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated cost of the standards proposed in this rule is $216.9 million per year in increased equipment costs, while the estimated annual benefits are $727.5 million in reduced equipment operating costs, $137.5 million in climate benefits, $192.1 million in health benefits. In this case, the net benefit would amount to $840.2 million per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the proposed standards is $190.1 million per year in increased equipment costs, while the estimated annual benefits are $796.7 million in reduced operating costs, $137.5 million in climate benefits, and $237.9 million in health benefits. In this case, the net benefit would amount to $982.0 million per year.

[12] To convert the time-series of costs and benefits into annualized values, DOE calculated a present value in 2021, the year used for discounting the NPV of total consumer costs and savings. For the benefits, DOE calculated a present value associated with each year's shipments in the year in which the shipments occur (*e.g.,* 2030), and then discounted the present value from each year to 2021. The calculation uses discount rates of 3 and 7 percent for all costs and benefits. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in the compliance year, that yields the same present value.

Table I.4 Annualized Monetized Benefits and Costs of Proposed Energy Conservation Standards for Room Air Conditioners for TSL 3

	Million 2020$/year		
	Primary Estimate	**Low-Net-Benefits Estimate**	**High-Net-Benefits Estimate**
3% discount rate			
Consumer Operating Cost Savings	796.7	751.9	847.8
Climate Benefits*	137.5	134.2	140.4
Health Benefits**	237.9	232.3	242.7
Total Benefits†	1,172.0	1,118.4	1,230.9
Consumer Incremental Product Costs‡	190.1	213.2	163.1
Net Benefits	982.0	905.2	1,067.7
7% discount rate			
Consumer Operating Cost Savings	727.5	693.3	768.4
Climate Benefits*	137.5	134.2	140.4
Health Benefits**	192.1	188.1	195.7
Total Benefits†	1,057.1	1,015.6	1,104.4
Consumer Incremental Product Costs‡	216.9	240.0	190.0
Net Benefits	840.2	775.7	914.5

Note: This table presents the costs and benefits associated with room ACs shipped in 2026–2055. These results include benefits to consumers which accrue after 2055 from the products shipped in 2026–2055.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC-CO_2), methane (SC-CH_4), and nitrous oxide (SC-N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the global social cost of greenhouse gases (SC-GHG). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC-GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates. See section IV.L of this document for more details.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.L of this document for more details.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate, but the Department does not have a single central SC-GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22-30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana v. Biden*, No. 21-cv-1074-JDC-KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from "adopting, employing, treating as binding, or relying upon" the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

‡ Costs include incremental equipment costs as well as installation costs

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DOE's analysis of the national impacts of the proposed standards is described in sections IV.H, IV.K and IV.L of this document.

D. Conclusion

DOE has tentatively concluded that the proposed standards represent the maximum improvement in energy efficiency that is technologically feasible and economically justified, and would result in the significant conservation of energy. Based on the analyses described previously, DOE has tentatively concluded that the benefits of the proposed standards to the Nation (energy savings, positive NPV of consumer benefits, consumer LCC savings, and emission reductions) would outweigh the burdens (loss of INPV for manufacturers and LCC increases for some consumers).

DOE also considered more-stringent energy efficiency levels as potential standards, and is still considering them in this rulemaking. However, DOE has tentatively concluded that the potential burdens of the more-stringent energy efficiency levels would outweigh the projected benefits.

Based on consideration of the public comments DOE receives in response to this document and related information collected and analyzed during the course of this rulemaking effort, DOE may adopt energy efficiency levels presented in this document that are either higher or lower than the proposed standards, or some combination of level(s) that incorporate the proposed standards in part.

II. Introduction

The following section briefly discusses the statutory authority underlying this proposed rule, as well as some of the relevant historical background related to the establishment of standards for room ACs.

A. Authority

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. These products include room ACs, the subject of this document. (42 U.S.C. 6292(a)(2)) EPCA prescribed energy conservation standards for these products (42 U.S.C. 6295(c)(1)), and directs DOE to conduct future rulemakings to determine whether to amend these standards. (42 U.S.C. 6295(c)(2)) EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions set forth under EPCA. (*See* 42 U.S.C. 6297(d))

Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6295(o)(3)(A) and 42 U.S.C. 6295(r)) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 42 U.S.C. 6295(s)) Similarly, DOE must use these test procedures to determine whether the products comply with standards adopted pursuant to EPCA. (42 U.S.C. 6295(s)) The DOE test procedures for room ACs appear at title 10 of the Code of Federal Regulations (''CFR'') part 430, subpart B, appendix F.

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including room ACs. Any new or amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary of Energy (''Secretary'') determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3))

Moreover, DOE may not prescribe a standard: (1) For certain products, including room ACs, if no test procedure has been established for the product, or (2) if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)–(B)) In deciding whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

Further, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA also contains what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons

have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

Additionally, EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. DOE must specify a different standard level for a type or class of product that has the same function or intended use, if DOE determines that products within such group: (A) Consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE must consider such factors as the utility to the consumer of the feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Finally, pursuant to the amendments contained in the Energy Independence and Security Act of 2007 (''EISA 2007''), Public Law 110–140, any final rule for new or amended energy conservation standards promulgated after July 1, 2010, is required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)–(B)) DOE's current test procedures for room ACs address standby mode and off mode energy use. In this rulemaking, DOE intends to incorporate such energy use into any amended energy conservation standards that it may adopt.

B. Background

1. Current Standards

In a direct final rule published on April 21, 2011 (''April 2011 Direct Final Rule''), DOE prescribed the current energy conservation standards for room ACs. 76 FR 22454. These standards are set forth in DOE's regulations at 10 CFR 430.32(b) and are repeated in Table II.1 where CEER stands for ''Combined Energy Efficiency Rating.''

Table II.1 Federal Energy Conservation Standards for Room Air Conditioners

Room AC Product Class	Minimum CEER, (*Btu/Wh*)
1. Without reverse cycle, with louvered sides, and less than 6,000 Btu/h	11.0
2. Without reverse cycle, with louvered sides and 6,000 to 7,999 Btu/h	11.0
3. Without reverse cycle, with louvered sides and 8,000 to 13,999 Btu/h	10.9
4. Without reverse cycle, with louvered sides and 14,000 to 19,999 Btu/h	10.7
5a. Without reverse cycle, with louvered sides and 20,000 Btu/h to 27,999 Btu/h	9.4
5b. Without reverse cycle, with louvered sides and 28,000 Btu/h or more	9.0
6. Without reverse cycle, without louvered sides, and less than 6,000 Btu/h	10.0
7. Without reverse cycle, without louvered sides and 6,000 to 7,999 Btu/h	10.0
8a. Without reverse cycle, without louvered sides and 8,000 to 10,999 Btu/h	9.6
8b. Without reverse cycle, without louvered sides and 11,000 to 13,999 Btu/h	9.5
9. Without reverse cycle, without louvered sides and 14,000 to 19,999 Btu/h	9.3
10. Without reverse cycle, without louvered sides and 20,000 Btu/h or more	9.4
11. With reverse cycle, with louvered sides, and less than 20,000 Btu/h	9.8
12. With reverse cycle, without louvered sides, and less than 14,000 Btu/h	9.3
13. With reverse cycle, with louvered sides, and 20,000 Btu/h or more	9.3
14. With reverse cycle, without louvered sides, and 14,000 Btu/h or more	8.7
15. Casement-Only	9.5
16. Casement-Slider	10.4

2. History of Standards Rulemaking for Room ACs

EPCA prescribed initial energy conservation standards for room ACs and further directed DOE to conduct two cycles of rulemakings to determine whether to amend these standards. (42 U.S.C. 6295(c)(1)–(2)) DOE completed the first of these rulemaking cycles on September 24, 1997, by adopting amended performance standards for room ACs manufactured on or after October 1, 2000. 62 FR 50122. Additionally, DOE completed a second rulemaking cycle to amend the standards for room ACs by issuing the April 2011 Direct Final Rule, in which DOE prescribed the current energy conservation standards for room ACs manufactured on or after April 21, 2014. 76 FR 22454 (April 21, 2011). DOE subsequently published a final rule amending the compliance date for the

current room AC standards to June 1, 2014. 76 FR 52852 (Aug. 24, 2011). In a separate notice, also published on August 24, 2011, DOE confirmed the adoption of these energy conservation standards in a notice of effective date and compliance dates for the April 2011 Direct Final Rule. 76 FR 52854.

As part of the current analysis, on June 18, 2015, DOE prepared a Request for Information (''June 2015 RFI''), which solicited information from the public to help DOE determine whether amended standards for room ACs would result in a significant amount of additional energy savings and whether those standards would be technologically feasible and economically justified.[13] 80 FR 34843.

Comments received following the publication of the June 2015 RFI helped DOE identify and resolve issues related to the subsequent preliminary analysis.[14] DOE published a notice of public meeting and availability of the preliminary technical support document (''TSD'') on June 17, 2020 (''June 2020 Preliminary Analysis''). 85 FR 36512.

DOE subsequently held a public meeting on August 5, 2020, to discuss and receive comments on the preliminary TSD. The preliminary TSD that presented the methodology and results of the preliminary analysis is available at: *www.regulations.gov/document/EERE-2014-BT-STD-0059-0013.*

DOE received comments in response to the June 2020 Preliminary Analysis from the interested parties listed in Table II.2.

Table II.2 June 2020 Preliminary Analysis Written Comments

Organization(s)	Reference in this NOPR	Organization Type
Appliance Standards Awareness Project, Consumer Federation of America, National Consumer Law Center (on behalf of its low-income clients), Natural Resources Defense Council	Joint Commenters	Efficiency Organizations
Association of Home Appliance Manufacturers	AHAM	Trade Association
California Investor-Owned Utilities	California IOUs	Utilities
Northwest Energy Efficiency Alliance	NEEA	Efficiency Organization
Institute for Policy Integrity at NYU School of Law, Montana Environmental Information Center, Natural Resources Defense Council, Sierra Club, Union of Concerned Scientists	Social Cost of Carbon Commenters (''SCoC Commenters'')	Efficiency Organizations
GE Appliances	GEA	Manufacturer
C. Keith Rice	Rice	Individual

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[15]

C. Deviation From Appendix A

In accordance with section 3(a) of 10 CFR part 430, subpart C, appendix A (''appendix A''), DOE notes that it is deviating from the provision in appendix A regarding the pre-NOPR stages for an energy conservation standards rulemaking. Section 6(d)(2) of appendix A specifies that the length of the public comment period for a NOPR will vary depending upon the circumstances of the particular rulemaking, but will not be less than 75 calendar days. For this NOPR, DOE has opted to instead provide a 60-day comment period. As stated, DOE requested comment in the June 2015 RFI on the technical and economic analyses and provided stakeholders a 76-day comment period. 80 FR 34843, 80 FR 44301. Additionally, DOE provided a 74-day comment period for the June 2020 preliminary analysis. 85 FR 36512, 85 FR 52280. DOE has relied on many of the same analytical assumptions and approaches as used in the preliminary assessment and has determined that a 60-day comment period, in conjunction

[13] Pursuant to amendments to appendix A to 10 CFR part 430, subpart C (''Appendix A'') DOE generally will issue an early assessment request for information announcing that DOE is considering initiating a rulemaking proceeding. Section 6(a)(1) of Appendix A; *see also* 85 FR 8626, 8637 (Feb. 14, 2020) and 86 FR 70892 (December 13, 2021). Section 6(a)(2) of Appendix A provides that if the DOE determines it is appropriate to proceed with a rulemaking, the preliminary stages of a rulemaking to issue or amend an energy conservation standard that DOE will undertake will be a Framework Document and Preliminary Analysis, or an Advance Notice of Proposed Rulemaking. Because this proposed rulemaking was already in progress at the time the relevant amendments to the Process Rule were published, DOE did not reinitiate the entire rulemaking process. Additionally, the June 2015 RFI presented the issues, analyses, and processes relevant to consideration of amended standards for room ACs.

[14] Comments are available at *www.regulations.gov/document/EERE-2014-BT-STD-0059-0001/comment.*

[15] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop energy conservation standards for room ACs. (Docket No. EERE–2014–BT–STD–0059, which is maintained at *www.regulations.gov/docket?D=EERE-2014-BT-STD-0059).* The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

with the prior comment periods, provides sufficient time for interested parties to review the proposed rule and develop comments.

III. General Discussion

DOE developed this proposal after considering oral and written comments, data, and information from interested parties that represent a variety of interests. The following discussion addresses issues raised by these commenters.

A. Product Classes and Scope of Coverage

When evaluating and establishing energy conservation standards, DOE divides covered products into product classes by the type of energy used or by capacity or other performance-related features that justify differing standards. In making a determination whether a performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE determines are appropriate. (42 U.S.C. 6295(q)) DOE's preliminary analysis indicated that the current room AC product classes are still appropriate.

B. Test Procedure

EPCA sets forth generally applicable criteria and procedures for DOE's adoption and amendment of test procedures. (42 U.S.C. 6293) Manufacturers of covered products must use these test procedures to certify to DOE that their product complies with energy conservation standards and to quantify the efficiency of their product. In addition, consistent with section 8(d)(1)(i) of appendix A, DOE will finalize amended test procedures that impact measured energy use or efficiency at least 180 days prior to the close of the comment period for a NOPR proposing new or amended energy conservation standards. DOE published a test procedure final rule on March 29, 2021, retaining the CEER metric used to express DOE's current energy conservation standards for room ACs in Btu/Wh. 86 FR 16446. DOE's test procedures for room ACs appear at appendix F to 10 CFR part 430, subpart B.

C. Technological Feasibility

1. General

In each energy conservation standards rulemaking, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the products or equipment that are the subject of the rulemaking. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially-available products or in working prototypes to be technologically feasible. Sections 6(b)(3)(i) and 7(b)(1) of appendix A.

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) Practicability to manufacture, install, and service; (2) adverse impacts on product utility or availability; (3) adverse impacts on health or safety, and (4) unique-pathway proprietary technologies. Sections 6(b)(3)(ii)–(v) and 7(b)(2)–(5) of appendix A. Section IV.B of this document discusses the results of the screening analysis for room ACs, particularly the designs DOE considered, those it screened out, and those that are the basis for the standards considered in this proposed rulemaking. For further details on the screening analysis for this proposed rulemaking, see chapter 4 of the NOPR TSD.

2. Maximum Technologically Feasible Levels

When DOE proposes to adopt an amended standard for a type or class of covered product, it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such product. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (''max-tech'') improvements in energy efficiency for room ACs, using the design parameters for the most efficient products available on the market or in working prototypes. The max-tech levels that DOE determined for this proposed rulemaking are described in section IV.C.1 of this document and in chapter 5 of the NOPR TSD.

D. Energy Savings

For each trial standard level (''TSL''), DOE projected energy savings from application of the TSL to room ACs purchased in the 30-year period that begins in the year of compliance with the proposed standards (2026–2055).[16] The savings are measured over the entire lifetime of a room AC purchased in the previous 30-year period. DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the no-new-standards case. The no-new-standards case represents a projection of energy consumption that reflects how the market for a product would likely evolve in the absence of amended energy conservation standards.

DOE used its national impact analysis (''NIA'') spreadsheet model to estimate national energy savings (''NES'') from potential amended or new standards for room ACs. The NIA spreadsheet model (described in section IV.H of this document) calculates energy savings in terms of site energy, which is the energy directly consumed by products at the locations where they are used. For electricity, DOE reports national energy savings in terms of primary energy savings, which is the savings in the energy that is used to generate and transmit the site electricity. DOE also calculates NES in terms of full-fuel cycle (''FFC'') energy savings. The FFC metric includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and thus presents a more complete picture of the impacts of energy conservation standards.[17] DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered products or equipment. For more information on FFC energy savings, see section IV.H.2 of this document.

1. Significance of Savings

To adopt any new or amended standards for a covered product, DOE must determine that such action would result in significant energy savings. (42 U.S.C. 6295(o)(3)(B)) Although the term ''significant'' is not defined in the EPCA, the U.S. Court of Appeals, for the District of Columbia Circuit in *Natural Resources Defense Council* v. *Herrington,* 768 F.2d 1355, 1373 (D.C. Cir. 1985), opined that Congress intended ''significant'' energy savings in the context of EPCA to be savings that were not ''genuinely trivial.''

The significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a

[16] Each TSL is composed of specific efficiency levels for each product class. The TSLs considered for this NOPR are described in section V.A of this document. DOE conducted a sensitivity analysis that considers impacts for products shipped in a 9-year period.

[17] The FFC metric is discussed in DOE's statement of policy and notice of policy amendment. 76 FR 51282 (Aug. 18, 2011), as amended at 77 FR 49701 (Aug. 17, 2012).

given rulemaking.[18] For example, the United States recently rejoined the Paris Agreement and will exert leadership in confronting the climate crisis. These actions have placed an increased emphasis on the importance of energy savings that reduce greenhouse gas emissions and help mitigate the climate crisis. Additionally, some covered products and equipment, particularly those providing space cooling, such as room ACs, are likely to consume significant energy during periods of peak energy demand. The impacts of these products on the energy infrastructure can be more pronounced than products with relatively constant demand. Lastly, in evaluating the significance of energy savings, DOE considers differences in primary energy and FFC effects for different covered products and equipment when determining whether energy savings are significant. Primary energy and FFC effects include the energy consumed in electricity production (depending on load shape), in distribution and transmission, and in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and thus present a more complete picture of the impacts of energy conservation standards.

Accordingly, DOE is evaluating the significance of energy savings on a case-by-case basis. DOE has initially determined the energy savings for the TSL proposed in this rulemaking are nontrivial, and, therefore, DOE considers them ''significant'' within the meaning of 42 U.S.C. 6295(o)(3)(B).

E. Economic Justification

1. Specific Criteria

As noted previously, EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII)) The following sections discuss how DOE has addressed each of those seven factors in this proposed rulemaking.

a. Economic Impact on Manufacturers and Consumers

In determining the impacts of a potential amended standard on manufacturers, DOE conducts an MIA, as discussed in section IV.J of this document. DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and capital requirements during the period between when a regulation is issued and when entities must comply with the regulation—and a long-term assessment over a 30-year period. The industry-wide impacts analyzed include (1) INPV, which values the industry on the basis of expected future cash flows, (2) cash flows by year, (3) changes in revenue and income, and (4) other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other product-specific regulatory requirements on manufacturers.

For individual consumers, measures of economic impact include the changes in LCC and PBP associated with new or amended standards. These measures are discussed further in the following section. For consumers in the aggregate, DOE also calculates the national net present value of the consumer costs and benefits expected to result from particular standards. DOE also evaluates the impacts of potential standards on identifiable subgroups of consumers that may be affected disproportionately by a standard.

b. Savings in Operating Costs Compared to Increase in Price (LCC and PBP)

EPCA requires DOE to consider the savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered product that are likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(II)) DOE conducts this comparison in its LCC and PBP analysis.

The LCC is the sum of the purchase price of a product (including its installation) and the operating expense (including energy, maintenance, and repair expenditures) discounted over the lifetime of the product. The LCC analysis requires a variety of inputs, such as product prices, product energy consumption, energy prices, maintenance and repair costs, product lifetime, and discount rates appropriate for consumers. To account for uncertainty and variability in specific inputs, such as product lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value.

The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost due to a more-stringent standard by the change in annual operating cost for the year that standards are assumed to take effect.

For its LCC and PBP analysis, DOE assumes that consumers will purchase the covered products in the first year of compliance with new or amended standards. The LCC savings for the considered efficiency levels are calculated relative to the case that reflects projected market trends in the absence of new or amended standards. DOE's LCC and PBP analysis is discussed in further detail in section IV.F of this document.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for adopting an energy conservation standard, EPCA requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section III.D of this document, DOE uses the NIA spreadsheet models to project national energy savings.

d. Lessening of Utility or Performance of Products

In establishing product classes and in evaluating design options and the impact of potential standard levels, DOE evaluates potential standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) Based on data available to DOE, the standards proposed in this document would not reduce the utility or performance of the products under consideration in this rulemaking.

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from a proposed standard. (42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination to the Secretary within 60

[18] The numeric threshold for determining the significance of energy savings established in a final rule published on February 14, 2020 (85 FR 8626, 8670), was subsequently eliminated in a final rule published on December 13, 2021 (86 FR 70892).

days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) DOE will transmit a copy of this proposed rule to the Attorney General with a request that the Department of Justice (''DOJ'') provide its determination on this issue. DOE will publish and respond to the Attorney General's determination in the final rule. DOE invites comment from the public regarding the competitive impacts that are likely to result from this proposed rule. In addition, stakeholders may also provide comments separately to DOJ regarding these potential impacts. See the **ADDRESSES** section for information to send comments to DOJ.

f. Need for National Energy Conservation

DOE also considers the need for national energy and water conservation in determining whether a new or amended standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(VI)) The energy savings from the proposed standards are likely to provide improvements to the security and reliability of the Nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the Nation's electricity system. DOE conducts a utility impact analysis to estimate how standards may affect the Nation's needed power generation capacity, as discussed in section IV.M of this document.

DOE maintains that environmental and public health benefits associated with the more efficient use of energy are important to take into account when considering the need for national energy conservation. The proposed standards are likely to result in environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases (''GHGs'') associated with energy production and use. As part of the analysis of the need for national energy and water conservation, DOE conducts an emissions analysis to estimate how potential standards may affect these emissions, as discussed in section IV.K of this document; the estimated emissions impacts are reported in section V.B.6 of this document.

g. Other Factors

In determining whether an energy conservation standard is economically justified, DOE may consider other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) To the extent DOE identifies any relevant information regarding economic justification that does not fit into the other categories described previously, DOE could consider such information under ''other factors.''

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the consumer of a product that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effects that proposed energy conservation standards would have on the payback period for consumers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable-presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to consumers, manufacturers, the Nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable presumption payback calculation is discussed in section IV.F.9 of this document.

IV. Methodology and Discussion of Related Comments

This section addresses the analyses DOE has performed for this proposed rulemaking with regard to room ACs. Separate subsections address each component of DOE's analyses.

DOE used several analytical tools to estimate the impact of the standards proposed in this document. The first tool is a spreadsheet that calculates the LCC savings and PBP of potential amended or new energy conservation standards. The national impacts analysis uses a second spreadsheet set that provides shipments projections and calculates national energy savings and net present value of total consumer costs and savings expected to result from potential energy conservation standards. DOE uses the third spreadsheet tool, the Government Regulatory Impact Model (''GRIM''), to assess manufacturer impacts of potential standards. These three spreadsheet tools are available on the DOE website for this proposed rulemaking: *www.regulations.gov/docket?D=EERE-2014-BT-STD-0059.* Additionally, DOE used output from the latest version of the Energy Information Administration's (''EIA's'') *Annual Energy Outlook* (''*AEO*''), a widely known energy projection for the United States, for the emissions and utility impact analyses.

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the products concerned, including the purpose of the products, the industry structure, manufacturers, market characteristics, and technologies used in the products. This activity includes both quantitative and qualitative assessments, based primarily on publicly-available information. The subjects addressed in the market and technology assessment for this proposed rulemaking include (1) a determination of the scope of the rulemaking and product classes, (2) manufacturers and industry structure, (3) existing efficiency programs, (4) shipments information, (5) market and industry trends, and (6) technologies or design options that could improve the energy efficiency of room ACs. The key findings of DOE's market assessment are summarized in the following sections. See chapter 3 of the NOPR TSD for further discussion of the market and technology assessment.

1. Scope of Coverage and Product Classes

In the June 2020 Preliminary Analysis, DOE did not identify any potential changes to the room AC scope of coverage or product classes. 85 FR 36512.

The Joint Commenters expressed concerns regarding DOE's current set of room AC product classes. (Joint Commenters, No. 20 at p. 1 [19]) The Joint Commenters disagreed with DOE's explanation that Product Classes 1 and 6 are necessary, despite having the same efficiency requirements as Product Classes 2 and 7, respectively, to recognize the value to certain consumer segments of a low-cost, low-cooling capacity room AC in Product Classes 1 and 6. They did not object to maintaining these product class distinctions based on cooling capacity, but suggested that cost must not be a rationale for maintaining the

[19] A notation in the form ''Joint Commenters, No. 20 at p. 1'' identifies a written comment: (1) Made by the Joint Commenters; (2) recorded in document number 20 that is filed in the docket of this energy conservation standards rulemaking (Docket No. EERE–2014–BT–STD–0059) and available for review at *www.regulations.gov;* and (3) which appears on page 1 of document number 20.

distinctions because cost is not a ''performance-related feature.'' *Id.*

DOE understands the Joint Commenters' concerns about cost being a rationale for distinguishing product classes. However, the cost is substantively related to the performance-related features used to distinguish between the product classes, namely product size and weight. The NOPR analysis, based on models currently on the market, identified different efficiency levels above the ENERGY STAR® qualification levels for Product Classes 1 and 2, showing that these product classes have performance-related distinctions between them.

While DOE is not proposing to combine product classes at this time, DOE is proposing a clarifying modification to the cooling capacity descriptors delineating the product classes, specifying that the capacity used to determine the product class of a basic model is the certified cooling capacity and expressing the capacity ranges to the nearest hundred British thermal units per hour (''Btu/h'') in accordance with the rounding instruction in 10 CFR 429.15(a)(3). For example, Product Class 2 currently specifies it includes room ACs with capacities ranging from 6,000 to 7,999 Btu/h; however, DOE recognizes that based on the rounding instruction in 10 CFR 429.15(a)(3), the upper range of this product class is, in practice, 7,900 Btu/h. Accordingly, DOE proposes in this NOPR to revise the threshold values of cooling capacity in the product class descriptions to the nearest hundred Btu/h that would not exceed the existing thresholds. DOE believes this slight modification that is being proposed for product class delineation is what manufacturers are using today in practice due to the rounding instruction at 10 CFR 429.15(a)(3) and will not impact compliance with current energy conservation standards. DOE is simply proposing to add clarity and consistency amongst two existing regulatory provisions.

DOE requests comment on the proposal to make clarifying amendments to the product class descriptions, but otherwise not make any changes to room AC product classes.

For ease of reviewing this NOPR, DOE is presenting the results of its analysis using the existing product class descriptions. The proposed new labeling of the product class thresholds using the rounded cooling capacity values are included in the proposed standards in Table I.1 and Table V.58 of this document.

2. Technology Options

In the preliminary market analysis and technology assessment, DOE identified 22 technology options that would likely improve the efficiency of room ACs, as measured by the DOE test procedure:

Table IV.1 Technology Options for Room Air Conditioners

Increased Heat Transfer Surface Area
1. Increased heat exchanger surface area (frontal area, fin density and depth of coil)
2. Condenser coil subcooler
3. Suction line heat exchanger
Increased Heat Transfer Coefficient
4. Improved fin and tube design
5. Hydrophilic coating on fins
6. Microchannel heat exchangers
7. Spray condensate on condenser coil
Component Improvements
8. Improved indoor blower and outdoor fan blade design
9. Improved blower/fan motor design
10. Improved compressor efficiency
Improved Installation, Insulation, and Airflow
11. Improved installation materials
12. Reduced evaporator air recirculation
13. Reduced thermal bridging and internal air leakage
Part-load Performance
14. Variable-speed compressors
15. Variable-speed drive fans and blowers
16. Thermostatic or electronic expansion valves
17. Thermostatic cyclic controls
18. Air and water economizers
Standby Power Improvements
19. Low standby-power electronics
20. High frequency switching power supply
Alternative Refrigerants
21. SNAP-approved refrigerants (R-32, R-441A, and R-290)
Other Improvements
22. Washable air filters

Several commenters provided feedback on some of these technology options. These comments are summarized below, along with DOE's responses.

a. Reduced Evaporator Air Recirculation

The Joint Commenters referenced a 2013 National Renewable Energy Laboratory (''NREL'') study in which room AC performance was found to degrade with evaporator air recirculation, with the cooling coefficient of performance (''COP'') decreasing by 7 percent on average.[20] [21] The Joint Commenters emphasized NREL's conclusion that the room AC energy efficiency ratio (''EER'') could be improved by at least 1 Btu/Wh using simple and low-cost methods such as supplying air from the bottom rather than the top of the interior face, or providing an attachment fin to separate supply and return airflows. The Joint Commenters noted that DOE mentioned the results of this NREL study in the preliminary TSD but did not consider reduced evaporator air recirculation in the engineering analysis. Thus, given the large potential energy savings, the Joint Commenters urged DOE to investigate how to model the efficiency improvement associated with reduced evaporator air recirculation. (Joint Commenters, No. 20 at p. 2)

DOE is aware of, and has reviewed the 2013 NREL study cited by the Joint Commenters, and notes that that study had a limited sample of four room ACs from only two different manufacturers (Frigidaire and GE/Haier), and found a wide range of COP degradation due to evaporator air recirculation, from losses as low as 2 percent to as high as 19 percent. Without intensive airflow modeling of each unit analyzed in the DOE teardown sample, more data on evaporator air recirculation in the market as a whole, and test data from a unit incorporating the sort of airflow changes suggested by NREL (DOE is not aware of such a unit on the market), DOE is unable to properly assess the impacts, both positive and negative of evaporator air recirculation reduction as a technology. Therefore, DOE is not incorporating this technology into its engineering analysis. DOE seeks

[20] As determined using experimental infrared camera imaging techniques applied to units outside of controlled calorimeter chamber conditions.

[21] *s3.amazonaws.com/szmanuals/f50601c1a4960b3d7627df44cc951d28.*

additional comment on whether evaporator air recirculation should be included in the engineering analysis.

b. Compressors

AHAM and GEA stated that their data do not support DOE's assumptions regarding the efficiency of single-speed compressors. (AHAM, No. 19 at p. 12; GEA, No. 26 at pp. 1–2)

Feedback given to DOE by manufacturers during interviews supported the commenters' assertion that the efficiency of the most efficient single-speed compressor available was overestimated in the June 2020 Preliminary Analysis. Upon further analysis, DOE has reduced its estimate for the efficiency of the most efficient single-speed R–410a compressor available, from 13.1 to 10.9 Btu/Wh, based on a comprehensive survey of compressor catalogues and information provided by manufacturers, as discussed further in chapter 3 of the NOPR TSD. However, as discussed below, DOE also implemented a changeover from R–410A to R–32 refrigerant, resulting in the most efficient available single-speed compressor being 12.7 Btu/Wh. DOE requests comment on the updated single-speed compressor maximum efficiency estimates.

c. Significant New Alternatives Policy (SNAP)—Approved Refrigerants

In the June 2020 Preliminary Analysis, DOE discussed the potential for alternative refrigerants, restricted to the Significant New Alternatives Policy (''SNAP'')—approved refrigerants (*i.e.,* R–32, R–441A, R–290),[22] but decided to forgo implementing them in the engineering analysis because they either did not significantly improve unit efficiency or DOE lacked sufficient technical and economic data to assess the costs and benefits of a changeover. AHAM, the California IOUs, Joint Commenters, and NEEA disagreed with DOE's decision not to consider these alternative refrigerants in the engineering analysis. They stated that alternative refrigerants are already in use for some product classes to meet current energy conservation standards (baseline) and ENERGY STAR (Efficiency Level (''EL 2'')) levels. (AHAM, No. 19 at pp. 10–11; California IOUs, No. 23 at p. 3; Joint Commenters, No. 20 at p. 2; NEEA, No. 24 at pp. 4–5; NEEA, Public Meeting Transcript, No. 18 at pp. 59–60)[23] AHAM emphasized the significant costs associated with changing refrigerant type. (AHAM, No. 19 at pp. 10–11) The California IOUs, Joint Commenters, and NEEA specifically noted that room ACs using R–32 are now widely available in the United States, suggesting that the use of alternative refrigerants is not cost prohibitive to manufacturers, as DOE stated in the preliminary TSD. NEEA stated that manufacturers using R–32 in air conditioning systems have generally found energy savings ranging from 8 to 11 percent. AHAM, the California IOUs, and NEEA noted that there is currently a proposed rule from the California Air Resource Board (''CARB'') that would ban all refrigerants with global warming potential (''GWP'') equal to or greater than 750 in new residential and commercial AC systems beginning in 2023 and would likely push additional manufacturers to explore alternative refrigerants.[24] (AHAM, No. 19 at pp. 10–11; California IOUs, No. 23 at p. 3; Joint Commenters, No. 20 at p. 2; NEEA, No. 24 at pp. 4–5; NEEA, Public Meeting Transcript, No. 18 at pp. 59–60) The Joint Commenters referenced a study performed by the Oak Ridge National Laboratory (''ORNL'') in which ORNL developed a high-efficiency room AC to determine the viability of a window AC unit with an EER over 13.0 Btu/Wh and found that using a ''drop-in'' 85-percent R–32 mixture as the refrigerant in place of R–410A boosted efficiency by about 3 percent and, thus, that pure R–32 would offer an additional efficiency gain. The Joint Commenters referenced another ORNL study in which a room AC unit was modified to use propane (R–290) and demonstrated an increase in EER of 17 percent. The Joint Commenters also stated that, while any cost impacts to consumers and/or manufacturers should be considered as part of the economic analysis, cost cannot be a consideration in determining what is technologically feasible. (Joint Commenters, No. 20 at p. 2) Thus, AHAM, the California IOUs, Joint Commenters, and NEEA urged DOE to further investigate alternative refrigerants as a technology option. (AHAM, No. 19 at pp. 10–11; California IOUs, No. 23 at p. 3; Joint Commenters, No. 20 at p. 2; NEEA, No. 24 at pp. 4–5) NEEA specifically urged DOE to consider R–32. (NEEA, No. 24 at pp. 4–5) The California IOUs encouraged DOE to work closely with CARB, the American Society of Heating, Refrigerating and Air-Conditioning Engineers (''ASHRAE'') Standing Standard Project Committee 15—Safety Standard for Refrigeration Systems, and the Air-Conditioning, Heating, and Refrigeration Institute (''AHRI'') Low-GWP Alternative Refrigeration Evaluation Program to address in this rulemaking the efficiency benefits from using low-GWP refrigerants in room ACs. (California IOUs, No. 23 at p. 3)

DOE is aware that R–32 refrigerant is currently in use in the room AC market and that adoption of the refrigerant in room ACs is increasing, in part due to the CARB regulation regarding low-GWP refrigerants. R–32 has a GWP of 675, just under a third of the GWP of R–410a, which is 2,090. However, the research findings on efficiency impacts due to the transition from R–410A to R–32 are inconsistent, ranging from a 2-percent decrease in efficiency to the 8- to 11-percent increase cited by NEEA. Due to these inconsistent data, DOE did not consider efficiency gains due to R–32 implementation alone. However, as discussed previously, DOE found that the most efficient single-speed compressors available on the market use R–32 refrigerant, so DOE did incorporate a changeover to R–32 in the engineering analysis to capture the compressor efficiency gains that are technologically feasible by implementing improved-efficiency single-speed compressors (which use R–32 refrigerant) in place of existing baseline-efficiency single-speed compressors (which use R–410A refrigerant). DOE requests comment on the approach to addressing alternative refrigerants in this engineering analysis.

B. Screening Analysis

DOE uses the following five screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production and reliable installation and servicing of a technology in commercial products could not be achieved on the scale

[22] For the latest information on EPA SNAP regulations, visit: *www.epa.gov/snap/snap-regulations.*

[23] A notation in the form ''NEEA, Public Meeting Transcript, No. 18 at pp. 59–60'' identifies an oral comment that DOE received on August 25, 2020 during the public meeting, and was recorded in the public meeting transcript in the docket for this energy conservation standards rulemaking (Docket No. EERE–2014–BT–STD–0059). This particular notation refers to a comment (1) made by the Northwest Energy Efficiency Alliance during the public meeting; (2) recorded in document number 18, which is the public meeting transcript that is filed in the docket of this energy conservation standards rulemaking; and (3) which appears on pages 59 through 60 of document number 18.

[24] See *https://ww2.arb.ca.gov/rulemaking/2020/hfc2020* for more information on the CARB refrigerant rulemaking.

necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility or product availability.* If it is determined that a technology would have significant adverse impact on the utility of the product to significant subgroups of consumers or would result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the United States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

(5) *Unique-Pathway Proprietary Technologies.* If a design option utilizes proprietary technology that represents a unique pathway to achieving a given efficiency level, that technology will not be considered further due to the potential for monopolistic concerns.

Sections 6(b)(3) and 7(b) of appendix A.

In summary, if DOE determines that a technology, or a combination of technologies, fails to meet one or more of the listed five criteria, it will be excluded from further consideration in the engineering analysis. The subsequent sections include comments from interested parties pertinent to the screening criteria, DOE's evaluation of each technology option against the screening analysis criteria, and whether DOE determined that a technology option should be excluded (''screened out'') based on the screening criteria.

1. Screened-Out Technologies

In the June 2020 Preliminary Analysis, DOE considered screening out air and water economizers and suction-line heat exchangers in the screening analysis, based on their negative impacts on product utility to consumers and on manufacturing impracticality.

AHAM agreed with DOE screening out these technologies. AHAM stated, as DOE noted, air and water economizers and suction line heat exchangers would increase the size and weight of room ACs, which would negatively impact consumer utility and require retooling. AHAM further stated that suction line heat exchangers could also decrease compressor lifetime. (AHAM, No. 19 at p. 10)

DOE agrees with the comments made by AHAM and proposes to screen out the same technologies in this NOPR analysis. For additional details, see chapter 4 of the NOPR TSD. DOE requests comment on the technologies screened out in the NOPR screening analysis.

2. Remaining Technologies

Through a review of each technology, DOE tentatively concludes that all of the other identified technologies listed in section IV.A.2 of this document met all five screening criteria to be examined further as design options in DOE's NOPR analysis. In summary, DOE did not screen out the following technology options:

Table IV.2 Retained Design Options for Room Air Conditioners

Increased Heat Transfer Surface Area
1. Increased heat exchanger surface area (frontal area, fin density and depth of coil)
2. Condenser coil subcooler
Increased Heat Transfer Coefficient
3. Improved fin and tube design
4. Hydrophilic coating on fins
5. Microchannel heat exchangers
6. Spray condensate on condenser coil
Component Improvements
7. Improved indoor blower and outdoor fan blade design
8. Improved blower/fan motor design
9. Improved compressor efficiency
Improved Installation, Insulation, and Airflow
10. Improved installation materials
11. Reduced evaporator air recirculation
12. Reduced thermal bridging and internal air leakage
Part-Load Performance
13. Variable-speed compressors
14. Variable-speed drive fans and blowers
15. Thermostatic or electronic expansion valves
16. Thermostatic cyclic controls
Standby Power Improvements
17. Low standby-power electronics
Alternative Refrigerants
18. SNAP-approved refrigerants (R-32, R-441A, and R-290)
Other Improvements
19. Washable air filters

DOE determined that these technology options are technologically feasible because they are being used or have previously been used in commercially available products or working prototypes. DOE also finds that all of the remaining technology options meet the other screening criteria (*i.e.,* practicable to manufacture, install, and service; do not result in adverse impacts on consumer utility, product availability, health, or safety; and do not represent unique-pathway proprietary technologies). For additional details, see chapter 4 of the NOPR TSD.

C. Engineering Analysis

The purpose of the engineering analysis is to establish the relationship between the efficiency and cost of room ACs. There are two elements to consider in the engineering analysis; the selection of efficiency levels to analyze (*i.e.,* the ''efficiency analysis'') and the determination of product cost at each efficiency level (*i.e.,* the ''cost analysis''). In determining the performance of higher-efficiency products, DOE considers technologies and design option combinations not eliminated by the screening analysis. For each product class, DOE estimates the baseline cost, as well as the incremental cost for the product at efficiency levels above the baseline. The output of the engineering analysis is a set of cost-efficiency ''curves'' that are used in downstream analyses (*i.e.,* the LCC and PBP analyses and the NIA).

1. Efficiency Analysis

DOE typically uses one of two approaches to develop energy efficiency levels for the engineering analysis: (1) Relying on observed efficiency levels in the market (*i.e.,* the efficiency-level approach), or (2) determining the incremental efficiency improvements associated with incorporating specific design options to a baseline model (*i.e.,* the design-option approach). Using the efficiency-level approach, the efficiency levels established for the analysis are determined based on the market distribution of existing products (in other words, based on the range of efficiencies and efficiency level ''clusters'' that already exist on the market). Using the design option approach, the efficiency levels established for the analysis are determined through detailed engineering calculations and/or computer simulations of the efficiency improvements from implementing specific design options that have been identified in the technology assessment. DOE may also rely on a combination of these two approaches. For example, the efficiency-level approach (based on actual products on the market) may be extended using the design option approach to ''gap fill'' levels (to bridge large gaps between other identified efficiency levels) and/or to extrapolate to the max-tech level (particularly in cases where the max-tech level exceeds

the maximum efficiency level currently available on the market).

In this proposed rulemaking, DOE relies on a combination of these two approaches. For each product class, DOE analyzed a few units from different manufacturers to ensure the analysis was representative of various designs on the market. The analysis involved physically disassembling commercially available products, reviewing publicly available cost information, and modeling equipment cost. From this information, DOE estimated the manufacturer production costs (''MPCs'') for a range of products currently available on the market. DOE then considered the design options manufacturers would likely rely on to improve product efficiencies. From this information, DOE estimated the cost and efficiency impacts of incorporating specific design options at each efficiency level.

DOE analyzed six efficiency levels as part of the engineering analysis: (1) The current DOE standard (baseline); (2) an intermediate level above the baseline but below the ENERGY STAR level, either halfway between the two or at a level where a number of models were certified (EL 1); (3) the ENERGY STAR efficiency criterion (EL 2); (4) the efficiency attainable by a unit with the most efficient R–32 single-speed compressor on the market (EL 3); (5) an intermediate level representing the efficiency of variable-speed units on the market, as tested by DOE using the recently amended test procedure (EL 4); and (6) the maximum technologically feasible (max-tech) efficiency (EL 5).

In evaluating the technologies manufacturers could use to achieve the analyzed efficiency levels, DOE considered design options which made the largest impact on unit efficiency and for which the cost-efficiency relationship was well defined. Accordingly, DOE implemented increased heat exchanger area, condenser coil subcoolers, improved blower motor efficiency, improved compressor efficiency, variable-speed compressors, and low standby-power electronic controls as design options, some or all of which were used to estimate the cost required to reach each efficiently level. DOE did not consider for analysis certain technologies that met the screening criteria but were unable to be evaluated for one or more of the following reasons: (1) Data are not available to evaluate the energy efficiency characteristics of the technology, (2) available data suggest that the efficiency benefits of the technology are negligible, and (3) certain technologies cannot be measured according to the conditions and methods specified in the existing test procedure. Further information on how the design options were chosen and implemented in the engineering analysis is available in chapter 5 of the NOPR TSD.

a. Baseline Efficiency

For each product class, DOE generally selects a baseline model as a reference point for each class, and measures changes resulting from potential energy conservation standards against the baseline. The baseline model in each product class represents the characteristics of a product typical of that class (*e.g.,* capacity, physical size). Generally, a baseline model is one that just meets current energy conservation standards, or, if no standards are in place, the baseline is typically the most common or least efficient unit on the market.

For this NOPR, DOE selected 19 baseline units, of the 48 total units selected, that fell within 12 of the 16 room AC product classes as reference points for each analyzed product class, against which DOE measured changes that would result from amended energy conservation standards to support the engineering, LCC, and PBP analyses. The baseline units in each of the analyzed product classes represent the basic characteristics of equipment in that class

b. Higher Efficiency Levels

As part of DOE's analysis, the maximum available efficiency level is the highest efficiency unit currently available on the market. DOE also defines the ''max-tech'' efficiency level to represent the maximum possible efficiency for a given product. As discussed in chapter 5 of the NOPR TSD, for the max-tech level, DOE modeled replacing permanent split capacitor (''PSC'') fan motors with more efficient electronically commutated motors (''ECMs''), replacing single-speed compressors with the maximum efficiency variable-speed compressors available, reducing standby power to the minimum observed in DOE's teardown sample, and increasing the cabinet and heat exchanger to the largest feasible sizes to improve efficiency. For all product classes, the max-tech level identified for EL 5 exceeds any other regulatory or voluntary efficiency criteria currently in effect.

DOE notes that the max-tech level is based entirely on modeled combinations of design options that have not yet been combined in a commercially available product. Notably, the key design option, variable-speed compressors, are nascent in room ACs, and because there are no models on the market or prototypes that implement these highest efficiency variable-speed compressors, the efficiency level at max-tech for each product class is a numerical estimation. This is in contrast to the variable-speed compressors currently implemented in room ACs on the market today, for which performance has been characterized through testing. Furthermore, the room AC test procedure measures variable-speed unit performance differently than test procedures for other air conditioning products, so limited performance and efficiency data are available for the most efficient examples of this emergent technology for room ACs.

Additionally, the most efficient variable-speed compressors that were implemented in the analysis at the max-tech efficiency level are manufactured by one manufacturer and have rated EERs between 11.2 and 11.7 Btu/Wh, with a range of rated capacities between 4,705 Btu/h and 16,170 Btu/h. Given the lack of information regarding availability of these highest efficiency variable-speed compressors, and the limited number of variable-speed compressors rated at or near the compressors considered for the max-tech efficiency level, there may not be widespread availability of these high-efficiency variable-speed compressors.

The Joint Commenters and NEEA encouraged DOE to consider evaluating additional efficiency levels, particularly an intermediate level between EL 3 and EL 4. According to the Joint Commenters and NEEA, the most efficient products available today fall between these two efficiency levels. (Joint Commenters, No. 20 at pp. 2–3; NEEA, No. 24 at pp. 3 and 7) DOE agrees that the most efficient available units should be represented in the engineering analysis. In particular, variable-speed models, of which an increasing number of models are available, were not included in a separate efficiency level in the preliminary engineering analysis as a stand-alone design option. Therefore, DOE included a new efficiency level (EL 4) in the NOPR engineering analysis, between EL 3 and the max-tech level (EL 4 in the preliminary analysis, now EL 5 for this NOPR). This new EL 4 is an intermediate efficiency level that represents the efficiency of variable-speed units on the market, as tested by DOE using the recently amended test procedure. DOE modeled all teardown units to reach this efficiency level in the engineering analysis by replacing each single-speed compressor with a variable-speed compressor and

adjusting the rated efficiency of the modeled variable-speed compressor to achieve the target overall CEER value. DOE requests comment on the new efficiency level (EL 4) in the engineering analysis.

AHAM and GEA stated that any energy standard levels achievable only with variable-speed compressors should not be selected and asserted that EL 3 and above would require the use of variable-speed compressors. AHAM and GEA further stated that manufacturers would likely begin using variable-speed compressors to meet energy conservation standards at EL 3. GEA supported AHAM's position and noted that incorporating variable-speed compressors into existing room AC units requires platform-level changes to room AC designs and manufacturing facilities. GEA further stated that, while variable-speed compressors are becoming available in some products, the technology is not sufficiently cost-effective to use as the basis for setting an energy standard level for this proposed rulemaking. Thus, AHAM and GEA urged DOE to adjust its analysis to reflect the use of variable-speed compressors at EL 3. (AHAM, No. 19 at pp. 11–12; GEA, No. 26 at pp. 1–2)

As discussed in section IV.A.2.b of this document, DOE adjusted its estimated efficiency for the most efficient available single-speed compressors, thus slightly reducing the CEER level for EL 3, but along with the additional proposed changeover to more efficient compressors that use R–32 refrigerant, room ACs that implement single-speed compressors are still expected to meet EL 3. Therefore, DOE did not revise its analysis to assume that the use of variable-speed compressors would be necessary to achieve EL 3. DOE requests comment on the approach to design EL 3 as the level reached by the most efficient single-speed room ACs.

2. Cost Analysis

The cost analysis portion of the engineering analysis is conducted using one or a combination of cost approaches. The selection of cost approach depends on a suite of factors, including the availability and reliability of public information, characteristics of the regulated product, the availability and timeliness of purchasing the product on the market. The cost approaches are summarized as follows:

- *Physical teardowns:* Under this approach, DOE physically dismantles a commercially available product, component-by-component, to develop a detailed bill of materials for the product.
- *Catalog teardowns:* In lieu of physically deconstructing a product, DOE identifies each component using parts diagrams (available from manufacturer websites or appliance repair websites, for example) to develop the bill of materials (''BOM'') for the product.
- *Price surveys:* If neither a physical nor catalog teardown is feasible (for example, for tightly integrated products such as fluorescent lamps, which are infeasible to disassemble and for which parts diagrams are unavailable) or cost-prohibitive and otherwise impractical (*e.g.,* large commercial boilers), DOE conducts price surveys using publicly available pricing data published on major online retailer websites and/or by soliciting prices from distributors and other commercial channels.

In the present case, DOE conducted the analysis using physical teardowns. The resulting BOM provides the basis for the MPC estimates. DOE estimated the cost of the highest efficiency single-speed and variable-speed compressors implemented in EL 3 and EL 5, respectively, by extrapolating the costs from price surveys of other compressors. DOE used this approach because, as discussed previously, DOE is not aware of these most efficient single-speed and variable-speed compressors being implemented in any available room ACs to date.

3. Cost-Efficiency Results

The results of the engineering analysis are presented as cost-efficiency data for each of the efficiency levels for each of the product classes that were analyzed, as well as those extrapolated from a product class with similar cooling capacity and features. DOE developed estimates of MPCs for each unit in the teardown sample, and also performed additional modeling for each of the teardown samples, to develop a comprehensive set of MPCs at each efficiency level. DOE then consolidated the resulting MPCs for each of DOE's teardown units and modeled units using a weighted average for product classes in which DOE analyzed units from multiple manufacturers. DOE's weighting factors were based on a market penetration analysis for each of the manufacturers within each product class. The resulting weighted-average incremental MPCs (*i.e.,* the additional costs manufacturers would likely incur by producing room ACs at each efficiency level compared to the baseline) are provided in Tables 5.5.5 and 5.5.6 in chapter 5 of the NOPR TSD. See chapter 5 of the NOPR TSD for additional detail on the engineering analysis. DOE requests comment on the incremental MPCs from the NOPR engineering analysis.

D. Markups Analysis

The markups analysis develops appropriate markups (*e.g.,* retailer markups, distributor markups, contractor markups) in the distribution chain and sales taxes to convert the MPC estimates derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analysis and in the manufacturer impact analysis. At each step in the distribution channel, companies mark up the price of the product to cover business costs and profit margin.

To account for manufacturers' non-production costs and profit margin, DOE applied a non-production cost multiplier (the manufacturer markup) to the MPC. The resulting manufacturer selling price (''MSP'') is the price at which the manufacturer distributes a unit into commerce. DOE developed an average manufacturer markup by examining the annual Securities and Exchange Commission (''SEC'') 10–K reports filed by publicly traded manufacturers primarily engaged in appliance manufacturing and whose combined product range includes room ACs.

For room ACs, DOE further developed baseline and incremental markups for each link in the distribution chain (after the product leaves the manufacturer). Baseline markups are applied to the price of products with baseline efficiency, while incremental markups are applied to the difference in price between baseline and higher-efficiency models (the incremental cost increase). The incremental markup is typically less than the baseline markup and is designed to maintain similar per-unit operating profit before and after new or amended standards.[25]

DOE relied on economic data from the U.S. Census Bureau to estimate average baseline and incremental markups. Specifically, DOE used the 2017 Annual Retail Trade Survey for the ''electronics and appliance stores'' sector to develop retailer markups;[26] and the 2017 Annual Wholesale Trade Survey for the ''household appliances, and electrical and electronic goods merchant

[25] Because the projected price of standards-compliant products is typically higher than the price of baseline products, using the same markup for the incremental cost and the baseline cost would result in higher per-unit operating profit. While such an outcome is possible, DOE maintains that in markets that are reasonably competitive it is unlikely that standards would lead to a sustainable increase in profitability in the long run.

[26] U.S. Census Bureau, *Annual Retail Trade Survey.* 2017. *www.census.gov/programs-surveys/arts.html.*

wholesalers'' sector to estimate wholesaler markups.[27]

Chapter 12 of the NOPR TSD provides additional detail on the manufacturer markup and chapter 6 of this NOPR TSD provides additional detail on DOE's development of the baseline and incremental retail markups.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of room ACs at different efficiencies in representative U.S. single-family homes, multi-family residences, manufactured housing, and commercial buildings, and to assess the energy savings potential of increased room AC efficiency. The energy use analysis estimates the range of energy use of room ACs in the field (*i.e.,* as they are actually used by consumers). The energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the monetary savings in consumer operating costs that could result from adoption of amended or new standards.

To estimate annual room AC use and energy consumption in the June 2020 Preliminary Analysis, DOE first calculated the number of operating hours in cooling mode for each room AC in the residential and commercial samples using the reported energy use for room air conditioning in the Residential Energy Consumption Survey (''RECS'') 2015 [28] and Commercial Building Energy Consumption Survey (''CBECS'') 2012,[29] along with estimates of the EER of the room AC(s) in each sample home or building. DOE based the latter on the reported age (or simulated age) of the unit and historical data on shipment-weighted average EER. In the June 2020 Preliminary Analysis, the estimated mean number of cooling mode operating hours for the residential room AC sample is 912 hours for the 6,000 to 7,999 Btu/h product class, 636 hours for the 8,000 to 13,999 Btu/h product classes, 422 hours for the 14,999 to 19,999 Btu/h product class, and 261 hours for the ≥20,000 Btu/h product class. The estimated mean number of cooling mode operating hours for the commercial room AC sample is 746 hours for the 6,000 to 7,999 Btu/h product class, 868 hours for the 8,000 to 13,999 Btu/h product classes, 921 hours for the 14,999 to 19,999 Btu/h product class, and 1,073 hours for the ≥20,000 Btu/h product class. DOE assumed that units plugged in, but not in cooling mode, would be in standby mode and included the contribution of standby power consumption in its energy use model.

AHAM agreed that, in the absence of field data on annual operating hours, DOE should use the most recent version of RECS and CBECS to establish the annual operating hours for residential room ACs. (AHAM, No. 19 at p. 15)

NEEA believes DOE has identified energy savings associated with room ACs, but contends that there are more energy savings achievable. NEEA encourages DOE to look at more of the efficiency technology options and how they perform the energy analysis in order to get more savings. (NEEA, Public Meeting Transcript, No. 18 at pp. 8–9) NEEA suggested modifying the energy use analysis to capture more of the benefits of other technologies in the market that are not necessarily captured in the current test procedure. (*Id.* at pp. 57–58)

DOE notes that the standards rulemaking must recommend efficiency levels that are both economically justified and technologically feasible. The availability of technologies used to achieve different efficiency levels are identified in the market and technology assessment (see chapter 3 of the NOPR TSD). DOE's engineering analysis analyzes technologies in currently available room AC units. The energy use analysis uses the efficiency levels and power consumption values from the engineering analysis. Estimates for energy consumption are based on available data of how room ACs are operated in the field. DOE welcomes information about additional technologies that can be analyzed in the rulemaking process.

NEEA recommended that DOE include fan-only hours in its analysis and take into account energy savings from variable-speed fans and motors. NEEA stated that fan-only operation is likely to account for a significant number of operating hours, resulting in a significant portion of overall energy use. (NEEA, No. 24 at p. 5) Rice suggested measuring the energy consumption of the fan-mode during cooling mode operation when the fan typically runs continuously while the compressor cycles. If it is not accounted for, Rice recommended, at a minimum, that the energy use information on the Energy Label indicate that the energy costs is based on the economy mode setting. (Rice, No. 25 at p. 3)

DOE is unaware of a data set that can be used to estimate the amount of time room ACs spend in fan-only mode. For this NOPR analysis, DOE included the impact of fan-only mode energy consumption to the total energy use consumption, based on available data for portable ACs. Based on field metering data of portable ACs, fan-only mode is estimated at 30 percent of cooling mode hours.[30] DOE assumed that models below ENERGY STAR efficiency level would operate in fan-only mode 30 percent of cooling mode hours. For ELs that meet or exceed the ENERGY STAR level, DOE assumed a reduction in the amount of time the unit spent in fan-only mode based on the ENERGY STAR Version 4.2 for room ACs criterion requiring that the unit run in off-cycle fan mode less than 17 percent of the time spent in off-cycle mode. Thus, for ELs that meet or exceed the ENERGY STAR efficiency level, DOE assumed units would operate in fan-only mode 5 percent of cooling mode hours. DOE welcomes feedback on its approach and any additional data that can be provided to estimate the amount of time spent in fan-only mode.

DOE notes that the Federal Trade Commission is responsible for the information included on the yellow EnergyGuide labels.

Edison Electric Institute (''EEI'') noted that, in northern climates, many consumers unplug their units or even take them out of the windows during the wintertime, meaning the 8,000 standby hours value used in the annual energy use calculation formula could be an overestimate. EEI suggested gathering more data on this. (EEI, Public Meeting Transcript, No. 18 at pp. 51–52)

DOE agrees that many consumers unplug their room AC units in the non-cooling seasons in northern climates. However, DOE is not aware of reliable, publicly available data for hours spent in standby and off modes in room ACs. DOE recognizes that a room AC may be unplugged for a certain percentage of time, and, therefore, will not be in either standby mode or off mode. For the purposes of this NOPR analysis, DOE estimates that approximately half of room ACs are unplugged for half of the year. The ''unplugged'' time associated

[27] U.S. Census Bureau, *Annual Wholesale Trade Survey.* 2017. *www.census.gov/awts.*

[28] U.S. Department of Energy-Energy Information Administration, Residential Energy Consumption Survey, 2015 Public Use Microdata Files, 2015. Washington, DC. Available online at: *www.eia.doe.gov/emeu/recs/recspubuse15/pubuse15.html.* DOE will update all the 2015 RECS data to 2020 RECS if it is available prior to the final rule.

[29] U.S. Department of Energy-Energy Information Administration, Commercial Buildings Energy Consumption Survey, 2012 Public Use Microdata Files, 2012. Washington, DC. Available online at: *www.eia.doe.gov/emeu/cbecs/cbecspubuse12/pubuse12.html.* DOE will update all 2012 CBECS data to 2018 CBECS when it becomes available.

[30] Burke *et al.,* 2014. ''Using Field-Metered Data to Quantify Annual Energy Use of Residential Portable Air Conditioners.'' LBNL, Berkeley, CA. LBNL Report LBNL–6469E. September 2014.

with these units is averaged over all units. DOE estimates active mode based on RECS inputs and time spent in fan-only mode based on available data for portable ACs. Standby hours comprise the remaining time. See chapter 7 of the NOPR TSD for further discussion.

The California IOUs noted that, in the LCC Excel spreadsheet downloaded from DOE's website, for product class (''PC'') 2, the cooling mode operating hours are 2,922 hours, but for PC 3, the cooling mode operating hours are only 217 hours.[31] The California IOUs expressed concern at the cooling mode operating hour difference between PC 2 and PC 3. (California IOUs, Public Meeting Transcript, No. 18 at pp. 55–56)

DOE's LCC spreadsheet model uses a Monte Carlo simulation in its LCC calculations. Operating hours vary for each house in the household sample and are used as an input into the LCC calculations. The hours mentioned in the California IOUs comment represent the operating hours for one household in the sample and are not representative of the full household sample, or an entire Monte Carlo simulation. The average hours of use for the full sample used for each product class can be found in chapter 7 of the NOPR TSD.

Appliance Standards Awareness Project (''ASAP''), Rice, California IOUs, NEEA, and the Joint Commenters encouraged DOE to investigate modifications to the energy use model to account for potential energy savings by variable-speed units. ASAP stated that variable-speed units would be able to reduce cycling losses in addition to providing additional part-load benefits. (ASAP, Public Meeting Transcript, No. 18 at p. 54) Rice noted that DOE's energy use methodology in the June 2020 Preliminary Analysis does not capture the benefits of part load operation and suggested applying a performance adjustment factor (''PAF'') for ELs with variable-speed compressors. (Rice, No. 25 at p. 2) NEEA and the California IOUs further stated the energy use model in the June 2020 Preliminary Analysis only used the full-load energy EER of the compressors to calculate energy savings, meaning the analysis does not capture any inefficiencies due to single-speed compressor cycling at part load. (California IOUs, No. 23 at p. 2; NEEA, No. 24 at p. 5) The Joint Commenters noted that in addition to significantly reducing cycling losses, variable-speed operation improves heat exchanger effectiveness at reduced cooling loads, resulting in additional energy savings. (Joint Commenters, No. 20 at pp. 3–4)

For this NOPR analysis, DOE modified its approach to calculating energy use for models that use a variable-speed compressor to account for the reduced energy consumption during part load operation. Unlike single-speed compressors, variable-speed compressors have the ability to operate at part load depending on the cooling load. The amount of the time spent in part load operation will depend on the local climate of the household or business operating the room AC. For example, room ACs in milder climates will spend more time in part load operation relative to a household in a hot climate where a compressor is likely to run at maximum load. DOE accounted for geographic-dependent climate variability by calculating U.S. State-dependent PAFs using historical climate data spanning the period from 2008–2016 from the National Oceanic and Atmospheric Administration.[32] For each state in the U.S., DOE performed a temperature bin analysis to calculate within the cooling season (June through August) the fraction of time the outdoor dry bulb temperature was in one of four temperature bins: 80–84 degrees Fahrenheit (''°F''), 85–89 °F, 90–94 °F, and 95–99 °F. DOE then calculated the corresponding PAF for each state using the methodology developed for variable-speed drive units in the test procedure and applied the PAF to the EER at full load. DOE requests feedback on its approach to calculating the energy-use of variable-speed compressors and would welcome field metered data to further investigate the varying amounts of energy use due to single-speed and variable-speed units.

Rice stated that the off-cycle energy use term in the June 2020 Preliminary Analysis energy-use model is inappropriate for a variable-speed room AC. Rice stated that it should be modified to account for lower standby energy usage due to longer run times in the cooling season for variable-speed units in meeting the cooling season load. Rice notes that since DOE's calculation of energy use in cooling mode assumes operation at full rated cooling capacity, it is inappropriate for use in the standby energy use term for variable-speed room ACs. (Rice, No. 25 at p. 2)

DOE's test procedure requires that the low compressor speed at the low test condition achieve a capacity that is 47–57 percent of the ''peak'' rated capacity. Therefore, DOE would not expect a variable-speed compressor unit to enter off-cycle mode above loads 47 percent of the rated capacity, which is close to a representative of outdoor temperature conditions of 82 °F. In this NOPR analysis, DOE calculates the energy use of variable-speed units using a geographic-dependent performance adjustment factor to account for time the unit spends at partial load. DOE is unaware of a data-set that would allow for the estimation of the change in cooling run time of variable-speed units relative to a single-speed unit. DOE welcomes any available information or data that can be used to improve assumptions in the energy use model.

The California IOUs noted that DOE uses EER to estimate average annual energy use, however, only CEER is listed for each energy use results tables in chapter 7 of the preliminary TSD. To minimize confusion that CEER was used to calculate the average annual energy use, the California IOUs recommended that DOE add EER to energy use tables along with the corresponding CEER for each EL. (California IOUs, No. 23 at p. 3)

DOE has included both EER and CEER in the energy use results tables in the NOPR TSD.

Chapter 7 of the NOPR TSD provides details on DOE's energy use analysis for room ACs.

F. Life-Cycle Cost and Payback Period Analysis

DOE conducted LCC and PBP analyses to evaluate the economic impacts on individual consumers of potential energy conservation standards for room ACs. The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE used the following two metrics to measure consumer impacts:

☐ The LCC is the total consumer expense of an appliance or product over the life of that product, consisting of total installed cost (manufacturer selling price, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the product.

☐ The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP

[31] The Room Air Conditioning Life-Cycle Cost Analysis Spreadsheets (EERE–2014–BT–STD–0059–0010) can be found at *beta.regulations.gov/document/EERE-2014-BT-STD-0059-0010.*

[32] National Oceanic and Atmospheric Administration. *Quality Controlled Local Climate Data. www.ncdc.noaa.gov/cdo-web/.*

by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

For any given efficiency level, DOE measures the change in LCC relative to the LCC in the no-new-standards case, which reflects the estimated efficiency distribution of room ACs in the absence of new or amended energy conservation standards. In contrast, the PBP for a given efficiency level is measured relative to the baseline product.

For each considered efficiency level in each product class, DOE calculated the LCC and PBP for a nationally representative set of housing units and commercial buildings. As stated previously, DOE developed household samples from the 2015 RECS [33] and commercial building samples from the 2012 CBECS. For each sample household or building, DOE determined the energy consumption for the room AC and the appropriate energy price. By developing a representative sample of households and commercial buildings, the analysis captured the variability in energy consumption and energy prices associated with the use of room ACs.

Inputs to the calculation of total installed cost include the cost of the product—which includes MPCs, manufacturer markups, retailer and distributor markups, and sales taxes—and installation costs. Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, repair and maintenance costs, product lifetimes, and discount rates. DOE created distributions of values for product lifetime, discount rates, and sales taxes, with probabilities attached to each value, to account for their uncertainty and variability.

The computer model DOE uses to calculate the LCC and PBP relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and room AC user samples. For this rulemaking, the Monte Carlo approach is implemented in MS Excel together with the Crystal Ball™ add-on.[34] The model calculated the LCC and PBP for products at each efficiency level for 10,000 housing units or commercial buildings per simulation run. The analytical results include a distribution of 10,000 data points showing the range of LCC savings for a given efficiency level relative to the no-new-standards case efficiency distribution. In performing an iteration of the Monte Carlo simulation for a given consumer, product efficiency is chosen based on its probability. If the chosen product efficiency is greater than or equal to the efficiency of the standard level under consideration, the LCC and PBP calculation reveals that a consumer is not impacted by the standard level. By accounting for consumers who already purchase more-efficient products, DOE avoids overstating the potential benefits from increasing product efficiency.

DOE calculated the LCC and PBP for all consumers of room ACs as if each were to purchase a new product in the expected year of required compliance with new or amended standards. Amended standards would apply to room ACs manufactured 3 years after the date on which any new or amended standard is published. (42 U.S.C. (m)(4)(A)(i)) For purposes of its analysis, DOE used 2026 as the first year of compliance with any amended standards for room ACs.

Table IV.3 summarizes the approach and data DOE used to derive inputs to the LCC and PBP calculations. The subsections that follow provide further discussion. Details of the spreadsheet model, and of all the inputs to the LCC and PBP analyses, are contained in chapter 8 of the NOPR TSD and its appendices.

Table IV.3 Summary of Inputs and Methods for the LCC and PBP Analysis*

Inputs	Source/Method
Product Cost	Derived by multiplying MPCs by manufacturer and retailer markups and sales tax, as appropriate. Used historical data to derive a price scaling index to project product costs.
Installation Costs	Assumed no change with efficiency level.
Annual Energy Use	The total annual energy use by operating mode multiplied by the hours per year in each mode. Variability: Based on the 2015 RECS and 2012 CBECS.
Energy Prices	Electricity: Based on Edison Electric Institute data for 2020. Variability: Regional energy prices determined for each Census Division.
Energy Price Trends	Based on *AEO 2021* price projections by Census Division.
Repair and Maintenance Costs	Assumed no change with efficiency level for maintenance costs. Repair costs estimated for each product class and efficiency level.
Product Lifetime	Weibull probability distribution developed from historical shipments, *American Housing Survey* and *RECS*, with an average lifetime of 9 years
Discount Rates	Approach involves identifying all possible debt or asset classes that might be used to purchase the considered appliances, or might be affected indirectly. Primary data source was the Federal Reserve Board's Survey of Consumer Finances.
Compliance Date	2026

* References for the data sources mentioned in this table are provided in the sections following the table or in chapter 8 of the NOPR TSD.

[33] DOE will update all the 2015 RECS data to 2020 RECS if it is available prior to the final rule. Similarly, DOE will update all 2012 CBECS data to 2018 CBECS when it becomes available.

[34] Crystal Ball™ is commercially-available software tool to facilitate the creation of these types of models by generating probability distributions and summarizing results within Excel, available at *www.oracle.com/middleware/technologies/crystalball.html* (last accessed August 31, 2021).

1. Product Cost

To calculate consumer product costs, DOE multiplied the MPCs developed in the engineering analysis by the markups described previously (along with sales taxes). DOE used different markups for baseline products and higher-efficiency products because DOE applies an incremental markup to the increase in MSP associated with higher-efficiency products.

Economic literature and historical data suggest that the real costs of many products may trend downward over time according to ''learning'' or ''experience'' curves. Experience curve analysis implicitly includes factors such as efficiencies in labor, capital investment, automation, materials prices, distribution, and economies of scale at an industry-wide level. To derive the learning rate parameter for room ACs that utilize single-speed compressors, DOE obtained historical Producer Price Index (''PPI'') data for room ACs from the Bureau of Labor Statistics (''BLS''). A PPI specific to ''room air-conditioners and dehumidifiers, except portable dehumidifiers'' was available for the time period between 1990 and 2009.[35] After 2009, PPI data was only available for the broader product family of ''refrigeration and forced air heating equipment,'' which includes room ACs, spanning the years 2010–2020.[36] Inflation-adjusted price indices were calculated by dividing the PPI series by the gross domestic product index from Bureau of Economic Analysis for the same years. Using data from 1990–2020, the estimated learning rate (defined as the fractional reduction in price expected from each doubling of cumulative production) is 25 percent.

The Joint Commenters suggested an analysis with learning rates associated with specific technology options or components. (Joint Commenters, No. 20 at pp. 4–5)

DOE considered the inclusion of variable-speed compressors as a technology option in EL 4 and EL 5. To develop future prices specific for that technology, DOE applied a different price trend to the controls portion of the variable-speed compressors that contributes to the price increments moving from EL 3 (an efficiency level achieved with the highest efficiency single-speed compressor) to EL 4 and EL 5. DOE used PPI data on ''semiconductors and related device manufacturing'' between 1967 and 2020 to estimate the historic price trend of electronic components in the control.[37] The regression performed as an exponential trend line fit results in an R-square of 0.99, with an annual price decline rate of 6.3 percent. See chapter 8 of the NOPR TSD for further details on this topic.

The Joint Commenters noted that DOE's estimate of the learning rate for room ACs is likely a conservative estimate of how prices will decline over time. (Joint Commenters, No. 20 at pp. 4–5)

A retrospective analysis of the April 2011 Direct Final Rule for room ACs[38] compared the room AC average model-level price changes based on web-scraped retail price data from 2013 to 2017 (ex-post data) and the price factor index for the corresponding period derived in the April 2011 Direct Final Rule (ex-ante data). The result shows that the ex-ante data and ex-post data share similar price declining trends, and thus provide independent validation of the experience curve methodology adopted by DOE in the rulemaking analysis. To account for the uncertainties in the experience curve estimation, DOE also considered two alternative product price forecasts for room ACs (a high price decline and a low price decline scenarios and estimated their impacts on the consumer NPV for various standard levels (see section IV.H.3 of this document for details).

DOE requests comments on its assumption and methodology for determining equipment price trends.

2. Installation Cost

Installation cost includes labor, overhead, and any miscellaneous materials and parts needed to install the product. As in the June 2020 Preliminary Analysis, DOE found no evidence that installation costs would be impacted with increased efficiency levels and, thus, did not include installation costs in the LCC calculation.

3. Annual Energy Consumption

For each sampled household or business, DOE determined the energy consumption for a room AC at different efficiency levels using the approach described previously in section IV.E of this document.

a. Rebound Effect

Higher-efficiency room ACs reduce the operating costs for a consumer, which can lead to greater use of room ACs. A direct rebound effect occurs when a product that is made more efficient is used more intensively, such that the expected energy savings from the efficiency improvement may not fully materialize. At the same time, consumers benefit from increased utilization of products due to rebound. Overall consumer welfare (taking into account additional costs and benefits) is generally understood to increase from rebound. DOE did not find any data on the rebound effect that is specific to room ACs. In the April 2011 Direct Final Rule, DOE estimated a rebound of 15 percent for room ACs for the NIA but did not include rebound in the LCC analysis. 76 FR 22454, 22511. Given the uncertainty and lack of data specific to room ACs, DOE did not include the rebound effect in the LCC analysis for this NOPR. DOE does include rebound in the NIA for a conservative estimate of national energy savings and the corresponding impact to consumer NPV. As in the April 2011 Direct Final Rule, DOE used a rebound effect of 15 percent for room ACs. See sections IV.H.2 and IV.H.3 of this document for further details on how the rebound effect is applied in the NIA.

4. Energy Prices

Because marginal electricity price more accurately captures the incremental savings associated with a change in energy use from higher efficiency, it provides a better representation of incremental change in consumer costs than average electricity prices. Therefore, DOE applied average electricity prices for the energy use of the product purchased at baseline efficiency, and marginal electricity prices for the incremental change in energy use associated with the other efficiency levels considered.

DOE derived annual electricity prices in 2020 for each census division using data from EEI Typical Bills and Average Rates reports.[39] For the residential sector, DOE used the EEI data to define a marginal price as the ratio of the change in the bill to the change in energy consumption. For the commercial sector, marginal prices depend on both the change in electricity consumption and the change in monthly

[35] Room air-conditioners and dehumidifiers, except portable dehumidifiers PPI series ID: PCU3334153334156; *www.bls.gov/ppi/.*

[36] Air-conditioning, refrigeration, and forced air heating equipment manufacturing, Primary Products PPI series ID: PCU333415333415P; *www.bls.gov/ppi/.*

[37] Semiconductors and related device manufacturing PPI series ID: PCU334413334413; *www.bls.gov/ppi/.*

[38] Ganeshalingam, M., Ni, C., and Yang, H-C. 2021. A Retrospective Analysis of the 2011 Direct Final Rule for Room Air Conditioners. Lawrence Berkeley National Laboratory. LBNL-2001413.

[39] Edison Electric Institute. Typical Bills and Average Rates Report. 2020. Winter 2020, Summer 2020: Washington, DC.

peak-coincident demand. DOE used the EEI data to estimate both marginal energy charges and marginal demand charges.

DOE calculated weighted-average values for average and marginal price for the nine census divisions for both the residential and commercial sectors. As the EEI data are published separately for summer and winter, DOE calculated seasonal prices for each division and sector. See chapter 8 of the NOPR TSD for details.

To estimate energy prices in future years, DOE multiplied the average regional energy prices by a projection of annual change in national-average residential and commercial energy price in *AEO 2021.*[40] *AEO 2021* has an end year of 2050. To estimate electricity price trends after 2050, DOE used the average annual rate of change in electricity price from 2035 through 2050.

Rice suggested that consideration be given to showing energy cost information for both economy and cool mode settings to account for units with higher efficiency blower motor/fan assemblies that would have lower energy costs relative to less efficient blowers/fans in off-cycle mode. (Rice, No. 25 at p. 3)

As described in section IV.E of this document, DOE includes the energy contribution of fan-mode including time spent in off-cycle mode. DOE determines energy costs for the full range of product classes and efficiency levels.

5. Maintenance and Repair Costs

Repair costs are associated with repairing or replacing product components that have failed in an appliance; maintenance costs are associated with maintaining the operation of the product. Typically, small incremental increases in product efficiency produce no, or only minor, changes in repair and maintenance costs compared to baseline efficiency products. In this NOPR analysis, DOE did not include maintenance costs in the LCC.

In the June 2020 Preliminary Analysis, DOE assumed that repair frequencies are low and increase for the higher-capacity units due to more expensive equipment costs. DOE assumed that 1 percent of small-sized units (below 8,000 Btu/h), 2 percent of medium-sized units (8,000 to 20,000 Btu/h), and 3 percent of large-sized units (above 20,000 Btu/h) are maintained or repaired each year. DOE assumed that an average service call and repair/maintenance takes about 1 hour for small and medium-sized units and 2 hours for large units, and that the average material cost is equal to one-half of the incremental equipment cost. DOE maintains these assumptions in the NOPR analysis.

6. Product Lifetime

For room ACs, DOE developed a distribution of lifetimes from which specific values are assigned to the appliances in the samples. DOE conducted an analysis of actual lifetime in the field using a combination of historical shipments data, the stock of the considered appliances in the *American Housing Survey,* and responses in RECS on the age of the appliances in the homes. The data allowed DOE to estimate a survival function, which provides an average appliance lifetime. This analysis yielded a lifetime probability distribution with an average lifetime for room ACs of approximately 9 years. See chapter 8 of the NOPR TSD for further details.

7. Discount Rates

In the calculation of the LCC, DOE applies discount rates appropriate to residential and commercial sectors to estimate the present value of future operating costs. DOE estimated a distribution of residential and commercial discount rates for room ACs based on consumer financing costs and the opportunity cost of consumer funds (for the residential sector) and cost of capital of publicly traded firms (for the commercial sector).

For households, DOE applies weighted-average discount rates calculated from consumer debt and asset data, rather than marginal or implicit discount rates.[41] DOE notes that the LCC does not analyze the appliance purchase decision, so the implicit discount rate is not relevant in this model. The LCC estimates net present value over the lifetime of the product, so the appropriate discount rate will reflect the general opportunity cost of household funds, taking this time scale into account. Given the long time horizon modeled in the LCC, the application of a marginal interest rate associated with an initial source of funds is inaccurate. Regardless of the method of purchase, consumers are expected to continue to rebalance their debt and asset holdings over the LCC analysis period, based on the restrictions consumers face in their debt payment requirements and the relative size of the interest rates available on debts and assets. DOE estimates the aggregate impact of this rebalancing using the historical distribution of debts and assets.

To establish residential discount rates for the LCC analysis, DOE identified all relevant household debt or asset classes in order to approximate a consumer's opportunity cost of funds related to appliance energy cost savings. It estimated the average percentage shares of the various types of debt and equity by household income group using data from the Federal Reserve Board's *Survey of Consumer Finances*[42] (''SCF'') for 1995, 1998, 2001, 2004, 2007, 2010, 2013, 2016, and 2019. Using the SCF and other sources, DOE developed a distribution of rates for each type of debt and asset by income group to represent the rates that may apply in the year in which amended standards would take effect. DOE assigned each sample household a specific discount rate drawn from one of the distributions. The average rate across all types of household debt and equity and income groups, weighted by the shares of each type, is 4.3 percent. See chapter 8 of the NOPR TSD for further details on the development of consumer discount rates.

For commercial-sector room ACs, DOE used the cost of capital to estimate the present value of cash flows to be derived from a typical company project or investment. Most companies use both debt and equity capital to fund investments, so the cost of capital is the weighted-average cost to the firm of equity and debt financing. This corporate finance approach is referred to as the weighted-average cost of capital. DOE used currently available economic data in developing discount rates.

8. Energy Efficiency Distribution in the No-New-Standards Case

To accurately estimate the share of consumers that would be affected by a potential energy conservation standard at a particular efficiency level, DOE's LCC analysis considered the projected distribution (market shares) of product efficiencies under the no-new-standards

[40] Energy Information Administration. *Annual Energy Outlook 2021 with Projections to 2050.* Washington, DC. Available at *www.eia.gov/forecasts/aeo/.*

[41] The implicit discount rate is inferred from a consumer purchase decision between two otherwise identical goods with different first cost and operating cost. It is the interest rate that equates the increment of first cost to the difference in net present value of lifetime operating cost, incorporating the influence of several factors: Transaction costs; risk premiums and response to uncertainty; time preferences; interest rates at which a consumer is able to borrow or lend.

[42] U.S. Board of Governors of the Federal Reserve System. Survey of Consumer Finances. 1995, 1998, 2001, 2004, 2007, 2010, 2013, 2016, and 2019. (Last accessed August 20, 2021.) *www.federalreserve.gov/econresdata/scf/scfindex.htm.*

case (*i.e.,* the case without amended or new energy conservation standards).

DOE utilized confidential 2019 shipments data disaggregated by product class and efficiency provided by AHAM in response to the June 2020 Preliminary Analysis to estimate the efficiency distribution in 2019. In the preliminary analysis, DOE assumed an annual 0.25 percent increase in shipment-weighted CEER to develop the efficiency distribution in 2026. The efficiency trend used in this NOPR is supported by a retrospective analysis of the April 2011 Direct Final Rule which used a similar efficiency trend.[43] For this NOPR, DOE assumed this trend applied to efficiency levels with single-speed compressors (EL 0, EL 1, EL 2, and EL 3). DOE assumed the adoption of variable-speed technologies (EL 4 and EL 5) would follow a Bass diffusion curve which describes how new technologies diffuse into the consumer market.[44] DOE assumed that shipments to variable-speed technologies would account for 5 percent of shipments in each product class by 2026. The estimated market shares for the no-new-standards case for room ACs in 2026 are shown in Table IV.4 through Table IV.6 of this document. See chapter 8 of the NOPR TSD for further information on the derivation of the efficiency distributions.

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Table IV.4 Room Air Conditioners without Reverse Cycle and with Louvered Sides: No-New-Standards Case Market Shares in 2026

Efficiency Level	<6,000 Btu/h (PC1)		6,000–7,999 Btu/h (PC2)		8,000–13,999 Btu/h (PC3)	
	Efficiency *CEER*	Market Share %	Efficiency *CEER*	Market Share %	Efficiency *CEER*	Market Share %
Baseline	11.0	7.7%	11.0	0.0%	10.9	0.0%
1	11.4	85.2%	11.4	74.6%	11.4	31.1%
2	12.1	2.1%	12.1	18.3%	12.0	63.0%
3	13.1	0.0%	13.7	2.1%	14.3	0.9%
4	16.0	5.0%	16.0	5.0%	16.0	5.0%
5	20.2	0.0%	20.2	0.0%	22.4	0.0%
Efficiency Level	**14,000–19,999 Btu/h (PC4)**		**20,000–27,999 Btu/h (PC5a)**		**>=28,000 Btu/h (PC5b)**	
	Efficiency *CEER*	Market Share %	Efficiency *CEER*	Market Share %	Efficiency *CEER*	Market Share %
Baseline	10.7	0.0%	9.4	0.0%	9.0	40.3%
1	11.1	0.0%	9.8	8.7%	9.4	45.7%
2	11.8	94.7%	10.3	86.2%	9.9	9.0%
3	14.0	0.3%	11.8	0.0%	10.3	0.0%
4	16.0	5.0%	13.8	5.0%	13.2	5.0%
5	20.6	0.0%	19.1	0.0%	16.7	0.0%

[43] Ganeshalingam, M., Ni, C., and Yang, H-C. 2021. A Retrospective Analysis of the 2011 Direct Final Rule for Room Air Conditioners. Lawrence Berkeley National Laboratory. LBNL-2001413.

[44] Bass, F. M. A New Product Growth Model for Consumer Durables. *Management Science.* 1969. 15(5): pp. 215–227.

Table IV.5 Room Air Conditioners without Reverse Cycle and without Louvered Sides: No-New-Standards Case Market Shares in 2026

Efficiency Level	8,000–10,999 Btu/h (PC 8a)		11,000–13,999 Btu/h (PC8b)		14,000–19,999 Btu/h (PC9)	
	Efficiency *CEER*	Market Share %	Efficiency *CEER*	Market Share %	Efficiency *CEER*	Market Share %
Baseline	9.6	0.0%	9.50	0.0%	9.3	39.1%
1	10.1	11.4%	10.00	0.0%	9.7	46.9%
2	10.6	83.6%	10.50	94.3%	10.2	9.0%
3	12.3	0.0%	12.32	0.7%	10.9	0.0%
4	14.1	5.0%	12.80	5.0%	13.7	5.0%
5	18.7	0.0%	19.09	0.0%	16.6	0.0%

Table IV.6 Room Air Conditioners with Reverse Cycle, Casement-Slider: No-New-Standards Case Market Shares in 2026

Efficiency Level	w/ Louvers (PC11)		wo/ Louvers (PC12)		Casement-Slider (PC16)	
	<20,000 Btu/h		<14,000 Btu/h			
	Efficiency *CEER*	Market Share %	Efficiency *CEER*	Market Share %	Efficiency *CEER*	Market Share %
Baseline	9.8	50.7%	9.3	39.1%	10.4	34.4%
1	10.4	35.2%	9.7	46.9%	10.8	51.6%
2	10.8	9.0%	10.2	9.0%	11.4	9.0%
3	12.3	0.0%	11.3	0.0%	13.2	0.0%
4	14.4	5.0%	13.7	5.0%	15.3	5.0%
5	18.7	0.0%	16.2	0.0%	19.7	0.0%

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DOE requests feedback on its approach to projecting the efficiency distribution in 2026.

9. Payback Period Analysis

The payback period is the amount of time it takes the consumer to recover the additional installed cost of more-efficient products, compared to baseline products, through energy cost savings. Payback periods are expressed in years. Payback periods that exceed the life of the product mean that the increased total installed cost is not recovered in reduced operating expenses.

The inputs to the PBP calculation for each efficiency level are the change in total installed cost of the product and the change in the first-year annual operating expenditures relative to the baseline. The PBP calculation uses the same inputs as the LCC analysis, except that discount rates are not needed.

As noted previously, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii)) For each considered efficiency level, DOE determined the value of the first year's energy savings by calculating the energy savings in accordance with the applicable DOE test procedure, and multiplying those savings by the average energy price projection for the year in which compliance with the amended standards would be required.

G. Shipments Analysis

DOE uses projections of annual product shipments to calculate the national impacts of potential amended or new energy conservation standards on energy use, NPV, and future manufacturer cash flows.[45] The shipments model takes an accounting approach, tracking market shares of each product class and the vintage of units in the stock. Stock accounting uses product shipments as inputs to estimate the age distribution of in-service product stocks for all years. The age distribution of in-service product stocks is a key input to calculations of both the NES and NPV, because operating costs for any year depend on the age distribution of the stock.

Total shipments for room ACs are developed by considering the demand from replacements for units in stock that fail and the demand from first-time owners in existing households. DOE calculated shipments due to replacements using the retirement function developed for the LCC analysis. DOE calculated shipments due to first-time owners in existing households using estimates from room AC saturation in RECS 2015 and projections of housing stock from *AEO 2021.* See chapter 8 of the NOPR TSD for details.

DOE considers the impacts on shipments from changes in product purchase price and operating cost associated with higher energy efficiency levels using a price elasticity and an efficiency elasticity. As in the June 2020 Preliminary Analysis, DOE employs a 0.2-percent efficiency elasticity rate and a price elasticity of −0.45 in its shipments model. These values are based on analysis of aggregated data for five residential appliances including room ACs.[46] The market impact is defined as the difference between the product of price elasticity of demand and the change in price due to a standard level, and the product of the efficiency elasticity and the change in operating costs due to a standard level.

ASAP and the Joint Commenters noted that the efficiency elasticity was omitted from chapter 9 of the preliminary TSD. (ASAP, Public Meeting Transcript, No. 18 at pp. 94–95; Joint Commenters, No. 20 at p. 5) ASAP and the Joint Commenters encouraged DOE to confirm and clarify whether the efficiency elasticity is considered in calculating the standards-case shipments. (Joint Commenters, No. 20 at p. 5)

Chapter 9 of the NOPR TSD has been updated to display the impact of the price and efficiency elasticity in calculating the standards-case shipments.

AHAM recommended that DOE do as it generally does and rely on shipment-weighted data in its analysis and provided DOE data for 2019 shipments by product class. (AHAM, No. 19 at p. 9)

DOE appreciates the 2019 shipments by product class and efficiency level provided by AHAM and has updated the NOPR to reflect the AHAM data.

NEEA noted that DOE's shipment projections are likely low and do not follow the market's historical trends—DOE's analysis showed a very small growth in annual shipments through 2052 to a peak of approximately 8.5 million units per year. NEEA stated that this slow growth trend does not match the historic growth seen in the room AC market. For the number of replacement units, NEEA recommended that DOE amend its analysis to consider early retirement of units driven by new features, such as increased efficiency and smart rooms ACs, which could increase the number of shipments. For new units, NEEA recommended that DOE consider an increasing market penetration factor to account for the growth of room AC use in climates where cooling has not been needed traditionally. (NEEA, No. 24 at pp. 5–6)

DOE notes that between 2014 and 2019, room AC shipments have been approximately 7 million units with no clear indication of steady growth over that period. DOE determines the replacement market from lifetime estimates of room ACs. Early retirement of units to purchase more efficient and/or units with additional features are currently accounted for in the lifetime distribution. A retrospective analysis of the April 2011 Direct Final Rule for room ACs,[47] which also accounted for shipments due to replacements and first-time owners, generally found that DOE projections matched with AHAM shipments data in 2017 and 2018. DOE acknowledges that a warming climate could increase purchase of room ACs in climates where cooling has not been needed traditionally, but it is not aware of any data that would facilitate an accurate estimate of this future demand. DOE welcomes shipments data that include markets in addition to replacement and first-time user markets.

Chapter 9 of the NOPR TSD provides additional details on the shipments analysis.

DOE requests comment on its general methodology for estimating shipments.

H. National Impact Analysis

The NIA assesses the NES and the NPV from a national perspective of total consumer costs and savings that would be expected to result from new or amended standards at specific efficiency levels.[48] (''Consumer'' in this context refers to consumers of the product being regulated.) DOE calculates the NES and NPV for the potential standard levels considered based on projections of annual product shipments, along with the annual energy consumption and total installed cost data from the energy use and LCC analyses. For the present analysis, DOE projected the energy savings, operating cost savings, product costs, and NPV of consumer benefits over the lifetime of room ACs sold from 2026 through 2055.

DOE evaluates the impacts of new or amended standards by comparing a case without such standards with standards-case projections. The no-new-standards case characterizes energy use and consumer costs for each product class in the absence of new or amended energy conservation standards. For this projection, DOE considers historical trends in efficiency and various forces that are likely to affect the mix of efficiencies over time. DOE compares the no-new-standards case with projections characterizing the market for each product class if DOE adopted new or amended standards at specific energy efficiency levels (*i.e.,* the TSLs or standards cases) for that class. For the standards cases, DOE considers how a given standard would likely affect the market shares of products with efficiencies greater than the standard.

DOE uses a spreadsheet model to calculate the energy savings and the national consumer costs and savings from each TSL. Interested parties can review DOE's analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses typical values (as opposed to probability distributions) as inputs.

Table IV.7 summarizes the inputs and methods DOE used for the NIA analysis for the NOPR. Discussion of these inputs and methods follows the table.

[45] DOE uses data on manufacturer shipments as a proxy for national sales, as aggregate data on sales are lacking. In general, one would expect a close correspondence between shipments and sales.

[46] Fujita, K. (2015) Estimating Price Elasticity using Market-Level Appliance Data. Lawrence Berkeley National Laboratory, LBNL–188289.

[47] Ganeshalingam, M., Ni, C., and Yang, H-C. 2021. A Retrospective Analysis of the 2011 Direct Final Rule for Room Air Conditioners. Lawrence Berkeley National Laboratory. LBNL-2001413.

[48] The NIA accounts for impacts in the 50 states.

See chapter 10 of the NOPR TSD for further details.

Table IV.7 Summary of Inputs and Methods for the National Impact Analysis

Inputs	Method
Shipments	Annual shipments from shipments model.
Compliance Date of Standard	2026
Efficiency Trends	Bass diffusion curve to allocate shipments to ELs with variable-speed technology and annual 0.25% increase in shipment-weighted CEER for ELs with single-speed technology.
Annual Energy Consumption per Unit	Calculated for each efficiency level based on inputs from energy use analysis.
Total Installed Cost per Unit	Calculated for each efficiency level based on inputs from the LCC analysis.
Repair and Maintenance Cost per Unit	Calculated for each efficiency level on inputs from the LCC analysis.
Electricity Price	Estimated average and marginal electricity prices from the LCC analysis based on EEI data.
Electricity Price Trends	*AEO* 2021 projections (to 2050) and extrapolation using a fixed annual rate of price change between 2035 and 2050 thereafter.
Energy Site-to-Primary and FFC Conversion	A time-series conversion factor based on *AEO* 2021.
Discount Rate	3 percent and 7 percent
Present Year	2021

1. Product Efficiency Trends

A key component of the NIA is the trend in energy efficiency projected for the no-new-standards case and each of the standards cases. Section IV.F.7 of this document describes how DOE developed an energy efficiency distribution for the no-new-standards case (which yields a shipment-weighted average efficiency) for each of the considered product classes for the year of anticipated compliance with an amended or new standard. To project the trend in efficiency absent amended standards for room ACs over the entire shipments projection period, DOE assumed that market share for ELs with variable-speed technologies would follow a Bass diffusion curve, while the shipment-weighted CEER for ELs with single-speed compressors would increase annually by 0.25 percent in CEER based on historical trends in shipment-weighted efficiency.[49] The approach is further described in chapter 10 of the NOPR TSD.

In its reference scenario, DOE assumed that variable-speed technologies would comprise 25 percent of the market by the end of the analysis period (2055). DOE also performed sensitivity scenarios assuming a low penetration of variable-speed technologies (10 percent of the market in 2055) and a high penetration of variable-speed technologies (50 percent of the market in 2055). The results of these scenarios can be found in appendix 10E of the NOPR TSD. DOE requests comment on its approach to projecting market share for variable-speed technologies over the course of the analysis period.

For the standards cases, DOE used a ''roll-up'' scenario to establish the shipment-weighted efficiency for the year that standards are assumed to become effective in 2026. In the year of compliance, the market shares of products in the no-new-standards case that do not meet the standard under consideration would ''roll up'' to the minimum EL that meets the standard, and the market share of products above the standard would remain unchanged. As in the no-new-standards case, DOE assumed an annual increase of 0.25 percent in CEER over the analysis period for ELs with single-speed technology.

The Joint Commenters noted that data on sales over the past decade suggest that the ''roll-up'' scenario considered by DOE may underestimate the savings from amended standards and suggested DOE consider reevaluating the use of the ''roll-up'' scenario for estimating the market distribution of each efficiency level following the adoption of a standard. (Joint Commenters, No. 20 at p. 5)

DOE acknowledges multiple drivers in the room AC market, one of which is the amended standard process. Although DOE uses a roll-up to allocate market share by efficiency level in the year a standard is enacted, an efficiency trend is applied in subsequent years in the standards case to account for the observed historical trends in efficiency. See chapter 10 of the NOPR TSD for details.

2. National Energy Savings

The national energy savings analysis involves a comparison of national energy consumption of the considered products between each potential standards case (TSL) and the case with no new or amended energy conservation standards. DOE calculated the national energy consumption by multiplying the number of units (stock) of each product (by vintage or age) by the unit energy consumption (also by vintage). DOE calculated annual NES based on the difference in national energy consumption for the no-new standards case and for each higher efficiency standard case. DOE estimated energy consumption and savings based on site energy and converted the electricity consumption and savings to primary energy (*i.e.,* the energy consumed by power plants to generate site electricity) using annual conversion factors derived

[49] Ganeshalingam, M., Ni, C., and Yang, H-C. 2021. A Retrospective Analysis of the 2011 Direct Final Rule for Room Air Conditioners. Lawrence Berkeley National Laboratory. LBNL–2001413.

from *AEO 2021.* Cumulative energy savings are the sum of the NES for each year over the timeframe of the analysis.

Use of higher-efficiency products is occasionally associated with a direct rebound effect, which refers to an increase in utilization of the product due to the reduction in operating cost induced by improved efficiency. A direct rebound effect occurs when a product that is made more efficient is used more intensively, reducing expected energy savings from the efficiency improvement. At the same time, consumers can benefit from increased utilization of products due to the direct rebound effect. DOE did not find any data on the rebound effect specific to room ACs, but it applied a rebound effect of 15 percent as suggested by Sorrell *et al.*[50] and was done in the April 2011 Direct Final Rule. The calculated NES at each efficiency level is therefore reduced by 15 percent. DOE also included the rebound effect in the NPV analysis accounting for the additional net benefit from increased room AC usage as described in section IV.H.3 of this document.

In 2011, in response to the recommendations of a committee on ''Point-of-Use and Full-Fuel-Cycle Measurement Approaches to Energy Efficiency Standards'' appointed by the National Academy of Sciences, DOE announced its intention to use FFC measures of energy use and greenhouse gas and other emissions in the national impact analyses and emissions analyses included in future energy conservation standards rulemakings. 76 FR 51281 (Aug. 18, 2011). After evaluating the approaches discussed in the August 18, 2011 notice, DOE published a statement of amended policy in which DOE explained its determination that EIA's National Energy Modeling System (''NEMS'') is the most appropriate tool for its FFC analysis and its intention to use NEMS for that purpose. 77 FR 49701 (Aug. 17, 2012). NEMS is a public domain, multi-sector, partial equilibrium model of the U.S. energy sector[51] that EIA uses to prepare its *Annual Energy Outlook.* The FFC factors incorporate losses in production and delivery in the case of natural gas (including fugitive emissions) and additional energy used to produce and deliver the various fuels used by power plants. The approach used for deriving FFC measures of energy use and emissions is described in appendix 10B of the NOPR TSD.

EEI suggested incorporating the *AEO* full-fuel-cycle conversion for DOE's next update. (EEI, Public Meeting Transcript, No. 18 at pp. 83–84)

For this NOPR analysis, DOE reports the full-fuel-cycle energy savings in its NIA using inputs from *AEO 2021.* See chapter 10 of the NOPR TSD for a full description.

3. Net Present Value Analysis

The inputs for determining the NPV of the total costs and benefits experienced by consumers are (1) total annual installed cost, (2) total annual operating costs (energy costs and repair and maintenance costs), and (3) a discount factor to calculate the present value of costs and savings. DOE calculates net savings each year as the difference between the no-new-standards case and each standards case in terms of total savings in operating costs versus total increases in installed costs. DOE calculates operating cost savings over the lifetime of each product shipped during the projection period.

As discussed in section IV.F.6 of this document, DOE developed room AC price trends based on historical PPI data. DOE applied the same trends to project prices for each product class at each considered efficiency level. By 2055, the end date of the analysis period, the average single-speed compressor room AC price is projected to drop 23 percent and the variable-speed compressor room AC price is projected to drop about 37 percent relative to 2020. DOE's projection of product prices is described in appendix 10C of the NOPR TSD.

To evaluate the effect of uncertainty regarding the price trend estimates, DOE investigated the impact of alternate product price projections on the consumer NPV for the considered TSLs for room ACs. In addition to the default price trend, DOE considered high and low product price sensitivity cases. In the high price scenario, DOE based the price decline of the non-variable speed controls portion on room AC PPI data limited to the period between the period 1990–2009, which shows a faster price decline relative to the full time series. For the variable-speed controls portion, DOE used a faster price decline derived from the lower bound of the 95 percent confidence interval fitting PPI data for semiconductors. In the low price decline scenario, DOE assumed a constant price for the non-variable-speed controls portion of the price and a slower price decline estimate for the variable-speed controls portion derived from the upper bound of the 95 percent confidence interval fitting PPI data for semiconductors over the analysis period. The derivation of these price trends and the results of these sensitivity cases are described in appendix 10C of the NOPR TSD. The operating cost savings are energy cost savings, which are calculated using the estimated energy savings in each year and the projected price of electricity. To estimate energy prices in future years, DOE multiplied the average regional energy prices by the projection of annual national-average residential and commercial energy price changes in the Reference case from *AEO 2021,* which has an end year of 2050. For the years after 2050, DOE used the average annual rate of change in electricity price from 2035 through 2050. As part of the NIA, DOE also analyzed scenarios that used inputs from variants of the *AEO 2021* Reference case that have lower and higher economic growth. Those cases have lower and higher energy price trends compared to the Reference case. NIA results based on these cases are presented in appendix 10C of the NOPR TSD.

As described in section IV.H.2 of this document, DOE assumed a 15 percent rebound from an increase in utilization of the product arising from the increase in efficiency (*i.e.,* the direct rebound effect). In considering the consumer welfare gained due to the direct rebound effect, DOE accounted for change in consumer surplus attributed to additional cooling from the purchase of a more efficient unit. Overall consumer welfare is generally understood to be enhanced from rebound. The net consumer impact of the rebound effect is included in the calculation of operating cost savings in the consumer NPV results. See appendix 10F of the NOPR TSD for details on DOE's treatment of the monetary valuation of the rebound effect. DOE requests comments on its approach to monetizing the impact of the rebound effect.

In calculating the NPV, DOE multiplies the net savings in future years by a discount factor to determine their present value. For this NOPR, DOE estimated the NPV of consumer benefits using both a 3-percent and a 7-percent real discount rate. DOE uses these discount rates in accordance with guidance provided by the Office of Management and Budget (''OMB'') to Federal agencies on the development of regulatory analysis.[52] The discount rates

[50] Sorrell, S., J. Dimitropoulos, M. Sommerville. 2009. Empirical estimates of the direct rebound effect: A review. Energy Policy 37 (2009) 1356–1371.

[51] For more information on NEMS, refer to *The National Energy Modeling System: An Overview 2009,* DOE/EIA–0581(2009), October 2009. Available at *www.eia.gov/forecasts/aeo/index.cfm.*

[52] United States Office of Management and Budget. *Circular A–4: Regulatory Analysis.*

for the determination of NPV are in contrast to the discount rates used in the LCC analysis, which are designed to reflect a consumer's perspective. The 7-percent real value is an estimate of the average before-tax rate of return to private capital in the U.S. economy. The 3-percent real value represents the ''social rate of time preference,'' which is the rate at which society discounts future consumption flows to their present value.

I. Consumer Subgroup Analysis

In analyzing the potential impact of new or amended energy conservation standards on consumers, DOE evaluates the impact on identifiable subgroups of consumers that may be disproportionately affected by a new or amended national standard. The purpose of a subgroup analysis is to determine the extent of any such disproportional impacts. DOE evaluates impacts on particular subgroups of consumers by analyzing the LCC impacts and PBP for those particular consumers from alternative standard levels. For this NOPR, DOE analyzed the impacts of the considered standard levels on two subgroups: (1) Low-income households and (2) senior-only households. The analysis used subsets of the 2015 RECS sample composed of households that meet the criteria for the two subgroups and shows the percentages of those both negatively and positively impacted. DOE used the LCC and PBP spreadsheet model to estimate the impacts of the considered efficiency levels on these subgroups for product classes with a sufficient sample size in 2015 RECS to perform a Monte Carlo analysis. Chapter 11 of the NOPR TSD describes the consumer subgroup analysis.

J. Manufacturer Impact Analysis

1. Overview

DOE performed a MIA to estimate the impacts of amended energy conservation standards on manufacturers of room ACs. The MIA has both quantitative and qualitative aspects and includes analyses of projected industry cash flows, the INPV, investments in research and development (''R&D'') and manufacturing capital, and domestic manufacturing employment. Additionally, the MIA seeks to determine how amended energy conservation standards might affect manufacturing capacity and competition, as well as how standards contribute to overall regulatory burden. Finally, the MIA serves to identify any disproportionate impacts on manufacturer subgroups, including small business manufacturers.

The quantitative part of the MIA primarily relies on the Government Regulatory Impact Model (''GRIM''), an industry cash flow model with inputs specific to this rulemaking. The key GRIM inputs include data on the industry cost structure, unit production costs, product shipments, manufacturer markups, and investments in R&D and manufacturing capital required to produce compliant products. The key GRIM outputs are the INPV, which is the sum of industry annual cash flows over the analysis period, discounted using the industry-weighted average cost of capital, and the impact to domestic manufacturing employment. The model uses standard accounting principles to estimate the impacts of more-stringent energy conservation standards on a given industry by comparing changes in INPV and domestic manufacturing employment between a no-new-standards case and the various standards cases (TSLs). To capture the uncertainty relating to manufacturer pricing strategies following amended standards, the GRIM estimates a range of possible impacts under different manufacturer markup scenarios.

The qualitative part of the MIA addresses manufacturer characteristics and market trends. Specifically, the MIA considers such factors as a potential standard's impact on manufacturing capacity, competition within the industry, the cumulative impact of other Federal product-specific regulations, and impacts on manufacturer subgroups. The complete MIA is outlined in chapter 12 of the NOPR TSD.

DOE conducted the MIA for this proposed rulemaking in three phases. In Phase 1 of the MIA, DOE prepared a profile of the room AC manufacturing industry based on publicly available data and information from its market and technology assessment, engineering analysis, and shipments analysis. This preparation included a top-down analysis of room AC manufacturers that DOE used to derive preliminary financial parameters for the GRIM (*e.g.,* materials, labor, overhead, and depreciation expenses; selling, general, and administrative expenses (''SG&A''); and R&D expenses). DOE also used public sources of information to further calibrate its initial characterization of the room AC manufacturing industry, including company filings of form 10–K from the SEC,[53] corporate annual reports, the April 2011 Direct Final Rule, and the U.S. Census Bureau's *Economic Census.*[54] DOE also relied on subscription-based resources such as reports from Dun & Bradstreet.[55]

In Phase 2 of the MIA, DOE prepared a framework industry cash-flow analysis to quantify the potential impacts of amended energy conservation standards. The GRIM uses several factors to determine a series of annual cash flows starting with the announcement of the standard and extending over a 30-year period following the compliance date of the standard. These factors include annual expected revenues, costs of sales, SG&A and R&D expenses, taxes, and capital expenditures. In general, energy conservation standards can affect manufacturer cash flow in three distinct ways: (1) Creating a need for increased investment, (2) raising production costs per unit, and (3) altering revenue due to higher per-unit prices and changes in sales volumes.

In addition, during Phase 2, DOE developed interview guides to distribute to manufacturers of room ACs in order to develop other key GRIM inputs, including product and capital conversion costs, and to gather additional information on the anticipated effects of energy conservation standards on revenues, direct employment, capital assets, industry competitiveness, and subgroup impacts.

In Phase 3 of the MIA, DOE conducted structured, detailed interviews with representative manufacturers. During these interviews, DOE discussed engineering, manufacturing, procurement, and financial topics to validate assumptions used in the GRIM and to identify key issues or concerns. See section IV.J.3 of this document for a description of the key issues raised by manufacturers during the interviews. As part of Phase 3, DOE also evaluated subgroups of manufacturers that may be disproportionately impacted by amended standards or that may not be accurately represented by the average cost assumptions used to develop the industry cash flow analysis. Such manufacturer subgroups may include small business manufacturers, low-volume manufacturers, niche players, and/or manufacturers exhibiting a cost structure that largely differs from the

September 17, 2003. Section E. Available at *obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* (last accessed June 15, 2021).

[53] *www.sec.gov/edgar/searchedgar/companysearch.html.*

[54] *www.census.gov/programs-surveys/qpc/data/tables.html.*

[55] *app.dnbhoovers.com.*

industry average. DOE identified one subgroup for a separate impact analysis: Small business manufacturers. The small business subgroup is discussed in section VII.B of this document, ''Review under the Regulatory Flexibility Act'' and in chapter 12 of the NOPR TSD.

2. Government Regulatory Impact Model and Key Inputs

DOE uses the GRIM to quantify the changes in cash flow due to amended standards that result in a higher or lower industry value. The GRIM uses a standard, annual discounted cash-flow analysis that incorporates manufacturer costs, markups, shipments, and industry financial information as inputs. The GRIM models changes in costs, distribution of shipments, investments, and manufacturer margins that could result from an amended energy conservation standard. The GRIM spreadsheet uses the inputs to arrive at a series of annual cash flows, beginning in 2021 (the base year of the MIA analysis) and continuing to 2055. DOE calculated INPVs by summing the stream of annual discounted cash flows during this period. For manufacturers of room ACs, DOE used a real discount rate of 7.2 percent, which was derived from public financial data and then modified according to feedback received during manufacturer interviews.

The GRIM calculates cash flows using standard accounting principles and compares changes in INPV between the no-new-standards case and each standards case. The difference in INPV between the no-new-standards case and a standards case represents the financial impact of the amended energy conservation standard on manufacturers. As discussed previously, DOE developed critical GRIM inputs using a number of sources, including publicly available data, results of the engineering analysis, and information gathered during the course of manufacturer interviews. The GRIM results are presented in section V.B.2 of this document. Additional details about the GRIM, the discount rate, and other financial parameters can be found in chapter 12 of the NOPR TSD.

a. Manufacturer Production Costs

Manufacturing more efficient equipment is typically more expensive than manufacturing baseline equipment due to the use of more complex components, which are typically more costly than baseline components. The changes in the MPCs of covered products can affect the revenues, gross margins, and cash flow of the industry. DOE models the relationship between efficiency and MPCs as a part of its engineering analysis. For a complete description of the MPCs, see chapter 5 of the NOPR TSD.

b. Shipments Projections

The GRIM estimates manufacturer revenues based on total unit shipment projections and the distribution of those shipments by product class and by efficiency level. Changes in sales volumes and efficiency mix over time can significantly affect manufacturer finances. For this analysis, the GRIM uses the NIA's annual shipment projections derived from the shipments analysis. See chapter 9 of the NOPR TSD for additional details on DOE's shipments projections.

c. Product and Capital Conversion Costs

Amended energy conservation standards could cause manufacturers to incur conversion costs to bring their production facilities and equipment designs into compliance. DOE evaluated the level of conversion-related expenditures that would be needed to comply with each considered efficiency level in each product class. For the MIA, DOE classified these conversion costs into two major groups: (1) Product conversion costs, and (2) capital conversion costs. Product conversion costs are investments in research, development, testing, marketing, and other non-capitalized costs necessary to make product designs comply with amended energy conservation standards. Capital conversion costs are investments in property, plant, and equipment necessary to adapt or change existing production facilities such that new compliant product designs can be fabricated and assembled. All conversion-related investments occur between the year of publication of the final rule and the year by which manufacturers must comply with the new standard.

To calculate the MPCs for room ACs at and above the baseline, DOE performed teardowns for representative units. The data generated from these analyses were then used to estimate the capital investments in equipment, tooling, and conveyor required of original equipment manufacturers (''OEMs'') at each efficiency level, taking into account such factors as product design, raw materials, purchased components, and fabrication method. Changes in equipment, tooling, and conveyer were used to estimate capital conversion costs. Additionally, capital conversion costs accounted for investments in appearance tooling made by manufacturers that are not OEMs.

DOE relied on feedback from industry to evaluate the product conversion costs industry would likely incur at the considered standard levels. DOE integrated feedback from manufacturers, both OEM and non-OEM, on redesign effort and staffing to estimate product conversion cost. Manufacturer numbers were aggregated to protect confidential information.

The conversion cost figures used in the GRIM can be found in section V.B.2 of this document. For additional information on the capital and product conversion costs, see chapter 12 of the NOPR TSD.

d. Manufacturer Markup Scenarios

MSPs include direct manufacturing production costs (*i.e.,* labor, materials, and overhead estimated in DOE's MPCs) and all non-production costs (*i.e.,* SG&A, R&D, and interest), along with profit. To calculate the MSPs in the GRIM, DOE applied non-production cost markups to the MPCs estimated in the engineering analysis for each product class and efficiency level. Modifying these markups in the standards case yields different sets of impacts on manufacturers. For the MIA, DOE modeled two standards-case manufacturer markup scenarios to represent uncertainty regarding the potential impacts on prices and profitability for manufacturers following the implementation of amended energy conservation standards: (1) A preservation of gross margin percentage markup scenario, and (2) a preservation of per-unit operating profit markup scenario. These scenarios lead to different manufacturer markup values that, when applied to the MPCs, result in varying revenue and cash flow impacts.

Under the preservation of gross margin percentage scenario, DOE applied a single uniform ''gross margin percentage'' markup across all efficiency levels, which assumes that manufacturers would be able to maintain the same amount of profit as a percentage of revenues at all efficiency levels within a product class. As manufacturer production costs increase with efficiency, this scenario implies that the absolute dollar markup will increase as well. DOE assumed the industry-average manufacturer markup—which includes SG&A expenses, R&D expenses, interest, and profit—to be 1.26 for room ACs. Manufacturers tend to believe it is optimistic to assume that they would be able to maintain the same gross margin percentage markup as their production costs increase, particularly for minimally efficient products. Therefore, DOE assumes that this scenario represents a high bound to industry

profitability under an amended energy conservation standard.

In the preservation of operating profit scenario, as the cost of production goes up under a standards case, manufacturers are generally required to reduce their markups to a level that maintains base-case operating profit. DOE implemented this scenario in the GRIM by lowering the manufacturer markups at each TSL to yield approximately the same earnings before interest and taxes in the standards case as in the no-new-standards case in the year after the compliance date of the amended standards. The implicit assumption behind this manufacturer markup scenario is that the industry can only maintain its operating profit in absolute dollars after the standard. A comparison of industry financial impacts under the two markup scenarios is presented in section V.B.2.a of this document.

3. Manufacturer Interviews

DOE interviewed manufacturers representing approximately 40 percent of the basic models in DOE's Compliance Certification Database (''CCD''). Participants included OEMs and importers.

In interviews, DOE asked manufacturers to describe their major concerns regarding potential increases in energy conservation standards for room ACs. The following section highlights manufacturer concerns that helped inform the projected potential impacts of an amended standard on the industry. Manufacturer interviews are conducted under non-disclosure agreements (''NDAs''), so DOE does not document these discussions in the same way that it does public comments in the comment summaries and DOE's responses throughout the rest of this document.

a. Compressor Availability

For the June 2020 Preliminary Analysis, DOE selected EL 3 levels to represent an intermediate efficiency between EL 2 (the ENERGY STAR level) and EL 4 (the max-tech level) [56] that could be reached with single-speed compressor designs for all product classes. 85 FR 36512. In interviews, manufacturers raised concerns about the ability to meet the preliminary analysis' CEER values at EL 3 without the use of variable-speed compressors. Manufacturers asserted that the single-speed compressors necessary to meet the preliminary analysis EL 3 levels are not available to all manufacturers and encouraged DOE to base EL 3 on compressors that are widely available on the market.

b. Physical Design Constraints

Manufacturers noted that through-the-wall (''TTW'') products are designed to fit specific sleeve sizes and the market requires replacement products to fit existing sleeves. Additionally, window units are constrained by average window dimensions. Further, manufacturers noted that they design the boxed product to meet either 50 pound (''lb'') or 150 lb weight thresholds, reflecting requirements related to worker safety standards, parcel delivery service thresholds, and customer utility. Manufacturers noted that maintaining existing product dimensions is an important feature to their end-users, particularly in the replacement market.

c. Cost Increases and Component Shortages

Manufacturers noted that recent increases in raw material prices, escalating shipping and transportation costs, and limited component availability all affect manufacturer production costs. As a result, cost estimates based on historic 5-year averages would underestimate current production costs.

4. Discussion of MIA Comments

In response to the June 2020 Preliminary Analysis, interested parties submitted written comments addressing several topics including cumulative regulatory burden.

AHAM and GEA commented that DOE should include proposed changes to both standards and refrigerants, as well as the economic impact of U.S. tariffs on Chinese imports, when determining the cumulative regulatory burden placed on manufacturers. AHAM and GEA also urged DOE to incorporate the financial results of cumulative regulatory burden analysis into the GRIM to account for the time and resources needed to comply with concurrent regulations. (AHAM, No. 19 at pp. 12 and 17–19; GEA No. 26 at p. 2)

DOE analyzes cumulative regulatory burden pursuant to 10 CFR part 430, subpart C, appendix A. Pursuant to appendix A, the Department will recognize and consider the overlapping effects on manufacturers of new or revised DOE standards and other Federal regulatory actions affecting the same products or equipment. The results of this analysis can be found in section V.B.2.e of this document. DOE endeavors to provide analyses that take market conditions and the effect of other Federal regulatory actions into account, such as the U.S. tariffs on Chinese imports and the transition to alternative refrigerants. DOE incorporates these factors into their range of analyses, including the market and technology assessment, screening analysis, engineering analysis, energy usage analysis, NIA, and MIA.

In consideration of AHAM's comment on the possibility that California may prohibit HFCs and the resulting transition to alternative refrigerants (AHAM, No. 40 at p. 12), DOE evaluated potential impacts of CARB's proposed 750 GWP limit on the energy efficiency of new room ACs. This State regulation is specific to the products regulated by this NOPR and would require redesign of the covered product. Based on interviews and through review of market data, DOE found that all but one OEM is producing R–32 room AC models. Additionally, based on interview feedback, all OEMs intend to transition entirely to R–32 room ACs by 2023 regardless of DOE actions related to the energy conservation standards for room ACs. Thus, DOE did not consider the redesign costs related to R–32 to be conversion costs, as the change in refrigerant is independent of DOE actions related to any amended energy conservation standards.

DOE is aware of one OEM still in the process of redesigning room ACs to make use of R–32 and to comply with the requirements in Underwriters Laboratories (''UL'') Standard UL 60335–2–40, ''Household and Similar Electrical Appliances—Safety—Part 2–40: Particular Requirements for Electrical Heat Pumps, Air-Conditioners and Dehumidifiers'' (''UL 60335–2–40'') for their products that are manufactured in-house. To account for these investments, DOE incorporated an estimate of the on-going costs for that business into its GRIM.

Regarding U.S. tariffs on Chinese imports, tariff levels have escalated in recent years. At the time of the April 2011 Direct Final Rule, most room ACs imported into the U.S. were manufactured in China. Since that time, the Section 301 tariffs on room ACs increased to 10 percent in September 2018 and to 25 percent in May 2019.[57]

[56] For the June 2020 Preliminary Analysis, DOE analyzed five efficiency levels as part of its engineering analysis. In response to stakeholder comments to the preliminary analysis, DOE analyzed an additional efficiency level in the NOPR engineering analysis between EL 3 and the max-tech level (EL 4 in the preliminary analysis, now EL 5 for this NOPR).

[57] The Office of the United States Trade Representative (''USTR'') released a list of Chinese imports subject to new tariffs on September 18,

Continued

As result of tariffs, as noted by AHAM, ''some manufacturers have had to shift production to other countries to avoid the tariffs.'' (AHAM, No. 19 at pp. 18–19) DOE understands that these products are now made in countries in East Asia and Southeast Asia not subject to Section 301 tariffs. However, due to uncertainty about the exact countries of origin, DOE's engineering analysis continues to rely on data based on a Chinese point of origin. To revise MPCs to account for points of origin outside of China, DOE would require information on the countries of manufacture and 5-year averages for key inputs, such as fully burdened production labor wage rates and local raw material prices, used to develop MPCs.

To better model the impact of Section 301 tariffs on room AC products that continue to be manufactured in China, DOE requires additional information about the portion of products still manufactured in China and how the tariffs are absorbed by the entities along the room AC value chain, such as the foreign OEMs, U.S. importers, retailers, and consumers. Increases in retail price may affect consumer purchasing decisions, as captured by the price sensitivity modeled in the shipments analysis.

Additional details about cumulative regulatory burden and requests for comment can be found in section V.B.2.d of this document.

K. Emissions Analysis

The emissions analysis consists of two components. The first component estimates the effect of potential energy conservation standards on power sector and site (where applicable) combustion emissions of CO_2, NO_X, SO_2, and Hg. The second component estimates the impacts of potential standards on emissions of two additional greenhouse gases, CH_4 and N_2O, as well as the reductions to emissions of other gases due to ''upstream'' activities in the fuel production chain. These upstream activities comprise extraction, processing, and transporting fuels to the site of combustion.

The analysis of power sector emissions of CO_2, NO_X, SO_2, and Hg uses marginal emissions factors that were derived from data in *AEO 2021,* as described in section IV.M of this document. Details of the methodology are described in the appendices to chapters 13 and 15 of the NOPR TSD.

Power sector emissions of CO_2, CH_4, and N_2O are estimated using Emission Factors for Greenhouse Gas Inventories published by the EPA.[58] The FFC upstream emissions are estimated based on the methodology described in chapter 15 of the NOPR TSD. The upstream emissions include both emissions from extraction, processing, and transportation of fuel, and ''fugitive'' emissions (direct leakage to the atmosphere) of CH_4 and CO_2.

The emissions intensity factors are expressed in terms of physical units per megawatt-hours (''MWh'') or million British thermal units (''MMBtu'') of site energy savings. Total emissions reductions are estimated using the energy savings calculated in the national impact analysis.

1. Air Quality Regulations Incorporated in DOE's Analysis

DOE's no-new-standards case for the electric power sector reflects the *AEO 2021,* which incorporates the projected impacts of existing air quality regulations on emissions. *AEO 2021* generally represents current legislation and environmental regulations, including recent government actions that were in place at the time of preparation of *AEO 2021,* including the emissions control programs discussed in the following paragraphs.[59]

SO_2 emissions from affected electric generating units (''EGUs'') are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO_2 for affected EGUs in the 48 contiguous States and the District of Columbia (D.C.). (42 U.S.C. 7651 *et seq.*) SO_2 emissions from numerous States in the eastern half of the United States are also limited under the Cross-State Air Pollution Rule (''CSAPR''). 76 FR 48208 (Aug. 8, 2011). CSAPR requires these States to reduce certain emissions, including annual SO_2 emissions, and went into effect as of January 1, 2015.[60] *AEO 2021* incorporates implementation of CSAPR, including the update to the CSAPR ozone season program emission budgets and target dates issued in 2016, 81 FR 74504 (Oct. 26, 2016). Compliance with CSAPR is flexible among EGUs and is enforced through the use of tradable emissions allowances. Under existing EPA regulations, any excess SO_2 emissions allowances resulting from the lower electricity demand caused by the adoption of an efficiency standard could be used to permit offsetting increases in SO_2 emissions by another regulated EGU.

However, beginning in 2016, SO_2 emissions began to fall as a result of implementation of the Mercury and Air Toxics Standards (''MATS'') for power plants. 77 FR 9304 (Feb. 16, 2012). In the MATS final rule, EPA established a standard for hydrogen chloride as a surrogate for acid gas hazardous air pollutants (''HAP''), and also established a standard for SO_2 (a non-HAP acid gas) as an alternative equivalent surrogate standard for acid gas HAP. The same controls are used to reduce HAP and non-HAP acid gas; thus, SO_2 emissions are being reduced as a result of the control technologies installed on coal-fired power plants to comply with the MATS requirements for acid gas. To continue operating, coal power plants must have either flue gas desulfurization or dry sorbent injection systems installed. Both technologies, which are used to reduce acid gas emissions, also reduce SO_2 emissions. Because of the emissions reductions under the MATS, it is unlikely that excess SO_2 emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO_2 emissions by another regulated EGU. Therefore, energy conservation standards that decrease electricity

2018. The tariffs were set at 10 percent and had an effective date of September 24, 2018. Room ACs fall under Harmonized Tariffs Schedule (''HTS'') code 8415.10.30, ''Window or wall type air conditioning machines, self-contained,'' and were subject to those tariffs. The USTR press release on the adoption of the tariffs and the affected imports can be found at: *ustr.gov/about-us/policy-offices/press-office/press-releases/2018/september/ustr-finalizes-tariffs-200.* The Notice of Modification of Section 301 can be found at: *ustr.gov/sites/default/files/enforcement/301Investigations/83%20FR%2047974.pdf.*

Initially, the tariffs on room ACs were set to increase to 25 percent on January 1, 2019. The increase was delayed in subsequent negotiations. Ultimately the USTR raised tariffs on room ACs to 25 percent on May 10, 2019. The USTR press release on the increase in tariffs can be found at: *ustr.gov/sites/default/files/enforcement/301Investigations/83%20FR%2047974.pdf.* The Notice of Modification of Section 301 can be found at: *ustr.gov/sites/default/files/enforcement/301Investigations/84_FR_20459.pdf.*

[58] *www.epa.gov/sites/production/files/2016-09/documents/emission-factors_nov_2015_v2.pdf* (last accessed June 14, 2021).

[59] For further information, see the Assumptions to *AEO 2021* report that sets forth the major assumptions used to generate the projections in the Annual Energy Outlook. Available at *www.eia.gov/outlooks/aeo/assumptions/* (last accessed June 14, 2021).

[60] CSAPR requires states to address annual emissions of SO_2 and NO_X, precursors to the formation of fine particulate matter ($PM_{2.5}$) pollution, in order to address the interstate transport of pollution with respect to the 1997 and 2006 $PM_{2.5}$ National Ambient Air Quality Standards (''NAAQS''). CSAPR also requires certain states to address the ozone season (May–September) emissions of NO_X, a precursor to the formation of ozone pollution, in order to address the interstate transport of ozone pollution with respect to the 1997 ozone NAAQS. 76 FR 48208 (Aug. 8, 2011). EPA subsequently issued a supplemental rule that included an additional five states in the CSAPR ozone season program; 76 FR 80760 (Dec. 27, 2011) (Supplemental Rule).

generation would generally reduce SO_2 emissions. DOE estimated SO_2 emissions reduction using emissions factors based on *AEO2021.*

CSAPR also established limits on NO_X emissions for numerous States in the eastern half of the United States. Energy conservation standards would have little effect on NO_X emissions in those States covered by CSAPR emissions limits if excess NO_X emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_X emissions from other EGUs. In such case, NO_X emissions would remain near the limit even if electricity generation goes down. A different case could possibly result, depending on the configuration of the power sector in the different regions and the need for allowances, such that NO_X emissions might not remain at the limit in the case of lower electricity demand. In this case, energy conservation standards might reduce NO_X emissions in covered States. Despite this possibility, DOE has chosen to be conservative in its analysis and has maintained the assumption that standards will not reduce NO_X emissions in States covered by CSAPR. Energy conservation standards would be expected to reduce NO_X emissions in the States not covered by CSAPR. DOE used *AEO 2021* data to derive NO_X emissions factors for the group of States not covered by CSAPR.

The MATS limit mercury emissions from power plants, but they do not include emissions caps and, as such, DOE's energy conservation standards would be expected to slightly reduce Hg emissions. DOE estimated mercury emissions reduction using emissions factors based on *AEO 2021,* which incorporates the MATS.

L. Monetizing Emissions Impacts

As part of the development of this proposed rule, for the purpose of complying with the requirements of Executive Order 12866, DOE considered the estimated monetary benefits from the reduced emissions of CO_2, CH_4, N_2O, NO_X, and SO_2 that are expected to result from each of the TSLs considered. In order to make this calculation analogous to the calculation of the NPV of consumer benefit, DOE considered the reduced emissions expected to result over the lifetime of products shipped in the projection period for each TSL. This section summarizes the basis for the values used for monetizing the emissions benefits and presents the values considered in this NOPR.

On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law. DOE requests comment on how to address the climate benefits and other non-monetized effects of the proposal.

1. Monetization of Greenhouse Gas Emissions

For the purpose of complying with the requirements of Executive Order 12866, DOE estimates the monetized benefits of the reductions in emissions of CO_2, CH_4, and N_2O by using a measure of the social cost (''SC'') of each pollutant (*e.g.,* SC–GHGs). These estimates represent the monetary value of the net harm to society associated with a marginal increase in emissions of these pollutants in a given year, or the benefit of avoiding that increase. These estimates are intended to include (but are not limited to) climate-change-related changes in net agricultural productivity, human health, property damages from increased flood risk, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. DOE exercises its own judgment in presenting monetized climate benefits as recommended by applicable Executive orders and guidance, and DOE would reach the same conclusion presented in this proposed rulemaking in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases. DOE exercises its own judgment in presenting monetized climate benefits as recommended by applicable Executive Orders, and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases.

DOE estimated the global social benefits of CO_2, CH_4, and N_2O reductions (*i.e.,* SC–GHGs) using the estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG) (IWG, 2021). The SC–GHGs is the monetary value of the net harm to society associated with a marginal increase in emissions in a given year, or the benefit of avoiding that increase. In principle, SC–GHGs includes the value of all climate change impacts, including (but not limited to) changes in net agricultural productivity, human health effects, property damage from increased flood risk and natural disasters, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. The SC–GHGs therefore, reflects the societal value of reducing emissions of the gas in question by one metric ton. The SC–GHGs is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect CO_2, N_2O and CH4 emissions. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD), the DOE agrees that the interim SC–GHG estimates represent the most appropriate estimate of the SC–GHG until revised estimates have been developed reflecting the latest, peer-reviewed science.

The SC–GHGs estimates presented here were developed over many years, using transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. Specifically, in 2009, an interagency working group (IWG) that included the DOE and other executive branch agencies and offices was established to ensure that agencies were using the best available science and to promote consistency in the social cost of carbon (SC–CO2) values used across agencies. The IWG published SC–CO_2 estimates in 2010 that were developed from an ensemble of three widely cited integrated assessment models (IAMs) that estimate global climate damages using highly aggregated representations of climate processes and the global economy combined into a single modeling framework. The three IAMs were run using a common set of input assumptions in each model for future

population, economic, and CO_2 emissions growth, as well as equilibrium climate sensitivity (ECS)—a measure of the globally averaged temperature response to increased atmospheric CO^2 concentrations. These estimates were updated in 2013 based on new versions of each IAM. In August 2016 the IWG published estimates of the social cost of methane (SC–CH4) and nitrous oxide (SC–N2O) using methodologies that are consistent with the methodology underlying the SC–CO_2 estimates. The modeling approach that extends the IWG SC–CO2 methodology to non-CO2 GHGs has undergone multiple stages of peer review. The SC–CH4 and SC–N2O estimates were developed by Marten et al. (2015) and underwent a standard double-blind peer review process prior to journal publication. In 2015, as part of the response to public comments received to a 2013 solicitation for comments on the SC–CO2 estimates, the IWG announced a National Academies of Sciences, Engineering, and Medicine review of the SC–CO2 estimates to offer advice on how to approach future updates to ensure that the estimates continue to reflect the best available science and methodologies. In January 2017, the National Academies released their final report, Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide, and recommended specific criteria for future updates to the SC–CO2 estimates, a modeling framework to satisfy the specified criteria, and both near-term updates and longer-term research needs pertaining to various components of the estimation process (National Academies, 2017). Shortly thereafter, in March 2017, President Trump issued Executive Order 13783, which disbanded the IWG, withdrew the previous TSDs, and directed agencies to ensure SC–CO2 estimates used in regulatory analyses are consistent with the guidance contained in OMB's Circular A–4, ''including with respect to the consideration of domestic versus international impacts and the consideration of appropriate discount rates'' (E.O. 13783, Section 5(c)).

On January 20, 2021, President Biden issued Executive Order 13990, which re-established the IWG and directed it to ensure that the U.S. Government's estimates of the social cost of carbon and other greenhouse gases reflect the best available science and the recommendations of the National Academies (2017). The IWG was tasked with first reviewing the SC–GHG estimates currently used in Federal analyses and publishing interim estimates within 30 days of the E.O. that reflect the full impact of GHG emissions, including by taking global damages into account. The interim SC–GHG estimates published in February 2021, specifically the SC–CH4 estimates, are used here to estimate the climate benefits for this proposed rulemaking. The E.O. instructs the IWG to undertake a fuller update of the SC–GHG estimates by January 2022 that takes into consideration the advice of the National Academies (2017) and other recent scientific literature.

The February 2021 SC–GHG TSD provides a complete discussion of the IWG's initial review conducted under E.O. 13990. In particular, the IWG found that the SC–GHG estimates used under E.O. 13783 fail to reflect the full impact of GHG emissions in multiple ways. First, the IWG found that a global perspective is essential for SC–GHG estimates because it fully captures climate impacts that affect the United States and which have been omitted from prior U.S.-specific estimates due to methodological constraints. Examples of omitted effects include direct effects on U.S. citizens, assets, and investments located abroad, supply chains, and tourism, and spillover pathways such as economic and political destabilization and global migration. In addition, assessing the benefits of U.S. GHG mitigation activities requires consideration of how those actions may affect mitigation activities by other countries, as those international mitigation actions will provide a benefit to U.S. citizens and residents by mitigating climate impacts that affect U.S. citizens and residents. If the United States does not consider impacts on other countries, it is difficult to convince other countries to consider the impacts of their emissions on the United States. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with this assessment and, therefore, in this proposed rule DOE centers attention on a global measure of SC–CH4. This approach is the same as that taken in DOE regulatory analyses from 2012 through 2016. Prior to that, in 2008 DOE presented Social Cost of Carbon (SCC) estimates based on values the Intergovernmental Panel on Climate Change (IPCC) identified in literature at that time. As noted in the February 2021 SC–GHG TSD, the IWG will continue to review developments in the literature, including more robust methodologies for estimating a U.S.-specific SC–GHG value, and explore ways to better inform the public of the full range of carbon impacts. As a member of the IWG, DOE will continue to follow developments in the literature pertaining to this issue.

Second, the IWG found that the use of the social rate of return on capital (7 percent under current OMB Circular A–4 guidance) to discount the future benefits of reducing GHG emissions inappropriately underestimates the impacts of climate change for the purposes of estimating the SC–GHG. Consistent with the findings of the National Academies (2017) and the economic literature, the IWG continued to conclude that the consumption rate of interest is the theoretically appropriate discount rate in an intergenerational context (IWG 2010, 2013, 2016a, 2016b), and recommended that discount rate uncertainty and relevant aspects of intergenerational ethical considerations be accounted for in selecting future discount rates. As a member of the IWG involved in the development of the February 2021 SC–GHG TSD, DOE agrees with this assessment and will continue to follow developments in the literature pertaining to this issue.

While the IWG works to assess how best to incorporate the latest, peer reviewed science to develop an updated set of SC–GHG estimates, it set the interim estimates to be the most recent estimates developed by the IWG prior to the group being disbanded in 2017. The estimates rely on the same models and harmonized inputs and are calculated using a range of discount rates. As explained in the February 2021 SC–GHG TSD, the IWG has recommended that agencies to revert to the same set of four values drawn from the SC–GHG distributions based on three discount rates as were used in regulatory analyses between 2010 and 2016 and subject to public comment. For each discount rate, the IWG combined the distributions across models and socioeconomic emissions scenarios (applying equal weight to each) and then selected a set of four values recommended for use in benefit-cost analyses: An average value resulting from the model runs for each of three discount rates (2.5 percent, 3 percent, and 5 percent), plus a fourth value, selected as the 95th percentile of estimates based on a 3 percent discount rate. The fourth value was included to provide information on potentially higher-than-expected economic impacts from climate change. As explained in the February 2021 SC–GHG TSD, and DOE agrees, this update reflects the immediate need to have an operational SC–GHG for use in regulatory benefit-cost analyses and other applications that was developed using a transparent process, peer-reviewed methodologies, and the science available at the time of that process. Those estimates were

subject to public comment in the context of dozens of proposed rulemakings as well as in a dedicated public comment period in 2013.

DOE's derivations of the SC–GHG (*i.e.,* SC–CO_2, SC–N_2O, and SC–CH_4) values used for this NOPR are discussed in the following sections, and the results of DOE's analyses estimating the benefits of the reductions in emissions of these pollutants are presented in section V.B.6 of this document.

a. Social Cost of Carbon

The SC–CO_2 values used for this NOPR were generated using the values presented in the 2021 update from the IWG's February 2021 TSD. Table IV.8 shows the updated sets of SC–CO_2 estimates from the latest interagency update in 5-year increments from 2020 to 2050. The full set of annual values used is presented in Appendix 14A of the NOPR TSD. For purposes of capturing the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CO_2 values, as recommended by the IWG.[61]

Table IV.8 Annual SC-CO_2 Values from 2021 Interagency Update, 2020–2050 (2020$ per Metric Ton CO_2)

Year	Discount Rate			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
2020	14	51	76	152
2025	17	56	83	169
2030	19	62	89	187
2035	22	67	96	206
2040	25	73	103	225
2045	28	79	110	242
2050	32	85	116	260

In calculating the potential global benefits resulting from reduced CO_2 emissions, DOE used the values from the 2021 interagency report, adjusted to 2020$ using the implicit price deflator for gross domestic product (''GDP'') from the Bureau of Economic Analysis. For each of the four sets of SC–CO_2 cases specified, the values for emissions in 2020 were $14, $51, $76, and $152 per metric ton avoided (values expressed in 2020$). DOE derived values after 2050 based on the trend in 2020–2050 in each of the four cases in the IWG update. DOE derived values from 2051 to 2070 based on estimates published by EPA.[62] These estimates are based on methods, assumptions, and parameters identical to the 2020–2050 estimates published by the IWG. DOE derived values after 2070 based on the trend in 2060–2070 in each of the four cases in the IWG update.

DOE multiplied the CO_2 emissions reduction estimated for each year by the SC–CO_2 value for that year in each of the four cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SC–CO_2 values in each case. See chapter 13 for the annual emissions reduction. See appendix 14A for the annual SC–CO_2 values.

b. Social Cost of Methane and Nitrous Oxide

The SC–CH_4 and SC–N_2O values used for this NOPR were generated using the values presented in the 2021 update from the IWG.[63] Table IV.9 shows the updated sets of SC–CH_4 and SC–N_2O estimates from the latest interagency update in 5-year increments from 2020 to 2050. The full set of annual values used is presented in appendix 14A of the NOPR TSD. To capture the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC–CH_4 and SC–N_2O values, as recommended by the IWG.

[61] For example, the February 2021 TSD discusses how the understanding of discounting approaches suggests that discount rates appropriate for intergenerational analysis in the context of climate change may be lower than 3 percent.

[62] See EPA, *Revised 2023 and Later Model Year Light-Duty Vehicle GHG Emissions Standards: Regulatory Impact Analysis,* Washington, DC, December 2021. Available at: *https://www.epa.gov/system/files/documents/2021-12/420r21028.pdf* (last accessed January 13, 2022).

[63] Interagency Working Group on Social Cost of Greenhouse Gases, Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990, Washington, DC, February 2021. *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf?source=email.*

Table IV.9 Annual SC-CH_4 and SC-N_2O Values from 2021 Interagency Update, 2020–2050 (2020$ per Metric Ton)

Year	SC-CH_4				SC-N_2O			
	Discount Rate and Statistic				Discount Rate and Statistic			
	5%	3%	2.5%	3%	5%	3%	2.5 %	3%
	Average	Average	Average	95th percentile	Average	Average	Average	95th percentile
2020	670	1500	2000	3900	5800	18000	27000	48000
2025	800	1700	2200	4500	6800	21000	30000	54000
2030	940	2000	2500	5200	7800	23000	33000	60000
2035	1100	2200	2800	6000	9000	25000	36000	67000
2040	1300	2500	3100	6700	10000	28000	39000	74000
2045	1500	2800	3500	7500	12000	30000	42000	81000
2050	1700	3100	3800	8200	13000	33000	45000	88000

DOE multiplied the CH_4 and N_2O emissions reduction estimated for each year by the SC–CH_4 and SC–N_2O estimates for that year in each of the cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the cases using the specific discount rate that had been used to obtain the SC–CH_4 and SC–N_2O estimates in each case. See chapter 13 of the NOPR TSD for the annual emissions reduction. See appendix 14A of the NOPR TSD for the annual SC–CH_4 and SC–N_2O values.

2. Monetization of Other Air Pollutants

For this NOPR, DOE estimated the monetized value of NO_X and SO_2 emissions reductions from electricity generation using the latest benefit-per-ton estimates for that sector from the EPA's Benefits Mapping and Analysis Program.[64] DOE used EPA's values for $PM_{2.5}$-related benefits associated with NO_X and SO_2 and for ozone-related benefits associated with NO_X for 2025, 2030, 2035 and 2040, calculated with discount rates of 3 percent and 7 percent. DOE used linear interpolation to define values for the years not given in the 2025 to 2040 period; for years beyond 2040 the values are held constant. DOE derived values specific to the sector for room ACs using a method described in appendix 14B of the NOPR TSD.

DOE multiplied the emissions reduction (in tons) in each year by the associated $/ton values, and then discounted each series using discount rates of 3 percent and 7 percent as appropriate.

The SCoC Commenters presented reasons why DOE should, as it has in the past, monetize the full climate benefits of greenhouse gas emissions reductions, using the best available estimates, which were derived by the Interagency Working Group on the Social Cost of Greenhouse Gases. The SCoC Commenters also stated that DOE should factor these benefits into its choice of the maximum efficiency level that is economically justified, consistent with its statutory requirement to assess the national need to conserve energy under the Energy Policy and Conservation Act. (SCoC, No. 21 at p. 1)

On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

M. Utility Impact Analysis

The utility impact analysis estimates several effects on the electric power generation industry that would result from the adoption of new or amended energy conservation standards. The utility impact analysis estimates the changes in installed electrical capacity and generation that would result for each TSL. The analysis is based on published output from the NEMS associated with *AEO 2021.* NEMS produces the *AEO* Reference case, as well as a number of side cases that estimate the economy-wide impacts of changes to energy supply and demand. For the current analysis, impacts are quantified by comparing the levels of electricity sector generation, installed capacity, fuel consumption and emissions in the *AEO 2021* Reference case and various side cases. Details of the methodology are provided in the appendices to chapters 13 and 15 of the NOPR TSD.

The output of this analysis is a set of time-dependent coefficients that capture the change in electricity generation, primary fuel consumption, installed capacity and power sector emissions due to a unit reduction in demand for a given end use. These coefficients are multiplied by the stream of electricity savings calculated in the NIA to provide estimates of selected utility impacts of potential new or amended energy conservation standards.

N. Employment Impact Analysis

DOE considers employment impacts in the domestic economy as one factor in selecting a proposed standard. Employment impacts from new or amended energy conservation standards include both direct and indirect impacts. Direct employment impacts are any changes in the number of production and non-production employees of manufacturers of the products subject to standards.[65] The

[64] *Estimating the Benefit per Ton of Reducing $PM_{2.5}$ Precursors from 21 Sectors. www.epa.gov/benmap/estimating-benefit-ton-reducing-pm25-precursors-21-sectors.*

[65] As defined in the U.S. Census Bureau's 2016 *Annual Survey of Manufactures,* production workers include ''Workers (up through the line-supervisor level) engaged in fabricating, processing, assembling, inspecting, receiving, packing,

MIA addresses those impacts. Indirect employment impacts are changes in national employment that occur due to the shift in expenditures and capital investment caused by the purchase and operation of more-efficient appliances. Indirect employment impacts from standards consist of the net jobs created or eliminated in the national economy, other than in the manufacturing sector being regulated, caused by (1) reduced spending by consumers on energy, (2) reduced spending on new energy supply by the utility industry, (3) increased consumer spending on the products to which the new standards apply and other goods and services, and (4) the effects of those three factors throughout the economy.

One method for assessing the possible effects on the demand for labor of such shifts in economic activity is to compare sector employment statistics developed by the Labor Department's BLS. BLS regularly publishes its estimates of the number of jobs per million dollars of economic activity in different sectors of the economy, as well as the jobs created elsewhere in the economy by this same economic activity. Data from BLS indicate that expenditures in the utility sector generally create fewer jobs (both directly and indirectly) than expenditures in other sectors of the economy.[66] There are many reasons for these differences, including wage differences and the fact that the utility sector is more capital-intensive and less labor-intensive than other sectors. Energy conservation standards have the effect of reducing consumer utility bills. Because reduced consumer expenditures for energy likely lead to increased expenditures in other sectors of the economy, the general effect of efficiency standards is to shift economic activity from a less labor-intensive sector (*i.e.,* the utility sector) to more labor-intensive sectors (*e.g.,* the retail and service sectors). Thus, the BLS data suggest that net national employment may increase due to shifts in economic activity resulting from energy conservation standards.

DOE estimated indirect national employment impacts for the standard levels considered in this NOPR using an input/output model of the U.S. economy called Impact of Sector Energy Technologies version 4 (''ImSET'').[67] ImSET is a special-purpose version of the ''U.S. Benchmark National Input-Output'' (''I–O'') model, which was designed to estimate the national employment and income effects of energy-saving technologies. The ImSET software includes a computer-based I–O model having structural coefficients that characterize economic flows among 187 sectors most relevant to industrial, commercial, and residential building energy use.

DOE notes that ImSET is not a general equilibrium forecasting model, and that the uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Because ImSET does not incorporate price changes, the employment effects predicted by ImSET may over-estimate actual job impacts over the long run for this rule. Therefore, DOE used ImSET only to generate results for near-term timeframes, where these uncertainties are reduced. For more details on the employment impact analysis, see chapter 16 of the NOPR TSD.

V. Analytical Results and Conclusions

The following section addresses the results from DOE's analyses with respect to the considered energy conservation standards for room ACs. It addresses the TSLs examined by DOE, the projected impacts of each of these levels if adopted as energy conservation standards for room ACs, and the standards levels that DOE is proposing to adopt in this NOPR. Additional details regarding DOE's analyses are contained in the NOPR TSD supporting this document.

A. Trial Standard Levels

In general, DOE typically evaluates potential amended standards for products and equipment by grouping individual efficiency levels for each class into TSLs. Use of TSLs allows DOE to identify and consider manufacturer cost interactions between the product classes, to the extent that there are such interactions, and market cross elasticity from consumer purchasing decisions that may change when different standard levels are set. DOE analyzed the benefits and burdens of five TSLs for room ACs. DOE developed TSLs that combine efficiency levels for each analyzed product class. DOE presents the results for the TSLs in this document, while the results for all efficiency levels that DOE analyzed are in the NOPR TSD.

Table V.1 presents the TSLs and the corresponding efficiency levels that DOE has identified for potential amended energy conservation standards for room ACs. TSL 5 represents the max-tech energy efficiency for all product classes and corresponds to EL 5. TSL 4 corresponds to EL 4 for all product classes, consistent with the implementation of commercially available variable-speed compressors based on the current availability of variable speed compressors at cooling capacities ≥ 8,000 Btu/h. However, as of 2022, there are no models commercially available that incorporate variable-speed compressors for cooling capacities less than 8,000 Btu/h, and the uncertainties of the possibilities of incorporating variable-speed compressors in smaller units may have the potential to eliminate room ACs with the smallest cooling capacities from the market. TSL 3, therefore, is constructed with EL 4 for product classes with cooling capacities ≥ 8,000 Btu/h, corresponding to the inclusion of commercially available variable-speed compressors, and EL 3 for cooling capacities < 8,000 Btu/h, corresponding to the incorporation of maximum energy efficient single-speed compressors. TSL 2 corresponds to EL 3 for all product classes and represents room ACs with the maximum energy efficient single-speed compressor. TSL 1 corresponds to EL 2 for all product classes and represents the current ENERGY STAR level.

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warehousing, shipping (but not delivering), maintenance, repair, janitorial, guard services, product development, auxiliary production for plant's own use (*e.g.,* power plant), record keeping, and other closely associated services (including truck drivers delivering ready-mixed concrete)'' Non-production workers are defined as ''Supervision above line-supervisor level, sales (including a driver salesperson), sales delivery (truck drivers and helpers), advertising, credit, collection, installation, and servicing of own products, clerical and routine office functions, executive, purchasing, finance, legal, personnel (including cafeteria, *etc.*), professional and technical.''

[66] See U.S. Department of Commerce–Bureau of Economic Analysis. *Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (RIMS II).* 1997. U.S. Government Printing Office: Washington, DC. Available at *www.bea.gov/scb/pdf/regional/perinc/meth/rims2.pdf.*

[67] Livingston, O.V., S.R. Bender, M.J. Scott, and R.W. Schultz. *ImSET 4.0: Impact of Sector Energy Technologies Model Description and User Guide.* 2015. Pacific Northwest National Laboratory: Richland, WA. PNNL–24563.

Table V.1 Trial Standard Levels for Room Air Conditioners

Product Class	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
	CEER (Btu/Wh)				
Room AC without reverse cycle, with louvered sides					
<6,000 Btu/h (PC 1)	12.1	13.1	13.1	16.0	20.2
6,000 to 7,999 Btu/h (PC 2)	12.1	13.7	13.7	16.0	20.2
8,000 to 13,999 Btu/h (PC 3)	12.0	14.3	16.0	16.0	22.4
14,000 to 19,999 Btu/h (PC 4)	11.8	14.0	16.0	16.0	20.6
20,000 to 27,999 Btu/h (PC 5a)	10.3	11.8	13.8	13.8	19.1
≥28,000 Btu/h (PC 5b)	9.9	10.3	13.2	13.2	16.7
Room AC without reverse cycle, without louvered sides					
<6,000 Btu/h (PC 6)	11.0	12.8	12.8	14.7	19.4
6,000 to 7,999 Btu/h (PC 7)	11.0	12.8	12.8	14.7	19.4
8,000 to 10,999 Btu/h (PC 8a)	10.6	12.3	14.1	14.1	18.7
11,000 to 13,999 Btu/h (PC 8b)	10.5	12.3	13.9	13.9	19.1
14,000 to 19,999 Btu/h (PC 9)	10.2	10.9	13.7	13.7	16.6
≥20,000 Btu/h (PC 10)	10.3	11.0	13.8	13.8	16.8
Room AC with reverse cycle, with louvered sides					
<20,000 Btu/h (PC 11)	10.8	12.3	14.4	14.4	18.7
≥20,000 Btu/h (PC 13)	10.2	11.7	13.7	13.7	18.9
Room AC with reverse cycle, without louvered sides					
<14,000 Btu/h (PC 12)	10.2	11.3	13.7	13.7	16.2
≥14,000 Btu/h (PC 14)	9.6	11.2	12.8	12.8	17.5
Casement					
Casement-Only (PC 15)	10.5	12.2	13.9	13.9	18.1
Casement-Slide (PC 16)	11.4	13.2	15.3	15.3	19.7

DOE constructed the TSLs for this NOPR to include ELs representative of ELs with similar characteristics (*i.e.,* using similar technologies and/or efficiencies, and having roughly comparable equipment availability). The use of representative ELs provided for greater distinction between the TSLs. While representative ELs were included in the TSLs, DOE considered all efficiency levels as part of its analysis but did not include all efficiency levels in the TSLs.[68] DOE did not consider a TSL with EL 1 because DOE's projected efficiency distribution indicated a significant portion of the market would meet or exceed EL 1 in the no-new-standards case by the compliance year leading to smaller national energy savings and lower LCC savings for a standard set at EL 1 relative to EL 2. As such, the least efficient level considered for TSLs in this NOPR is EL 2.

B. Economic Justification and Energy Savings

1. Economic Impacts on Individual Consumers

DOE analyzed the economic impacts on room AC consumers by looking at the effects that potential amended standards at each TSL would have on the LCC and PBP. DOE also examined the impacts of potential standards on selected consumer subgroups. These analyses are discussed in the following sections.

a. Life-Cycle Cost and Payback Period

In general, higher-efficiency products affect consumers in two ways: (1) Purchase price increases and (2) annual operating costs decrease. Inputs used for calculating the LCC and PBP include total installed costs (*i.e.,* product price plus installation costs), and operating costs (*i.e.,* annual energy use, energy prices, energy price trends, repair costs, and maintenance costs). The LCC calculation also uses product lifetime and a discount rate. Chapter 8 of the NOPR TSD provides detailed information on the LCC and PBP analyses.

Table V.2 through Table V.25 show the LCC and PBP results for the TSLs considered for each product class. In the first of each pair of tables, the simple payback is measured relative to the baseline product. In the second of each pair of tables, impacts are measured relative to the efficiency distribution in the no-new-standards case in the compliance year (see section IV.F.8 of this document). Because some consumers purchase products with higher efficiency in the no-new-standards case, the average savings are less than the difference between the average LCC of the baseline product and the average LCC at each TSL. The savings refer only to consumers who are affected by a standard at a given TSL. Those who already purchase a product

[68] Efficiency levels that were analyzed for this NOPR are discussed in section IV.C.3 of this document. Results by efficiency level are presented in the NOPR TSD chapters 8, 10, and 12.

with efficiency at or above a given TSL are not affected. Consumers for whom the LCC increases at a given TSL experience a net cost.

Table V.2 Average LCC and PBP Results for Room Air Conditioners PC 1, Without Reverse Cycle and with Louvers, Less than 6,000 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	11.0	$370.65	$62.66	$468.55	$839.20	-	9.3
1	-	11.4	$372.06	$61.05	$456.64	$828.70	0.9	9.3
2	1	12.1	$374.95	$55.09	$412.42	$787.37	0.6	9.3
3	2,3	13.1	$379.10	$51.10	$382.87	$761.97	0.7	9.3
4	4	16.0	$464.91	$42.09	$316.27	$781.19	4.6	9.3
5	5	20.2	$477.52	$34.22	$257.85	$735.38	3.8	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.3 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 1, Without Reverse Cycle and with Louvers, Less than 6,000 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	11.4	$0.82	0%
1	12.1	$39.28	1%
2,3	13.1	$63.49	3%
4	16.0	$45.25	40%
5	20.2	$91.06	32%

* The savings represent the average LCC for affected consumers.

Table V.4 Average LCC and PBP Results for Room Air Conditioners PC 2, Without Reverse Cycle and with Louvers, 6,000–7,999 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	11.0	$407.59	$81.06	$616.44	$1,024.03	-	9.3
1	-	11.4	$409.87	$78.35	$595.94	$1,005.81	0.8	9.3
2	1	12.1	$413.43	$71.82	$546.61	$960.05	0.6	9.3
3	2,3	13.7	$421.94	$64.22	$489.11	$911.04	0.9	9.3
4	4	16.0	$511.73	$54.87	$418.34	$930.08	4.0	9.3
5	5	20.2	$562.03	$44.64	$341.01	$903.04	4.2	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.5 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 2, Without Reverse Cycle and with Louvers, 6,000–7,999 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	11.4	$0.00	0%
1	12.1	$34.23	2%
2,3	13.7	$80.02	5%
4	16.0	$62.00	40%
5	20.2	$89.03	43%

* The savings represent the average LCC for affected consumers.

Table V.6 Average LCC and PBP Results for Room Air Conditioners PC 3, Without Reverse Cycle, with Louvered Sides, and 8,000–13,999 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	10.9	$512.47	$104.95	$792.93	$1,305.40	-	9.3
1	-	11.4	$514.75	$101.34	$765.80	$1,280.55	0.6	9.3
2	1	12.0	$518.90	$92.17	$697.03	$1,215.93	0.5	9.3
3	2	14.3	$532.62	$78.23	$592.36	$1,124.98	0.8	9.3
4	3,4	16.0	$616.54	$67.97	$514.54	$1,131.08	2.8	9.3
5	5	22.4	$675.20	$50.21	$381.46	$1,056.67	3.0	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.7 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 3, Without Reverse Cycle, with Louvered Sides, and 8,000–13,999 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	11.4	$0.00	0%
1	12.0	$19.31	0%
2	14.3	$104.92	4%
3,4	16.0	$99.14	30%
5	22.4	$173.55	30%

* The savings represent the average LCC for affected consumers.

Table V.8 Average LCC and PBP Results for Room Air Conditioners PC 4, Without Reverse Cycle and with Louvers, 14,000–19,999 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	10.7	$642.61	$120.26	$903.35	$1,545.97	-	9.3
1	-	11.1	$644.60	$116.98	$878.91	$1,523.51	0.6	9.3
2	1	11.8	$651.70	$106.07	$797.78	$1,449.48	0.6	9.3
3	2	14.0	$662.16	$90.20	$679.66	$1,341.82	0.7	9.3
4	3,4	16.0	$769.44	$76.52	$577.36	$1,346.80	2.9	9.3
5	5	20.6	$813.45	$60.04	$454.84	$1,268.29	2.8	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.9 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 4, Without Reverse Cycle and with Louvers, 14,000–19,999 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	11.1	$0.00	0%
1	11.8	$0.00	0%
2	14.0	$102.30	1%
3,4	16.0	$97.49	35%
5	20.6	$176.00	32%

* The savings represent the average LCC for affected consumers.

Table V.10 Average LCC and PBP Results for Room Air Conditioners PC 5a, Without Reverse Cycle and with Louvers, 20,000–27,999 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	9.4	$800.55	$145.28	$1,057.96	$1,858.52	-	9.3
1	-	9.8	$803.27	$139.93	$1,019.56	$1,822.83	0.5	9.3
2	1	10.3	$819.84	$129.42	$944.08	$1,763.92	1.2	9.3
3	2	11.8	$831.48	$113.20	$827.62	$1,659.10	1.0	9.3
4	3,4	13.8	$938.90	$91.54	$670.41	$1,609.31	2.6	9.3
5	5	19.1	$1,011.43	$65.92	$486.74	$1,498.16	2.7	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.11 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 5a, Without Reverse Cycle and with Louvers, 20,000–27,999 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	9.8	$0.00	0%
1	10.3	$5.28	1%
2	11.8	$105.03	2%
3,4	13.8	$152.52	32%
5	19.1	$263.67	34%

* The savings represent the average LCC for affected consumers.

Table V.12 Average LCC and PBP Results for Room Air Conditioners PCs 5b, Without Reverse Cycle and with Louvers, Greater than 28,000 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	9.0	$848.65	$176.79	$1,288.42	$2,137.07	-	9.3
1	-	9.4	$851.46	$169.46	$1,235.83	$2,087.29	0.4	9.3
2	1	9.9	$855.66	$156.16	$1,140.31	$1,995.97	0.3	9.3
3	2	10.3	$859.12	$148.64	$1,086.31	$1,945.43	0.4	9.3
4	3,4	13.2	$998.92	$110.63	$811.63	$1,810.54	2.3	9.3
5	5	16.7	$1,049.36	$87.20	$643.64	$1,693.01	2.2	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.13 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 5b, Without Reverse Cycle and with Louvers, Greater than 28,000 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	9.4	$20.50	0%
1	9.9	$99.12	0%
2	10.3	$147.14	0%
3,4	13.2	$275.19	24%
5	16.7	$392.72	25%

* The savings represent the average LCC for affected consumers.

Table V.14 Average LCC and PBP Results for Room Air Conditioners PC 8a, Without Reverse Cycle and without Louvered Sides, 8,000–10,999 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	9.6	$526.19	$106.80	$806.94	$1,333.14	-	9.3
1	-	10.1	$529.28	$102.12	$771.88	$1,301.16	0.7	9.3
2	1	10.6	$532.73	$94.84	$717.22	$1,249.95	0.5	9.3
3	2	12.3	$543.73	$82.19	$622.28	$1,166.01	0.7	9.3
4	3,4	14.1	$649.32	$69.87	$528.88	$1,178.20	3.3	9.3
5	5	18.7	$681.04	$53.86	$408.91	$1,089.95	2.9	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.15 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 8a, Without Reverse Cycle and without Louvered Sides, 8,000–10,999 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	10.1	$0.00	0%
1	10.6	$5.67	0%
2	12.3	$85.72	4%
3,4	14.1	$74.28	37%
5	18.7	$162.53	29%

* The savings represent the average LCC for affected consumers.

Table V.16 Average LCC and PBP Results for Room Air Conditioners PC 8b, Without Reverse Cycle and without Louvered Sides, 11,000–13,999 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	9.5	$575.83	$131.04	$989.84	$1,565.68	-	9.3
1	-	10.0	$578.86	$125.53	$948.49	$1,527.35	0.5	9.3
2	1	10.5	$582.99	$114.83	$868.19	$1,451.18	0.4	9.3
3	2	12.3	$595.41	$99.04	$749.68	$1,345.10	0.6	9.3
4	3,4	13.9	$684.21	$85.02	$643.37	$1,327.58	2.4	9.3
5	5	19.1	$731.28	$63.62	$483.08	$1,214.36	2.3	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.17 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 8b, Without Reverse Cycle and without Louvered Sides, 11,000–13,999 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	10.0	$0.00	0%
1	10.5	$0.00	0%
2	12.3	$100.02	3%
3,4	13.9	$116.89	26%
5	19.1	$230.10	23%

* The savings represent the average LCC for affected consumers.

Table V.18 Average LCC and PBP Results for Room Air Conditioners PC 9, Without Reverse Cycle and without Louvered Sides, 14,000–19,999 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	9.3	$719.11	$117.88	$883.56	$1,602.67	-	9.3
1	-	9.7	$722.16	$113.34	$849.88	$1,572.04	0.7	9.3
2	1	10.2	$730.98	$104.87	$787.15	$1,518.13	0.9	9.3
3	2	10.9	$736.20	$98.41	$739.24	$1,475.44	0.9	9.3
4	3,4	13.7	$836.63	$75.96	$572.18	$1,408.81	2.8	9.3
5	5	16.6	$865.13	$63.30	$478.47	$1,343.60	2.7	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.19 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 9, Without Reverse Cycle and without Louvered Sides, 14,000–19,999 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	9.7	$11.98	1%
1	10.2	$58.37	3%
2	10.9	$98.98	2%
3,4	13.7	$162.64	24%
5	16.6	$227.85	24%

* The savings represent the average LCC for affected consumers.

Table V.20 Average LCC and PBP Results for Room Air Conditioners PC 11, With Reverse Cycle and with Louvered Sides, less than 20,000 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	9.8	$576.42	$105.97	$808.00	$1,384.41	-	9.3
1	-	10.4	$580.33	$100.68	$767.83	$1,348.17	0.7	9.3
2	1	10.8	$584.09	$92.59	$706.50	$1,290.59	0.6	9.3
3	2	12.3	$595.08	$82.32	$628.54	$1,223.62	0.8	9.3
4	3,4	14.4	$692.20	$69.57	$531.79	$1,223.99	3.2	9.3
5	5	18.7	$737.07	$55.29	$423.44	$1,160.51	3.2	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.21 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 11, With Reverse Cycle and with Louvered Sides, less than 20,000 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	10.4	$18.13	2%
1	10.8	$67.57	2%
2	12.3	$131.52	4%
3,4	14.4	$131.12	30%
5	18.7	$194.60	31%

* The savings represent the average LCC for affected consumers.

Table V.22 Average LCC and PBP Results for Room Air Conditioners PC 12, With Reverse Cycle and without Louvered Sides, less than 14,000 Btu/h

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	9.3	$641.40	$87.09	$655.95	$1,297.35	-	9.3
1	-	9.7	$644.16	$83.90	$632.10	$1,276.26	0.9	9.3
2	1	10.2	$652.09	$77.88	$587.01	$1,239.10	1.2	9.3
3	2	11.3	$659.94	$71.00	$535.57	$1,195.51	1.2	9.3
4	3,4	13.7	$714.83	$57.84	$436.71	$1,151.54	2.5	9.3
5	5	16.2	$741.39	$49.73	$376.08	$1,117.48	2.7	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.23 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 12, With Reverse Cycle and without Louvered Sides, less than 14,000 Btu/h

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	9.7	$8.12	2%
1	10.2	$39.97	7%
2	11.3	$81.20	7%
3,4	13.7	$122.74	20%
5	16.2	$156.81	24%

* The savings represent the average LCC for affected consumers.

Table V.24 Average LCC and PBP Results for Room Air Conditioners PC 16, Casement-Slider

EL	TSL	CEER	Average Costs *2020$*				Simple Payback *years*	Average Lifetime *years*
			Installed Cost	First Year's Operating Cost	Lifetime Operating Cost	LCC		
0	-	10.4	$501.23	$86.26	$656.88	$1,158.11	-	9.3
1	-	10.8	$503.64	$83.42	$635.46	$1,139.09	0.8	9.3
2	1	11.4	$507.10	$76.33	$581.83	$1,088.93	0.6	9.3
3	2	13.2	$516.42	$67.41	$514.31	$1,030.73	0.8	9.3
4	3,4	15.3	$616.56	$57.41	$438.70	$1,055.26	4.0	9.3
5	5	19.7	$641.98	$45.89	$351.50	$993.49	3.5	9.3

Note: The results for each TSL are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

Table V.25 Average LCC Savings Relative to the No-New-Standards Case for Room Air Conditioners PC 16, Casement-Slider

TSL	CEER	Life-Cycle Cost Savings	
		Average LCC Savings* *2020$*	Percent of Consumers that Experience Net Cost
-	10.8	$6.42	2%
1	11.4	$49.45	2%
2	13.2	$104.75	4%
3,4	15.3	$81.33	38%
5	19.7	$143.10	34%

* The savings represent the average LCC for affected consumers.

b. Consumer Subgroup Analysis

In the consumer subgroup analysis, DOE estimated the impact of the considered TSLs on low-income households and senior-only households for product classes with a sufficient sample size in RECS to perform a Monte Carlo analysis. DOE was unable to conduct a consumer subgroup analysis for Product Classes 4, 5a, 5b, and 9 for either low-income households or senior-only households due to insufficient sample size and does not report results for those product classes.[69] Table V.26 through Table V.41 compare the average LCC savings, PBP, percent of consumers negatively impacted, and percent of consumers positively impacted at each efficiency level for the consumer subgroups, along with corresponding values for the entire residential consumer sample for product classes with a sufficient sample size. In most cases, the values for low-income households and senior-only households at the considered efficiency levels are not substantially different from the average for all households. Chapter 11 of the NOPR TSD presents the complete LCC and PBP results for the subgroups.

[69] Product Classes 4, 5a, 5b, and 9 account for approximately 9 percent of the total room AC market.

Table V.26 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households: Room Air Conditioners PC 1, Without Reverse Cycle and with Louvers, Less than 6,000 Btu/h

		Average Life-Cycle Cost Savings* *2020$*			Simple Payback Period *years*		
EL	TSL	Low-Income Households‡	Senior-Only Households**	All Households†	Low-Income Households	Senior-Only Households**	All Households†
1	-	$0.86	-	$0.79	0.9	-	0.9
2	1	$40.12	-	$37.74	0.6	-	0.6
3	2,3	$64.92	-	$60.91	0.7	-	0.8
4	4	$52.08	-	$39.15	4.5	-	5.0
5	5	$98.55	-	$83.08	3.8	-	4.1

* The savings represent the average LCC for affected consumers. Negative values denoted in parentheses.
‡ Low-income households represent 60.0 percent of all households for this product class.
** Insufficient sample size to conduct subgroup analysis.
† The savings represent results of residential consumers only and exclude results from commercial consumers.

Table V.27 Comparison of Percent of Impacted Consumers for Consumer Subgroups and All Households: Room Air Conditioners PC 1, Without Reverse Cycle and with Louvers, Less than 6,000 Btu/h

		Percent of Consumers that Experience Net Cost			Percent of Consumers that Experience Net Benefit		
EL	TSL	Low-Income Households‡	Senior-Only Households**	All Households†	Low-Income Households	Senior-Only Households**	All Households†
1	-	0%	-	0%	8%	-	8%
2	1	0%	-	1%	93%	-	92%
3	2,3	0%	-	2%	95%	-	93%
4	4	35%	-	41%	60%	-	54%
5	5	26%	-	32%	74%	-	68%

‡ Low-income households represent 60.0 percent of all households for this product class.
** Insufficient sample size to conduct subgroup analysis.
† Results for residential consumers only and exclude results from commercial consumers.

Table V.28 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households: Room Air Conditioners PC 2, Without Reverse Cycle and with Louvers, 6,000–7,999 Btu/h

		Average Life-Cycle Cost Savings* *2020$*			Simple Payback Period *years*		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	$0.00	$0.00	$0.00	0.8	0.7	0.8
2	1	$36.28	$41.20	$35.27	0.6	0.5	0.6
3	2,3	$84.74	$96.89	$82.61	0.8	0.7	0.9
4	4	$67.05	$88.31	$65.64	3.9	3.5	4.0
5	5	$98.48	$130.37	$95.14	4.2	3.7	4.2

* The savings represent the average LCC for affected consumers. Negative values denoted in parentheses.
‡ Low-income households represent 50.1 percent of all households for this product class.
§ Senior-only households represent 24.7 percent of all households for this product class.
† The savings represent results of residential consumers only and exclude results from commercial consumers.

Table V.29 Comparison of Percent of Impacted Consumers for Consumer Subgroups and All Households: Room Air Conditioners PC 2, Without Reverse Cycle and with Louvers, 6,000–7,999 Btu/h

		Percent of Consumers that Experience Net Cost			Percent of Consumers that Experience Net Benefit		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	0%	0%	0%	0%	0%	0%
2	1	1%	2%	1%	74%	72%	73%
3	2,3	3%	5%	4%	90%	88%	89%
4	4	38%	31%	38%	58%	64%	57%
5	5	40%	33%	41%	60%	67%	59%

‡ Low-income households represent 50.1 percent of all households for this product class.
§ Senior-only households represent 24.7 percent of all households for this product class.
† Results for residential consumers only.

Table V.30 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households: Room Air Conditioners PC 3, Without Reverse Cycle, with Louvered Sides, and 8,000–13,999 Btu/h

		Average Life-Cycle Cost Savings* *2020$*			Simple Payback Period *years*		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	$0.00	$0.00	$0.00	0.6	0.7	0.7
2	1	$22.44	$17.94	$18.66	0.5	0.6	0.5
3	2	$122.51	$96.97	$101.79	0.7	0.8	0.8
4	3,4	$122.56	$81.51	$94.44	2.6	3.2	3.0
5	5	$218.31	$148.90	$165.48	2.7	3.3	3.2

* The savings represent the average LCC for affected consumers. Negative values denoted in parentheses.
‡ Low-income households represent 25.7 percent of all households for this product class.
§ Senior-only households represent 26.6 percent of all households for this product class.
† The savings represent results of residential consumers only and exclude results from commercial consumers.

Table V.31 Comparison of Percent of Impacted Consumers for Consumer Subgroups and All Households: Room Air Conditioners PC 3, Without Reverse Cycle, with Louvered Sides, and 8,000–13,999 Btu/h

		Percent of Consumers that Experience Net Cost			Percent of Consumers that Experience Net Benefit		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	0%	0%	0%	0%	0%	0%
2	1	0%	0%	0%	30%	30%	30%
3	2	4%	6%	4%	90%	88%	90%
4	3,4	28%	38%	29%	67%	57%	66%
5	5	27%	40%	30%	73%	60%	70%

‡ Low-income households represent 25.7 percent of all households for this product class.
§ Senior-only households represent 26.6 percent of all households for this product class.
† Results for residential consumers only.

Table V.32 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households: Room Air Conditioners PC 8a, Without Reverse Cycle and without Louvered Sides, 8,000–10,999 Btu/h

		Average Life-Cycle Cost Savings* *2020$*			Simple Payback Period *years*		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	$0.00	$0.00	$0.00	0.6	0.7	0.7
2	1	$6.90	$5.42	$5.55	0.5	0.6	0.6
3	2	$100.26	$79.59	$83.45	0.6	0.8	0.8
4	3,4	$96.07	$57.33	$70.43	3.0	3.7	3.5
5	5	$203.50	$139.26	$155.62	2.7	3.2	3.1

* The savings represent the average LCC for affected consumers. Negative values denoted in parentheses.
‡ Low-income households represent 25.7 percent of all households for this product class.
§ Senior-only households represent 26.6 percent of all households for this product class.
† The savings represent results of residential consumers only and exclude results from commercial consumers.

Table V.33 Comparison of Percent of Impacted Consumers for Consumer Subgroups and All Households: Room Air Conditioners PC 8a, Without Reverse Cycle and without Louvered Sides, 8,000–10,999 Btu/h

		Percent of Consumers that Experience Net Cost			Percent of Consumers that Experience Net Benefit		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	0%	0%	0%	0%	0%	0%
2	1	0%	0%	0%	11%	11%	11%
3	2	4%	5%	3%	91%	91%	92%
4	3,4	35%	46%	36%	61%	50%	59%
5	5	26%	38%	28%	74%	62%	72%

‡ Low-income households represent 25.7 percent of all households for this product class.
§ Senior-only households represent 26.6 percent of all households for this product class.
† Results for residential consumers only.

Table V.34 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households: Room Air Conditioners PC 8b, Without Reverse Cycle and without Louvered Sides, 11,000–13,999 Btu/h

		Average Life-Cycle Cost Savings* *2020$*			Simple Payback Period *years*		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	$0.00	$0.00	$0.00	0.5	0.6	0.6
2	1	$0.00	$0.00	$0.00	0.4	0.5	0.5
3	2	$117.02	$92.83	$97.18	0.5	0.7	0.7
4	3,4	$141.94	$96.54	$111.99	2.2	2.6	2.5
5	5	$280.86	$201.36	$221.12	2.1	2.6	2.5

* The savings represent the average LCC for affected consumers. Negative values denoted in parentheses.
‡ Low-income households represent 25.7 percent of all households for this product class.
§ Senior-only households represent 26.6 percent of all households for this product class.
† The savings represent results of residential consumers only and exclude results from commercial consumers.

Table V.35 Comparison of Percent of Impacted Consumers for Consumer Subgroups and All Households: Room Air Conditioners PC 8b, Without Reverse Cycle and without Louvered Sides, 11,000–13,999 Btu/h

		Percent of Consumers that Experience Net Cost			Percent of Consumers that Experience Net Benefit		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	0%	0%	0%	0%	0%	0%
2	1	0%	0%	0%	0%	0%	0%
3	2	3%	4%	3%	91%	90%	91%
4	3,4	24%	34%	25%	71%	61%	70%
5	5	20%	31%	22%	80%	69%	78%

‡ Low-income households represent 25.7 percent of all households for this product class.
§ Senior-only households represent 26.6 percent of all households for this product class.
† Results for residential consumers only.

Table V.36 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households: Room Air Conditioners PC 11, With Reverse Cycle and with Louvered Sides, less than 20,000 Btu/h

		Average Life-Cycle Cost Savings* *2020$*			Simple Payback Period *years*		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	$21.00	$19.73	$18.57	0.7	0.7	0.7
2	1	$77.89	$73.55	$69.29	0.5	0.5	0.6
3	2	$152.91	$143.97	$135.03	0.7	0.7	0.8
4	3,4	$160.90	$146.67	$136.12	2.9	3.0	3.2
5	5	$241.86	$220.82	$202.33	2.8	3.0	3.2

* The savings represent the average LCC for affected consumers. Negative values denoted in parentheses.
‡ Low-income households represent 39.4 percent of all households for this product class.
§ Senior-only households represent 25.0 percent of all households for this product class.
† The savings represent results of residential consumers only and exclude results from commercial consumers.

Table V.37 Comparison of Percent of Impacted Consumers for Consumer Subgroups and All Households: Room Air Conditioners PC 11, With Reverse Cycle and with Louvered Sides, less than 20,000 Btu/h

		Percent of Consumers that Experience Net Cost			Percent of Consumers that Experience Net Benefit		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	1%	2%	2%	49%	49%	49%
2	1	1%	2%	1%	85%	83%	84%
3	2	3%	5%	3%	93%	90%	92%
4	3,4	24%	30%	27%	72%	65%	68%
5	5	24%	31%	28%	76%	69%	72%

‡ Low-income households represent 39.4 percent of all households for this product class.
§ Senior-only households represent 25.0 percent of all households for this product class.
† Results for residential consumers only.

Table V.38 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households: Room Air Conditioners PC 12, With Reverse Cycle and without Louvered Sides, less than 14,000 Btu/h

		Average Life-Cycle Cost Savings* *2020$*			Simple Payback Period *years*		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	$9.52	$9.75	$8.10	0.8	0.8	0.9
2	1	$46.78	$47.40	$39.96	1.1	1.0	1.2
3	2	$94.76	$96.18	$81.15	1.1	1.0	1.2
4	3,4	$142.91	$146.29	$122.08	2.4	2.3	2.6
5	5	$186.10	$190.33	$156.32	2.5	2.5	2.8

* The savings represent the average LCC for affected consumers. Negative values denoted in parentheses.
‡ Low-income households represent 41.1 percent of all households for this product class.
§ Senior-only households represent 25.1 percent of all households for this product class.
† The savings represent results of residential consumers only and exclude results from commercial consumers.

Table V.39 Comparison of Percent of Impacted Consumers for Consumer Subgroups and All Households: Room Air Conditioners PC 12, With Reverse Cycle and without Louvered Sides, less than 14,000 Btu/h

		Percent of Consumers that Experience Net Cost			Percent of Consumers that Experience Net Benefit		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	1%	2%	1%	38%	37%	38%
2	1	4%	8%	6%	82%	78%	80%
3	2	4%	8%	6%	90%	87%	89%
4	3,4	16%	20%	19%	79%	75%	76%
5	5	19%	23%	22%	81%	77%	78%

‡ Low-income households represent 41.1 percent of all households for this product class.
§ Senior-only households represent 25.1 percent of all households for this product class.
† Results for residential consumers only.

Table V.40 Comparison of LCC Savings and PBP for Consumer Subgroups and All Households: Room Air Conditioners PC 16, Casement-Slider

		Average Life-Cycle Cost Savings* *2020$*			Simple Payback Period *years*		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	$7.03	$7.33	$6.38	0.8	0.8	0.9
2	1	$55.02	$57.23	$49.31	0.5	0.5	0.6
3	2	$117.04	$121.97	$104.50	0.7	0.7	0.8
4	3,4	$94.78	$100.47	$80.20	3.8	3.7	4.2
5	5	$167.19	$176.90	$142.02	3.3	3.2	3.6

* The savings represent the average LCC for affected consumers. Negative values denoted in parentheses.
‡ Low-income households represent 44.9 percent of all households for this product class.
§ Senior-only households represent 21.4 percent of all households for this product class.
† The savings represent results of residential consumers only and exclude results from commercial consumers.

Table V.41 Comparison of Percent of Impacted Consumers for Consumer Subgroups and All Households: Room Air Conditioners PC 16, Casement-Slider

		Percent of Consumers that Experience Net Cost			Percent of Consumers that Experience Net Benefit		
EL	TSL	Low-Income Households‡	Senior-Only Households§	All Households†	Low-Income Households	Senior-Only Households	All Households†
1	-	1%	3%	2%	32%	31%	32%
2	1	1%	3%	2%	84%	83%	84%
3	2	3%	7%	4%	92%	88%	91%
4	3,4	33%	36%	37%	62%	60%	58%
5	5	28%	32%	32%	72%	68%	68%

‡ Low-income households represent 44.9 percent of all households for this product class.
§ Senior-only households represent 21.4 percent of all households for this product class.
† Results for residential consumers only.

c. Rebuttable Presumption Payback

As discussed in section II.A of this document, EPCA establishes a rebuttable presumption that an energy conservation standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. (42 U.S.C. 6295(o)(2)(B)(iii)) In calculating a rebuttable presumption payback period for each of the considered TSLs, DOE used discrete values, and, as required by EPCA, based the energy use calculation on the DOE test procedure for room ACs. In contrast, the PBPs presented in section V.B.1.a of this document were calculated using distributions that reflect the range of energy use in the field.

Table V.42 presents the rebuttable-presumption payback periods for the considered TSLs for room ACs. While DOE examined the rebuttable-presumption criterion, it considered whether the standard levels considered for the NOPR are economically justified through a more detailed analysis of the economic impacts of those levels, pursuant to 42 U.S.C. 6295(o)(2)(B)(i), that considers the full range of impacts to the consumer, manufacturer, Nation, and environment. The results of that analysis serve as the basis for DOE to definitively evaluate the economic justification for a potential standard level, thereby supporting or rebutting the results of any preliminary determination of economic justification.

Table V.42 Rebuttable-Presumption Payback Periods

Product Class	Trial Standard Level				
	1	2	3	4	5
	years				
PC1: Room Air Conditioners, without reverse cycle, with louvered sides, and less than 6,000 Btu/h	1.0	1.0	1.0	7.0	5.3
PC2: Room Air Conditioners, without reverse cycle, with louvered sides, and 6,000 to 7,999 Btu/h	0.9	1.0	1.0	5.4	5.2
PC3: Room Air Conditioners, without reverse cycle, with louvered sides, and 8,000 to 13,999 Btu/h	0.6	0.8	3.5	3.5	3.1
PC4: Room Air Conditioners, without reverse cycle, with louvered sides, and 14,000 to 19,999 Btu/h	0.6	0.5	2.5	2.5	2.2
PC5a: Room Air Conditioners, without reverse cycle, with louvered sides, and 20,000 to 27,999 Btu/h	0.8	0.5	1.8	1.8	1.6
PC5b: Room Air Conditioners, without reverse cycle, with louvered sides, and 28,000 Btu/h or more	0.2	0.2	1.5	1.5	1.4
PC8a: Room Air Conditioners, without reverse cycle, without louvered sides, and 8,000 to 10,999 Btu/h	0.6	0.7	3.8	3.8	3.0
PC8b: Room Air Conditioners, without reverse cycle, without louvered sides, and 11,000 to 13,999 Btu/h	0.5	0.6	2.8	2.8	2.4
PC9: Room Air Conditioners, without reverse cycle, without louvered sides, and 14,000 to 19,999 Btu/h	0.7	0.6	2.2	2.2	1.9
PC11: Room Air Conditioners, with reverse cycle, with louvered sides, and less than 20,000 Btu/h	0.7	0.8	3.8	3.8	3.3
PC12: Room Air Conditioners, with reverse cycle, without louvered sides, and less than 14,000 Btu/h	1.3	1.1	3.1	3.1	2.9
PC16: Room Air Conditioners, Casement-Slider	0.7	0.8	4.8	4.8	3.9

2. Economic Impacts on Manufacturers

DOE performed an MIA to estimate the impact of amended energy conservation standards on manufacturers of room ACs. The following section describes the expected impacts on manufacturers at each considered TSL. Chapter 12 of the NOPR TSD explains the analysis in further detail.

a. Industry Cash Flow Analysis Results

In this section, DOE provides GRIM results from the analysis, which examines changes in the industry that would result from a standard. The following tables summarize the estimated financial impacts of potential amended energy conservation standards on manufacturers of room ACs, as well as the conversion costs that DOE estimates manufacturers of room ACs would incur at each TSL.

The impact of potential amended energy conservation standards were analyzed under two markup scenarios: (1) The preservation of gross margin percentage; and (2) the preservation of operating profit, as discussed in section IV.J.2.d of this document. The preservation of gross margin percentage scenario provides the upper bound while the preservation of operating profits scenario results in the lower (or more severe) bound to impacts of potential amended standards on industry.

Each of the modeled scenarios results in a unique set of cash flows and corresponding INPV for each TSL. INPV is the sum of the discounted cash flows to the industry from the base year through the end of the analysis period (2021–2055). The ''change in INPV'' results refer to the difference in industry value between the no-new-standards case and standards case at each TSL. To provide perspective on the short-run cash flow impact, DOE includes a comparison of free cash flow between the no-new-standards case and the standards case at each TSL in the year before amended standards would take effect. This figure provides an understanding of the magnitude of the required conversion costs relative to the cash flow generated by the industry in the no-new-standards case.

Conversion costs are one-time investments for manufacturers to bring their manufacturing facilities and product designs into compliance with potential amended standards. As described in section IV.J.2.c of this document, conversion cost investments occur between the year of publication of the final rule and the year by which manufacturers must comply with the new standard. The conversion costs can have a significant impact on the short-term cash flow on the industry and generally result in lower free cash flow in the period between the publication of the final rule and the compliance date of potential amended standards. Conversion costs are independent of the manufacturer markup scenarios and are not presented as a range in this analysis.

Table V.43 Manufacturer Impact Analysis Results for the Room Air Conditioner Industry*

	Units	No New STDs Case	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
INPV	$ MM	1,081	1,072 to 1,075	1,053 to 1,078	1,016 to 1,165	968 to 1,247	611 to 992
Change in INPV	%	-	(0.8) to (0.5)	(2.5) to (0.3)	(6.0) to 7.8	(10.4) to 15.4	(43.5) to (8.2)
Free Cash Flow (2025)	$ MM	72.6	66.8	60.0	64.1	62.8	(139.3)
Change in Free Cash Flow (2025)	%	-	(8.0)	(17.3)	(11.7)	(13.5)	(291.7)
Conversion Costs	$ MM	-	13.6	29.1	22.8	26.7	475.9

*Negative values denoted by parentheses.

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At TSL 1, the standard is set to existing ENERGY STAR levels (EL 2) for all product classes. DOE estimates the change in INPV to be minimal under both manufacturer markup scenarios. INPV is expected to range from −0.8 percent to −0.5 percent. At this level, free cash flow is estimated to decrease by 8.0 percent compared to the no-new-standards case value of $72.6 million in the year 2025, the year before the standards year. DOE's shipments analysis estimates approximately 75 percent of current shipments meet this level. At TSL 1, DOE does not expect industry to adopt new or larger chassis sizes. Capital conversion costs may be necessary for incremental updates in tooling. Product conversion costs are driven by specification, sourcing, and testing of more efficient compressors. DOE estimates capital conversion costs of $10.6 million and product conversion costs of $3.0 million. Conversion costs total $13.6 million.

At TSL 2, the standard reflects an efficiency level attainable by units with the most efficient R–32 single-speed compressor on the market, in combination with other design options,

for all product classes (EL 3). DOE estimates the change in INPV to range from −2.5 percent to −0.3 percent. At this level, free cash flow is estimated to decrease by 17.3 percent compared to the base-case value in the year before the standards year. DOE's shipments analysis estimates approximately 30 percent of current shipments meet this level. At TSL 2, DOE does not expect industry to adopt new or larger chassis designs. Capital conversion costs may be necessitated by the incorporation of additional design options, such as the inclusion of sub-cooling. Product conversion costs are driven by the need to redesign models to incorporate more efficient single-speed compressors as well as other design options. DOE estimates capital conversion costs of $24.3 million and product conversion costs of $4.8 million. Conversion costs total $29.1 million.

At TSL 3, the standard varies based by product class. For product classes with cooling capacities less than 8,000 Btu/h, the standard reflects an efficiency level attainable by units with the most efficient R–32 single-speed compressor on the market (EL 3) in combination with other design options. For product classes with cooling capacities greater than or equal to 8,000 Btu/h, the standard reflects an efficiency level consistent with the implementation commercially available variable-speed compressors (EL 4). DOE estimates the change in INPV to range from −6.0 percent to 7.8 percent. At this level, free cash flow is estimated to decrease by 11.7 percent compared to the base-case value in the year before the standards year. DOE's shipments analysis estimates approximately 1 percent of current shipments meet this level.

At this level, DOE does not expect industry to adopt new or larger chassis designs. For product classes with cooling capacities greater than or equal to the 8,000 Btu/h threshold, additional capital conversion costs may be necessary to adjust appearance tooling. DOE anticipates greater redesign efforts and product conversion costs as manufacturers move these products to variable-speed compressor designs. DOE estimates capital conversion costs of $6.2 million and product conversion costs of $16.6 million. Conversion costs total $22.8 million.

In interviews and through review of market data, DOE found that all but one OEM currently produce R–32 room AC models. Additionally, based on interview feedback, all OEMs intend to entirely transition to R–32 room ACs by 2023 regardless of DOE actions related to the energy conservation standards for room ACs. Thus, DOE did not consider the redesign costs related to R–32 as conversion costs that are the result of any amended energy conservation standards. However, DOE does take costs associated with the transition to low-GWP refrigerants into account in its modeling of the GRIM, as discussed in the cumulative regulatory burden portion of this notice in section V.B.2.d of this document.

At TSL 4, the standard reflects the efficiency consistent with the implementation of commercially available variable-speed compressors for all product classes (EL 4). DOE estimates the change in INPV to range from −10.4 percent to 15.4 percent. At this level, free cash flow is estimated to decrease by 13.5 percent compared to the base-case value in the year before the standards year. DOE's shipments analysis estimates that less than 1 percent of current shipments meet this level. At this level, DOE does not expect industry to adopt new or larger chassis designs. Capital conversion costs may be necessary for adjustments in appearance tooling. Compared to lower ELs, DOE anticipates significantly greater redesign efforts and product conversion costs as manufacturers move all products to variable-speed compressor designs. Based on DOE's CCD, DOE estimates that OEMs would need to redesign all product platforms to meet the efficiency levels required by TSL 4. DOE estimates capital conversion costs of $6.0 million and product conversion costs of $20.7 million. Conversion costs total $26.7 million.

At TSL 5, the standard reflects max-tech efficiency (EL 5) for all product classes. DOE estimates the change in INPV to range from −43.5 percent to −8.2 percent. At this level, free cash flow is estimated to decrease by 291.7 percent compared to the base-case value in the year before the standards year. In DOE's review of the market, no models currently meet this level. DOE estimates capital conversion costs of $455.0 million and product conversion costs of $20.8 million. Conversion costs total $475.9 million.[70]

At this level, DOE expects significant changes to chassis size for both window and TTW units. As a result, capital conversion costs increase significantly as manufacturers adjust equipment and tooling to accommodate new dimensions. As with EL 4, DOE anticipates significant redesign efforts and product conversion costs as manufacturers move all products to variable-speed compressor designs. OEMs would need to redesign all product platforms to meet the efficiency levels required by TSL 5.

At TSL 5, the large conversion costs result in a free cash flow dropping below zero in the years before the standard year. The negative free cash flow calculation indicates manufacturers may need to access cash reserves or outside capital to finance conversion efforts.

b. Direct Impacts on Employment

DOE's research indicates no room ACs are currently made in domestic production facilities. DOE expects that amended standards would have no impact on domestic production employment, which would remain at zero. Manufacturers maintain offices in the United States to handle design, marketing, technical support, and other business needs. Large changes in total annual shipments may lead to companies reducing their non-production room AC staff. However, DOE's shipments model does not forecast substantial changes in total annual shipments for the standards case. If total shipments remain relatively steady DOE would not expect any change to non-production employment as a result of amended standards. See section IV.G of this document for additional details on DOE's shipments analysis.

c. Impacts on Manufacturing Capacity

In interviews, manufacturers noted that the majority of room ACs are manufactured overseas by high-volume manufacturers producing product for a range of international markets. Manufacturers had few concerns about production line constraints below the max-tech level. However, at the max-tech level, some manufacturers noted concerns about having sufficient technical resources to oversee the redesign and testing of all room AC products to incorporate variable-speed technology.

Additionally, DOE notes that the most efficient variable-speed compressors that were implemented in the NOPR analysis are offered by only a single manufacturer. Based on public information, DOE was unable to determine the availability and pricing of these compressors. Given the lack of information regarding availability of these highest efficiency variable-speed compressors and the limited number of variable-speed compressors rated at or near the efficiency of compressors considered for the max-tech efficiency level, there may not be sufficient availability of the highest efficiency variable-speed compressors to meet the

[70] Capital conversion costs and product conversion costs may not sum to total due to independent rounding.

entire industry's production capacity needs at all cooling capacities of room ACs at EL 5.

d. Impacts on Subgroups of Manufacturers

Using average cost assumptions to develop industry cash-flow estimates may not capture the differential impacts among subgroups of manufacturers. Small manufacturers, niche players, or manufacturers exhibiting a cost structure that differs substantially from the industry average could be affected disproportionately. DOE investigated small businesses as a manufacturer subgroup that could be disproportionally impacted by energy conservation standards and could merit additional analysis. DOE did not identify any other adversely impacted manufacturer subgroups for this proposed rulemaking based on the results of the industry characterization.

DOE analyzes the impacts on small businesses in a separate analysis in section VII.B of this document as part of the Regulatory Flexibility Analysis. For a discussion of the impacts on the small business manufacturer subgroup, see the Regulatory Flexibility Analysis in section VI.B of this document and chapter 12 of the NOPR TSD.

e. Cumulative Regulatory Burden

One aspect of assessing manufacturer burden involves looking at the cumulative impact of multiple DOE standards and the product-specific regulatory actions of other Federal agencies that affect the manufacturers of a covered product or equipment. While any one regulation may not impose a significant burden on manufacturers, the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency. DOE requests information regarding the impact of cumulative regulatory burden on manufacturers of room ACs associated with multiple DOE standards or product-specific regulatory actions of other Federal agencies.

DOE evaluates product-specific regulations that will take effect approximately 3 years before or after the 2026 compliance date of any amended energy conservation standards for room ACs. This information is presented in Table V.44.

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Table V.44 Compliance Dates and Expected Conversion Expenses of Federal Energy Conservation Standards Affecting Room Air Conditioner Manufacturers

Federal Energy Conservation Standard	Number of Manufacturers*	Number of Manufacturers Affected from Today's Rule**	Approx. Standards Year	Industry Conversion Costs (*Millions $*)	Industry Conversion Costs / Product Revenue***
Commercial Warm Air Furnaces 81 FR 2420 (January 15, 2016)	16	1	2023	$7.5 to $22.2 (2014$)	1.7% to 5.1%†
Small, Large, and Very Large Commercial Package Air Conditioning and Heating Equipment 81 FR 2420 (January 15, 2016)	29	4	2018 and 2023‡	$520.8 (2014$)	4.9%
Residential Central Air Conditioners and Heat Pumps 82 FR 1786 (January 6, 2017)	51	8	2023	$342.6 (2015$)	0.5%
Portable Air Conditioners 85 FR 1378 (January 10, 2020)	11	5	2025	$320.9 (2015$)	6.7%
Commercial Packaged Boilers 85 FR 1592 (January 10, 2020)	43	1	2023	$21.2 (2015$)	2.3%

* This column presents the total number of manufacturers identified in the energy conservation standard rule contributing to cumulative regulatory burden.
** This column presents the number of manufacturers producing room AC equipment that are also listed as manufacturers in the listed energy conservation standard contributing to cumulative regulatory burden.
*** This column presents industry conversion costs as a percentage of product revenue during the conversion period. Industry conversion costs are the upfront investments manufacturers must make to sell compliant products/equipment. The revenue used for this calculation is the revenue from just the covered product/equipment associated with each row. The conversion period is the time frame over which conversion costs are made and lasts from the publication year of the final rule to the compliance year of the final rule. The conversion period typically ranges from 3 to 5 years, depending on the energy conservation standard.
†Low and high conversion cost scenarios were analyzed as part of this Direct Final Rule. The range of estimated conversion expenses presented here reflects those two scenarios.
‡The Direct Final Rule for Small, Large, and Very Large Commercial Package Air Conditioning and Heating Equipment adopts an amended standard in 2018 and a higher amended standard in 2023. The conversion costs are spread over an 8-year conversion period ending in 2022, with over 80 percent of the conversion costs occurring between 2019 and 2022.

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In addition to the Federal, product-specific cumulative regulatory burden described above, DOE considered the impacts of other factors in its review of burdens that could lead to industry constraints.

CARB's proposed 750 GWP limit for new room air conditioning equipment:

DOE evaluated potential impacts of CARB's proposed 750 GWP limit for new room ACs that would take effect in 2023.[71] This proposed State regulation is specific to the products regulated by this NOPR. Based on manufacturer interviews, DOE understands that all OEMs and major manufacturers intend to transition their complete portfolio of room AC offerings for the U.S. market to R–32 refrigerant to meet CARB's proposed requirement by 2023. DOE's research and testing indicates that the transition to R–32 would likely not have a negative impact on product efficiency.

DOE is aware of one OEM still in the process of redesigning room ACs to make use of R–32, including compliance with the relevant safety standard UL 60335–2–40.[72] The on-going effort to transition its room AC product lines to make use of R–32 requires a level of investment beyond the typical annual R&D expenditures. To account for these investments, both the product development to make use of R–32 and product updates to meet UL 60335–2–40, DOE has attempted to incorporate the on-going cost into its GRIM. DOE did not receive any quantitative estimates of the cost of the transition to R–32. For modeling purposes, DOE assumed that the transition to R–32 would require a doubling of R&D expenditures (2.2 percent of revenue) annually in the period between the base year and the compliance of the analysis for that business. This value is based on qualitative statements made by the OEM.

DOE requests comment on the magnitude of costs associated with transitioning room AC models to low-GWP refrigerants, such as R–32, along with the associated UL costs that would be incurred between the publication of this NOPR and the proposed compliance date of amended standards. Quantification and categorization of these costs, such as engineering efforts, testing lab time, UL certification costs, and capital investments, would enable DOE to refine its analysis.

Section 301 tariffs on certain Chinese goods:

Regarding U.S. tariffs on Chinese imports, tariff levels have escalated in recent years. At the time of the April 2011 Direct Final Rule, most room ACs imported into the United States were manufactured in China. Since that time, as discussed above, the Section 301 tariffs on room ACs increased to 10 percent in September 2018 and to 25 percent in May 2019. As result of tariffs, as noted by AHAM, ''some manufacturers have had to shift production to other countries to avoid the tariffs.'' (AHAM, No. 19 at pp. 18–19) DOE understands that these products are now made in countries in East Asia and Southeast Asia not subject to Section 301 tariffs. However, due to uncertainty about the exact countries of origin, DOE's engineering analysis continues to rely on data based on a Chinese point of origin. To revise MPCs to account for points of origin outside of China, DOE would require information on the countries of manufacture and 5-year averages for key inputs used to develop manufacturer production costs, such as fully-burdened production labor wage rates and local raw material prices.

To better model the impact of Section 301 tariffs on room ACs that continue to be manufactured in China, DOE requires additional information about the portion of products still manufactured there and how the tariffs are absorbed by the entities along the room AC value chain, such as the foreign OEMs, U.S. importers, retailers, and consumers. Increases in retail price may affect consumer purchasing decisions, as captured by the price sensitivity modeled in the shipments analysis.

DOE requests comment on the percentage of room ACs manufactured outside of China and the countries of origin, as well as information on the country-specific fully-burdened labor rates and key raw material prices.

DOE requests comment on the impact of tariffs on pricing at each step in the distribution chain, as well as the percentage change in retail price paid by the consumer as result of Section 301 tariffs.

3. National Impact Analysis

This section presents DOE's estimates of the national energy savings and the NPV of consumer benefits that would result from each of the TSLs considered as potential amended standards.

a. Significance of Energy Savings

To estimate the energy savings attributable to potential amended standards for room ACs, DOE compared their energy consumption under the no-new-standards case to their anticipated energy consumption under each TSL. The savings are measured over the entire lifetime of products purchased in the 30-year period that begins in the year of anticipated compliance with amended standards (2026–2055). Table V.45 presents DOE's projections of the national energy savings for each TSL considered for room ACs. The savings were calculated using the approach described in section IV.H.2 of this document.

Table V.45 Cumulative National Energy Savings for Room Air Conditioners; 30 Years of Shipments (2026–2055)

	Trial Standard Level				
	1	2	3	4	5
	quads				
Primary energy savings	0.28	0.91	1.35	1.79	3.31
FFC energy savings	0.29	0.94	1.40	1.86	3.44

OMB Circular A–4 [73] requires agencies to present analytical results, including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this proposed rulemaking, DOE undertook a sensitivity analysis using 9 years, rather than 30 years, of product shipments.

[71] *ww3.arb.ca.gov/board/res/2020/res20-37.pdf.*

[72] UL 60335–2–40 includes safety requirements for the use of flammable refrigerants in the covered product. *Standard for Household and Similar Electrical Appliances—Safety—Part 2–40: Requirements for Electrical Heat Pumps, Air-Conditioners and Dehumidifiers.* UL 60335–2–40, Edition 3:2019. Northbrook, IL: Underwriters' Laboratories.

[73] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* September 17, 2003. *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.*

The choice of a 9-year period is a proxy for the timeline in EPCA for the review of certain energy conservation standards and potential revision of and compliance with such revised standards.[74] The review timeframe established in EPCA is generally not synchronized with the product lifetime, product manufacturing cycles, or other factors specific to room ACs. Thus, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology. The NES sensitivity analysis results based on a 9-year analytical period are presented in Table V.46. The impacts are counted over the lifetime of room ACs purchased in 2026–2034.

Table V.46 Cumulative National Energy Savings for Room Air Conditioners; 9 Years of Shipments (2026–2034)

	Trial Standard Level				
	1	2	3	4	5
	quads				
Primary energy savings	0.11	0.37	0.51	0.65	1.08
FFC energy savings	0.12	0.38	0.53	0.67	1.12

b. Net Present Value of Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for consumers that would result from the TSLs considered for room ACs. In accordance with OMB's guidelines on regulatory analysis,[75] DOE calculated NPV using both a 7-percent and a 3-percent real discount rate. Table V.47 shows the consumer NPV results with impacts counted over the lifetime of products purchased in 2026–2055.

Table V.47 Cumulative Net Present Value of Consumer Benefits for Room Air Conditioners; 30 Years of Shipments (2026–2055)

Discount Rate	Trial Standard Level				
	1	2	3	4	5
	billion 2020$				
3 percent	2.71	8.55	10.56	12.21	22.59
7 percent	1.35	4.25	4.83	5.21	9.64

The NPV results based on the aforementioned 9-year analytical period are presented in Table V.48. The impacts are counted over the lifetime of products purchased in 2026–2034. As mentioned previously, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology or decision criteria.

Table V.48 Cumulative Net Present Value of Consumer Benefits for Room Air Conditioners; 9 Years of Shipments (2026–2034)

Discount Rate	Trial Standard Level				
	1	2	3	4	5
	billion 2020$				
3 percent	1.40	4.41	4.78	4.98	8.99
7 percent	0.87	2.70	2.76	2.69	4.95

The previous results reflect the use of a default trend to estimate the change in price for room ACs over the analysis period (see section IV.F.6 of this document). DOE also conducted a sensitivity analysis that considered one scenario with a low price decline and one scenario with a higher rate of price decline than the reference case. The results of these alternative cases are presented in appendix 10C of the NOPR TSD. In the high-price-decline case, the NPV of consumer benefits is higher than in the default case. In the fixed price case, the NPV of consumer benefits is lower than in the default case.

c. Indirect Impacts on Employment

It is estimated that amended energy conservation standards for room ACs would reduce energy expenditures for consumers of those products, with the resulting net savings being redirected to other forms of economic activity. These

[74] Section 325(m) of EPCA requires DOE to review its standards at least once every 6 years, and requires, for certain products, a 3-year period after any new standard is promulgated before compliance is required, except that in no case may any new standards be required within 6 years of the compliance date of the previous standards. While adding a 6-year review to the 3-year compliance period adds up to 9 years, DOE notes that it may undertake reviews at any time within the 6 year period and that the 3-year compliance date may yield to the 6-year backstop. A 9-year analysis period may not be appropriate given the variability that occurs in the timing of standards reviews and the fact that for some products, the compliance period is 5 years rather than 3 years.

[75] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* September 17, 2003. *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.*

expected shifts in spending and economic activity could affect the demand for labor. As described in section IV.N of this document, DOE used an input/output model of the U.S. economy to estimate indirect employment impacts of the TSLs that DOE considered. There are uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Therefore, DOE generated results for near-term timeframes (2026–2035), where these uncertainties are reduced.

The results suggest that the proposed standards would be likely to have a negligible impact on the net demand for labor in the economy. The net change in jobs is so small that it would be imperceptible in national labor statistics and might be offset by other, unanticipated effects on employment. Chapter 16 of the NOPR TSD presents detailed results regarding anticipated indirect employment impacts.

4. Impact on Utility or Performance of Products

As discussed in section III.E.1.d of this document, DOE has tentatively concluded that the standards proposed in this NOPR would not lessen the utility or performance of the room ACs under consideration in this proposed rulemaking.

5. Impact of Any Lessening of Competition

DOE considered any lessening of competition that would be likely to result from new or amended standards. As discussed in section III.E.1.e of this document, the Attorney General determines the impact, if any, of any lessening of competition likely to result from a proposed standard, and transmits such determination in writing to the Secretary, together with an analysis of the nature and extent of such impact. To assist the Attorney General in making this determination, DOE has provided DOJ with copies of this NOPR and the accompanying TSD for review. DOE will consider DOJ's comments on the proposed rule in determining whether to proceed to a final rule. DOE will publish and respond to DOJ's comments in that document. DOE invites comment from the public regarding the competitive impacts that are likely to result from this proposed rule. In addition, stakeholders may also provide comments separately to DOJ regarding these potential impacts. See the **ADDRESSES** section for information to send comments to DOJ.

6. Need of the Nation To Conserve Energy

Enhanced energy efficiency, where economically justified, improves the Nation's energy security, strengthens the economy, and reduces the environmental impacts (costs) of energy production. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. Chapter 15 of the NOPR TSD presents the estimated impacts on electricity generating capacity, relative to the no-new-standards case, for the TSLs that DOE considered in this proposed rulemaking.

Energy conservation resulting from potential energy conservation standards for room ACs is expected to yield environmental benefits in the form of reduced emissions of certain air pollutants and greenhouse gases. Table V.49 provides DOE's estimate of cumulative emissions reductions expected to result from the TSLs considered in this rulemaking. The emissions were calculated using the multipliers discussed in section IV.K of this document. DOE reports annual emissions reductions for each TSL in chapter 13 of the NOPR TSD.

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Table V.49 Cumulative Emissions Reduction for Room Air Conditioners Shipped in 2026–2055

	Trial Standard Level				
	1	2	3	4	5
Power Sector Emissions					
CO_2 (*million metric tons*)	9.74	31.08	46.13	61.03	112.32
SO_2 (*thousand tons*)	3.98	12.68	18.82	24.90	45.83
NO_X (*thousand tons*)	3.98	12.71	18.80	24.83	45.55
Hg (*tons*)	0.02	0.08	0.11	0.15	0.27
CH_4 (*thousand tons*)	0.71	2.28	3.37	4.45	8.16
N_2O (*thousand tons*)	0.10	0.32	0.47	0.62	1.13
Upstream Emissions					
CO_2 (*million metric tons*)	0.72	2.29	3.42	4.53	8.36
SO_2 (*thousand tons*)	0.05	0.17	0.26	0.34	0.63
NO_X (*thousand tons*)	10.66	33.97	50.61	67.08	123.95
Hg (*tons*)	0.00	0.00	0.00	0.00	0.00
CH_4 (*thousand tons*)	70.73	225.37	335.89	445.30	823.18
N_2O (*thousand tons*)	0.00	0.01	0.02	0.02	0.04
Total FFC Emissions					
CO_2 (*million metric tons*)	10.46	33.37	49.55	65.55	120.68
SO_2 (*thousand tons*)	4.03	12.86	19.08	25.24	46.45
NO_X (*thousand tons*)	14.64	46.68	69.41	91.92	169.50
Hg (*tons*)	0.02	0.08	0.11	0.15	0.28
CH_4 (*thousand tons*)	71.44	227.64	339.26	449.75	831.34
N_2O (*thousand tons*)	0.10	0.33	0.49	0.64	1.18

As part of the analysis for this rulemaking, DOE estimated monetary benefits likely to result from the reduced emissions of CO_2 that DOE estimated for each of the considered TSLs for room ACs. Section IV.L of this document discusses the SC–CO_2 values that DOE used. Table V.50 presents the value of CO_2 emissions reduction at each TSL.

Table V.50 Present Social Value of CO_2 Emissions Reduction for Room Air Conditioners Shipped in 2026–2055

TSL	SC-CO_2 Case			
	Discount Rate and Statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	million 2020$			
1	99.0	418.0	650.4	1,272.0
2	317.7	1,339.3	2,082.1	4,076.6
3	464.4	1,969.6	3,067.2	5,993.9
4	609.2	2,592.3	4,040.8	7,888.1
5	1,101.6	4,721.6	7,374.2	14,364.6

As discussed in section IV.L.1.b of this document, DOE estimated monetary benefits likely to result from the reduced emissions of CH_4 and N_2O that DOE estimated for each of the considered TSLs for room ACs. Table V.51 presents the value of the CH_4 emissions reduction at each TSL, and Table V.52 presents the value of the N_2O emissions reduction at each TSL.

Table V.51 Present Social Value of Methane Emissions Reduction for Room Air Conditioners Shipped in 2026–2055

TSL	SC-CH_4 Case			
	Discount Rate and Statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	million 2020$			
1	30.5	88.3	122.5	234.2
2	98.0	282.2	391.2	749.3
3	143.9	418.0	580.6	1,109.1
4	189.3	552.3	767.8	1,464.9
5	344.3	1,014.1	1,412.8	2,688.2

Table V.52 Present Social Value of Nitrous Oxide Emissions Reduction for Room Air Conditioners Shipped in 2026–2055

TSL	SC-N_2O Case			
	Discount Rate and Statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	million 2020$			
1	0.37	1.44	2.21	3.82
2	1.18	4.60	7.09	12.22
3	1.72	6.75	10.42	17.95
4	2.25	8.88	13.72	23.61
5	4.06	16.14	24.99	42.94

DOE is well aware that scientific and economic knowledge about the contribution of CO_2 and other GHG emissions to changes in the future global climate and the potential resulting damages to the world economy continues to evolve rapidly. Thus, any value placed on reduced GHG emissions in this proposed rulemaking is subject to change. That said, because of omitted damages, DOE agrees with the IWG that these estimates most likely underestimate the climate benefits of greenhouse gas reductions. DOE, together with other Federal agencies,

will continue to review methodologies for estimating the monetary value of reductions in CO_2 and other GHG emissions. This ongoing review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues. DOE notes that the proposed standards would be economically justified even without inclusion of monetized benefits of reduced GHG emissions.

DOE also estimated the monetary value of the economic benefits associated with SO_2 emissions reductions anticipated to result from the considered TSLs for room ACs. The dollar-per-ton values that DOE used are discussed in section IV.L.2 of this document. Table V.53 presents the present value for SO_2 for each TSL calculated using 7-percent and 3-percent discount rates.

Table V.53 Present Value of SO_2 Emissions Reduction for Room Air Conditioners Shipped in 2026–2055

TSL	SC-SO_2 Case	
	7% Discount Rate	3% Discount Rate
	million 2020$	
1	106.3	236.2
2	343.0	758.4
3	492.2	1,109.7
4	639.2	1,456.8
5	1,130.5	2,639.1

DOE also estimated the monetary value of the economic benefits associated with NO_X emissions reductions anticipated to result from the considered TSLs for room ACs. The dollar-per-ton values that DOE used are discussed in section IV.L.2 of this document. Table V.54 presents the present value for NO_X emissions reduction for each TSL calculated using 7-percent and 3-percent discount rates.

Table V.54 Present Value of NO_X Emissions Reduction for Room Air Conditioners Shipped in 2026–2055

TSL	SC-NO_X Case	
	7% Discount Rate	3% Discount Rate
	million 2020$	
1	285.7	643.9
2	922.2	2,067.7
3	1,326.6	3,032.6
4	1,724.1	3,985.0
5	3,056.7	7,236.1

The benefits of reduced CO_2, CH_4, and N_2O emissions are collectively referred to as climate benefits. The benefits of reduced SO_2 and NO_X emissions are collectively referred to as health benefits. For the time series of estimated monetary values of reduced emissions, see chapter 14 of the NOPR TSD.

7. Other Factors

The Secretary of Energy, in determining whether a standard is economically justified, may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) No other factors were considered in this analysis.

8. Summary of National Economic Impacts

Table V.55 presents the NPV values that result from adding the monetized estimates of the potential economic, climate, and health benefits resulting from reduced GHG, SO_2, and NO_X emissions to the NPV of consumer benefits calculated for each TSL considered in this rulemaking. The consumer benefits are domestic U.S. monetary savings that occur as a result of purchasing the covered room ACs, and are measured for the lifetime of products shipped in 2026–2055. The climate benefits associated with reduced GHG emissions resulting from the adopted standards are global benefits, and are also calculated based on the lifetime of room ACs shipped in 2026–2055. The climate benefits associated with four SC–GHG estimates are shown. DOE does not have a single central SC–GHG point estimate and it emphasizes the importance and value of considering the benefits calculated using all four SC–GHG estimates.

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Table V.55 NPV of Consumer Benefits Combined with Monetized Climate and Health Benefits from Emissions Reductions (billions 2020$)

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
3% discount rate for NPV of Consumer and Health Benefits (billion 2020$)					
5% d.r., Average SC-GHG case	3.7	11.8	15.3	18.5	33.9
3% d.r., Average SC-GHG case	4.1	13.0	17.1	20.8	38.2
2.5% d.r., Average SC-GHG case	4.4	13.9	18.4	22.5	41.3
3% d.r., 95th percentile SC-GHG case	5.1	16.2	21.8	27.0	49.6
7% discount rate for NPV of Consumer and Health Benefits (billion 2020$)					
5% d.r., Average SC-GHG case	1.9	5.9	7.3	8.4	15.3
3% d.r., Average SC-GHG case	2.3	7.1	9.0	10.7	19.6
2.5% d.r., Average SC-GHG case	2.5	8.0	10.3	12.4	22.6
3% d.r., 95th percentile SC-GHG case	3.3	10.4	13.8	16.9	30.9

The national operating cost savings are domestic U.S. monetary savings that occur as a result of purchasing the covered room ACs, and are measured for the lifetime of products shipped in 2026–2055. The benefits associated with reduced GHG emissions achieved as a result of the adopted standards are also calculated based on the lifetime of room ACs shipped in 2026–2055.

C. Conclusion

When considering new or amended energy conservation standards, the standards that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or amended standard must also result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

For this NOPR, DOE considered the impacts of amended standards for room ACs at each TSL, beginning with the maximum technologically feasible level, to determine whether that level was economically justified. Where the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy. DOE refers to this process as the ''walk-down'' analysis.

To aid the reader as DOE discusses the benefits and/or burdens of each TSL, tables in this section present a summary of the results of DOE's quantitative analysis for each TSL. In addition to the quantitative results presented in the tables, DOE also considers other burdens and benefits that affect economic justification. These include the impacts on identifiable subgroups of consumers who may be disproportionately affected by a national standard and impacts on employment.

DOE also notes that the economics literature provides a wide-ranging discussion of how consumers trade off upfront costs and energy savings in the absence of government intervention. Much of this literature attempts to explain why consumers appear to undervalue energy efficiency improvements. There is evidence that consumers undervalue future energy savings as a result of (1) a lack of information, (2) a lack of sufficient salience of the long-term or aggregate benefits, (3) a lack of sufficient savings to warrant delaying or altering purchases, (4) excessive focus on the short term, in the form of inconsistent weighting of future energy cost savings relative to available returns on other investments, (5) computational or other difficulties associated with the evaluation of relevant tradeoffs, and (6) a divergence in incentives (for example, between renters and owners, or builders and purchasers). Having less than perfect foresight and a high degree of uncertainty about the future, consumers may trade off these types of investments at a higher than expected rate between current consumption and uncertain future energy cost savings.

In DOE's current regulatory analysis, potential changes in the benefits and costs of a regulation due to changes in consumer purchase decisions are included in two ways. First, if consumers forego the purchase of a product in the standards case, this decreases sales for product manufacturers, and the impact on manufacturers attributed to lost revenue is included in the MIA. Second, DOE accounts for energy savings attributable only to products actually used by consumers in the standards case; if a standard decreases the number of products purchased by consumers, this decreases the potential energy savings from an energy conservation standard. DOE provides estimates of shipments and changes in the volume of product purchases in chapter 9 of the NOPR TSD. However, DOE's current analysis does not explicitly control for heterogeneity in consumer preferences, preferences across subcategories of products or specific features, or consumer price sensitivity variation according to household income.[76]

While DOE is not prepared at present to provide a fuller quantifiable framework for estimating the benefits and costs of changes in consumer purchase decisions due to an energy conservation standard, DOE is committed to developing a framework that can support empirical quantitative tools for improved assessment of the consumer welfare impacts of appliance standards. DOE has posted a paper that discusses the issue of consumer welfare impacts of appliance energy conservation standards, and potential enhancements to the methodology by which these impacts are defined and estimated in the regulatory process.[77] DOE welcomes comments on how to more fully assess the potential impact of energy conservation standards on consumer choice and how to quantify this impact in its regulatory analysis in future rulemakings.

[76] P.C. Reiss and M.W. White. Household Electricity Demand, Revisited. *Review of Economic Studies.* 2005. 72(3): pp. 853–883. doi: *10.1111/0034–6527.00354.*

[77] Sanstad, A.H. *Notes on the Economics of Household Energy Consumption and Technology Choice.* 2010. Lawrence Berkeley National Laboratory. *www1.eere.energy.gov/buildings/appliance_standards/pdfs/consumer_ee_theory.pdf* (last accessed June 16, 2021).

1. Benefits and Burdens of TSLs Considered for Room AC Standards

Table V.56 and Table V.57 summarize the quantitative impacts estimated for each TSL for room ACs. The national impacts are measured over the lifetime of room ACs purchased in the 30-year period that begins in the anticipated year of compliance with amended standards (2026–2055). The energy savings, emissions reductions, and value of emissions reductions refer to full-fuel-cycle results. DOE exercises its own judgment in presenting monetized climate benefits as recommended in applicable Executive Orders and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases. The efficiency levels contained in each TSL are described in section V.A of this document.

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Table V.56 Summary of Analytical Results for Room Air Conditioner TSLs:

National Impacts

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
Cumulative FFC National Energy Savings (*quads*)					
Quads	0.29	0.94	1.40	1.86	3.44
Cumulative FFC Emissions Reduction (Total FFC Emissions)					
CO_2 (*million metric tons*)	10.5	33.4	49.5	65.6	120.7
SO_2 (*thousand tons*)	4.0	12.9	19.1	25.2	46.5
NO_X (*thousand tons*)	14.6	46.7	69.4	91.9	169.5
Hg (*tons*)	0.0	0.1	0.1	0.1	0.3
CH_4 (*thousand tons*)	71.4	227.6	339.3	449.7	831.3
N_2O (*thousand tons*)	0.1	0.3	0.5	0.6	1.2
Present Value of Monetized Benefits and Costs (*3% discount rate, billion 2020$*)					
Consumer Operating Cost Savings	2.93	9.47	13.87	18.25	33.49
Climate Benefits*	0.51	1.63	2.39	3.15	5.75
Health Benefits**	0.88	2.83	4.14	5.44	9.88
Total Benefits†	4.32	13.92	20.41	26.85	49.12
Consumer Incremental Product Costs‡	0.22	0.92	3.31	6.04	10.90
Consumer Net Benefits	2.71	8.55	10.56	12.21	22.59
Total Net Benefits	4.10	13.00	17.10	20.81	38.22
Present Value of Monetized Benefits and Costs (*7% discount rate, billions 2020$*)					
Consumer Operating Cost Savings	1.48	4.79	6.89	8.96	16.06
Climate Benefits*	0.51	1.63	2.39	3.15	5.75
Health Benefits**	0.39	1.27	1.82	2.36	4.19
Total Benefits†	2.38	7.68	11.10	14.48	25.99
Consumer Incremental Product Costs‡	0.12	0.54	2.05	3.75	6.42
Consumer Net Benefits	1.35	4.25	4.83	5.21	9.64
Total Net Benefits	2.25	7.14	9.05	10.73	19.58

Note: This table presents the costs and benefits associated with room ACs shipped in 2026–2055. These results include benefits to consumers which accrue after 2055 from the products shipped in 2026–2055.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC-CO_2), methane (SC-CH_4), and nitrous oxide (SC-N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate), as shown in Table V.50 through Table V.52. Together these represent the global social cost of greenhouse gases (SC-GHG). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC-GHG point estimate. See section IV.L of this document for more details.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.L of this document for more details.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate, but the Department does not have a single central SC-GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates. See Table V.55 for net benefits using all four SC-GHG estimates. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22-30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana v. Biden*, No. 21-cv-1074-JDC-KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from "adopting, employing, treating as binding, or relying upon" the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

‡ Costs include incremental equipment costs as well as installation costs.

Table V.57 Summary of Analytical Results for Room Air Conditioner TSLs: Manufacturer and Consumer Impacts

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
Manufacturer Impacts					
Industry NPV (*million 2020$*) (No-new-standards case INPV = 1,081)	1,072 to 1,075	1,053 to 1,078	1,016 to 1,165	968 to 1,247	611 to 992
Industry NPV (*% change*)	(0.8) to (0.5)	(2.5) to (0.3)	(6.0) to 7.8	(10.4) to 15.4	(43.5) to (8.2)
Consumer Average LCC Savings (*2020$*)					
PC1: Room Air Conditioners, without reverse cycle, with louvered sides, and less than 6,000 Btu/h	$39.28	$63.49	$63.49	$45.25	$91.06
PC2: Room Air Conditioners, without reverse cycle, with louvered sides, and 6,000 to 7,999 Btu/h	$34.23	$80.02	$80.02	$62.00	$89.03
PC3: Room Air Conditioners, without reverse cycle, with louvered sides, and 8,000 to 13,999 Btu/h	$19.31	$104.92	$99.14	$99.14	$173.55
PC4: Room Air Conditioners, without reverse cycle, with louvered sides, and 14,000 to 19,999 Btu/h	$0.00	$102.30	$97.49	$97.49	$176.00
PC5a: Room Air Conditioners, without reverse cycle, with louvered sides, and 20,000 to 27,999 Btu/h	$5.28	$105.03	$152.52	$152.52	$263.67
PC5b: Room Air Conditioners, without reverse cycle, with louvered sides, and 28,000 Btu/h or more	$99.12	$147.14	$275.19	$275.19	$392.72
PC8a: Room Air Conditioners, without reverse cycle, without louvered sides, and 8,000 to 10,999 Btu/h	$5.67	$85.72	$74.28	$74.28	$162.53
PC8b: Room Air Conditioners, without reverse cycle, without louvered sides, and 11,000 to 13,999 Btu/h	$0.00	$100.02	$116.89	$116.89	$230.10
PC9: Room Air Conditioners, without reverse cycle, without louvered sides, and 14,000 to 19,999 Btu/h	$58.37	$98.98	$162.64	$162.64	$227.85
PC11: Room Air Conditioners, with reverse cycle, with louvered sides, and less than 20,000 Btu/h	$67.57	$131.52	$131.12	$131.12	$194.60
PC12: Room Air Conditioners, with reverse cycle, without louvered sides, and less than 14,000 Btu/h	$39.97	$81.20	$122.74	$122.74	$156.81
PC16: Room Air Conditioners, Casement-Slider	$49.45	$104.75	$81.33	$81.33	$143.10
Shipment-Weighted Average*	$27.35	$85.73	$85.64	$76.04	$133.84
Consumer Simple PBP (*years*)					
PC1: Room Air Conditioners, without reverse cycle, with louvered sides, and less than 6,000 Btu/h	0.6	0.7	0.7	4.6	3.8
PC2: Room Air Conditioners, without reverse cycle, with louvered sides, and 6,000 to 7,999 Btu/h	0.6	0.9	0.9	4.0	4.2

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
PC3: Room Air Conditioners, without reverse cycle, with louvered sides, and 8,000 to 13,999 Btu/h	0.5	0.8	2.8	2.8	3.0
PC4: Room Air Conditioners, without reverse cycle, with louvered sides, and 14,000 to 19,999 Btu/h	0.6	0.7	2.9	2.9	2.8
PC5a: Room Air Conditioners, without reverse cycle, with louvered sides, and 20,000 to 27,999 Btu/h	1.2	1.0	2.6	2.6	2.7
PC5b: Room Air Conditioners, without reverse cycle, with louvered sides, and 28,000 Btu/h or more	0.3	0.4	2.3	2.3	2.2
PC8a: Room Air Conditioners, without reverse cycle, without louvered sides, and 8,000 to 10,999 Btu/h	0.5	0.7	3.3	3.3	2.9
PC8b: Room Air Conditioners, without reverse cycle, without louvered sides, and 11,000 to 13,999 Btu/h	0.4	0.6	2.4	2.4	2.3
PC9: Room Air Conditioners, without reverse cycle, without louvered sides, and 14,000 to 19,999 Btu/h	0.9	0.9	2.8	2.8	2.7
PC11: Room Air Conditioners, with reverse cycle, with louvered sides, and less than 20,000 Btu/h	0.6	0.8	3.2	3.2	3.2
PC12: Room Air Conditioners, with reverse cycle, without louvered sides, and less than 14,000 Btu/h	1.2	1.2	2.5	2.5	2.7
PC16: Room Air Conditioners, Casement-Slider	0.6	0.8	4.0	4.0	3.5
Shipment-Weighted Average*	0.6	0.8	1.7	3.6	3.4
Percent of Consumers that Experience a Net Cost					
PC1: Room Air Conditioners, without reverse cycle, with louvered sides, and less than 6,000 Btu/h	1%	3%	3%	40%	32%
PC2: Room Air Conditioners, without reverse cycle, with louvered sides, and 6,000 to 7,999 Btu/h	2%	5%	5%	40%	43%
PC3: Room Air Conditioners, without reverse cycle, with louvered sides, and 8,000 to 13,999 Btu/h	0%	4%	30%	30%	30%
PC4: Room Air Conditioners, without reverse cycle, with louvered sides, and 14,000 to 19,999 Btu/h	0%	1%	35%	35%	32%
PC5a: Room Air Conditioners, without reverse cycle, with louvered sides, and 20,000 to 27,999 Btu/h	1%	2%	32%	32%	34%
PC5b: Room Air Conditioners, without reverse cycle, with louvered sides, and 28,000 Btu/h or more	0%	0%	24%	24%	25%
PC8a: Room Air Conditioners, without reverse cycle, without louvered sides, and 8,000 to 10,999 Btu/h	0%	4%	37%	37%	29%
PC8b: Room Air Conditioners, without reverse cycle, without louvered sides, and 11,000 to 13,999 Btu/h	0%	3%	26%	26%	23%

Category	TSL 1	TSL 2	TSL 3	TSL 4	TSL 5
PC9: Room Air Conditioners, without reverse cycle, without louvered sides, and 14,000 to 19,999 Btu/h	3%	2%	24%	24%	24%
PC11: Room Air Conditioners, with reverse cycle, with louvered sides, and less than 20,000 Btu/h	2%	4%	30%	30%	31%
PC12: Room Air Conditioners, with reverse cycle, without louvered sides, and less than 14,000 Btu/h	7%	7%	20%	20%	24%
PC16: Room Air Conditioners, Casement-Slider	2%	4%	38%	38%	34%
Shipment-Weighted Average*	1%	3%	16%	36%	33%

Parentheses indicate negative (-) values.
* Weighted by shares of each product class in total projected shipments in 2026.

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DOE first considered TSL 5, which represents the max-tech efficiency levels. TSL 5 would save an estimated 3.44 quads of energy, an amount DOE considers significant. Under TSL 5, the NPV of consumer benefit would be $9.64 billion using a discount rate of 7 percent, and $22.59 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 5 are 120.7 Mt of CO_2, 46.5 thousand tons of SO_2, 169.5 thousand tons of NO_X, 0.3 tons of Hg, 831.3 thousand tons of CH_4, and 1.2 thousand tons of N_2O. The estimated monetary value of the GHG emissions reduction (associated with the average SC–GHG at a 3-percent discount rate) at TSL 5 is $5.75 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 5 is $4.19 billion using a 7-percent discount rate and $9.88 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated combined monetized NPV at TSL 5 is $19.58 billion. Using a 3-percent discount rate for all consumer and emissions benefits and costs, the estimated combined monetized NPV at TSL 5 is $38.22 billion. The estimated total monetized NPV is provided for additional information; however, DOE primarily relies upon the consumer NPV when determining whether a standard level is economically justified.

At TSL 5, the shipment-weighted average LCC savings is $133.84. The simple payback period is 3.4 years. The fraction of consumers experiencing a net LCC cost is 33 percent.

At TSL 5, the projected change in manufacturer INPV ranges from a decrease of $470.1 million to a decrease of $88.4 million, which corresponds to decreases of 43.5 percent and 8.2 percent, respectively. At this level, free cash flow is estimated to decrease by 291.7 percent compared to the base-case value in the year before the standards year. Conversion costs total $475.9 million.

As discussed in sections IV.C.1–2 of this document, DOE believes there is uncertainty regarding the estimated compressor cost and availability of the highest efficiency variable-speed compressors across the full range of capacities at TSL 5, particularly in the smaller capacity room ACs. These uncertainties stem from the fact that the efficiency level for TSL 5 is obtained by using the highest efficiency variable-speed compressors that are currently available to be incorporated into room ACs at the time the analysis was competed. In addition, variable speed compressors representing these efficiencies are manufactured by just one manufacturer. It is unclear whether the highest efficiency variable-speed compressors will be available to all manufacturers of room ACs since there is only a single supplier at this time. In addition, these highest efficiency variable-speed compressors are not currently available in the full range of capacities, which could limit the current product offerings by manufacturers. Furthermore, due to the single supplier for these highest efficiency variable-speed compressors and their unknown manufacturing volume and potential bottlenecks for ramp-up manufacturing capabilities, there is a likelihood that there may not be sufficient supply to meet the demand of the market for the full range of cooling capacities for room ACs, should TSL 5 be selected. This may have the potential to eliminate room ACs of certain cooling capacities from the market as well impact the overall number of room ACs available on the market should TSL 5 be selected.

The Secretary tentatively concludes that at TSL 5 for room ACs, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the climate and health benefits would be outweighed by the impacts on manufacturers, including the conversion costs and profit margin impacts that could result in a large reduction in INPV, and the potential for product unavailability due to limitations in key components such as the highest efficiency variable-speed compressors necessary to reach the max-tech efficiency levels. Consequently, the Secretary has tentatively concluded that TSL 5 is not economically justified.

Then DOE considered TSL 4. TSL 4 would save an estimated 1.86 quads of energy, an amount DOE considers significant. Under TSL 4, the NPV of consumer benefit would be $5.21 billion using a discount rate of 7 percent, and $12.21 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 4 are 65.6 Mt of CO_2, 25.2 thousand tons of SO_2, 91.9 thousand tons of NO_X, 0.1 tons of Hg, 449.7 thousand tons of CH_4, and 0.6 thousand tons of N_2O. The estimated monetary value of the GHG emissions reduction (associated with the average SC–GHG at a 3-percent discount rate) at TSL 4 is $3.15 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 4 is $2.36 billion using a 7-percent discount rate and $5.44 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, health benefits from reduced SO_2 and NO_X

emissions, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated combined monetized NPV at TSL 4 is $10.73 billion. Using a 3-percent discount rate for all consumer and emissions benefits and costs, the estimated combined monetized NPV at TSL 4 is $20.81 billion. The estimated total monetized NPV is provided for additional information; however, DOE primarily relies upon the consumer NPV when determining whether a standard level is economically justified.

At TSL 4, the shipment-weighted average LCC impact is a savings of $76.04. The shipment-weighted simple payback period is 3.6 years. The fraction of consumers experiencing a net LCC cost is 36 percent.

At TSL 4, the projected change in manufacturer INPV ranges from a decrease of $112.9 million to an increase of $166.5 million, which corresponds to a decrease of 10.4 percent and an increase of 15.4 percent, respectively. At this level, free cash flow is estimated to decrease by 13.5 percent compared to the base-case value in the year before the standards year. Conversion costs total $26.7 million.

TSL 4 represents commercially available room ACs that implement variable-speed compressors, based on models with cooling capacities greater than 8,000 Btu/h. However, for room ACs with the smallest cooling capacities (*i.e.,* less than 8,000 Btu/h), uncertainties exist regarding both the availability of variable-speed compressors that can be integrated into these smaller-size units and the feasibility of incorporating these variable-speed compressors with related components into a more space-constrained chassis than for larger-capacity room ACs. There are no models commercially available that incorporate variable-speed compressors for cooling capacities less than 8,000 Btu/h, and the uncertainties may have the potential to eliminate room ACs with the smallest cooling capacities from the market, should TSL 4 be selected. While there are similarly no room ACs currently on the market with variable-speed compressors at cooling capacities greater than 22,000 Btu/h, other air conditioning products with such cooling capacities (*e.g.,* mini-split air conditioners) do exist in the U.S. market, thereby not giving rise to the same uncertainties as for the smallest cooling capacities.

The Secretary tentatively concludes that at TSL 4 for room ACs, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the climate and health benefits would be outweighed by the impacts on manufacturers, including the conversion costs and profit margin impacts that could result in a reduction in INPV and potential unavailability of key components for small-capacity product classes. Consequently, the Secretary has tentatively concluded that TSL 4 is not economically justified.

DOE then considered TSL 3, which would save an estimated 1.40 quads of energy, an amount DOE considers significant. Under TSL 3, the NPV of consumer benefit would be $4.83 billion using a discount rate of 7 percent, and $10.56 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 3 are 49.5 Mt of CO_2, 19.1 thousand tons of SO_2, 69.4 thousand tons of NO_X, 0.1 tons of Hg, 339.3 thousand tons of CH_4, and 0.5 thousand tons of N_2O. The estimated monetary value of the climate benefits from reduced GHG emissions (associated with the average SC–GHG at a 3-percent discount rate) at TSL 3 is $2.39 billion. The estimated monetary value of the health benefits from reduced SO_2 and NO_X emissions at TSL 3 is $1.82 billion using a 7-percent discount rate and $4.14 billion using a 3-percent discount rate.

Using a 7-percent discount rate for consumer benefits and costs, SO_2 reduction benefits, and NO_X reduction benefits, and the 3-percent discount rate for GHG social costs, the estimated combined monetized NPV at TSL 3 is $9.05 billion. Using a 3-percent discount rate for all consumer and emissions benefits and costs, the estimated combined monetized NPV at TSL 3 is $17.10 billion. The estimated total monetized NPV is provided for additional information; however, DOE primarily relies upon the consumer NPV when determining whether a standard level is economically justified.

At TSL 3, the shipment-weighted average LCC impact is a savings of $85.64. The shipment-weighted simple payback period is 1.7 years. The fraction of consumers experiencing a net LCC cost is 16 percent.

At TSL 3, the projected change in manufacturer INPV ranges from a decrease of $64.5 million to an increase of $84.1 million, which corresponds to a decrease of 6.0 percent and an increase of 7.8 percent, respectively. At this level, free cash flow is estimated to decrease by 11.7 percent compared to the base-case value in the year before the standards year. Conversion costs total $22.8 million.

After considering the analysis and weighing the benefits and burdens, the Secretary has tentatively concluded that a standard set at TSL 3 for room ACs would be economically justified. At this TSL, the average LCC savings for room AC consumers is positive. An estimated 16 percent of room AC consumers would experience a net cost. The FFC national energy savings are significant and the NPV of consumer benefits is positive using both a 3-percent and 7-percent discount rate. Notably, the benefits to consumers vastly outweigh the cost to manufacturers. At TSL 3, the NPV of consumer benefits, even measured at the more conservative discount rate of 7 percent, is over 75 times higher than the maximum estimated manufacturers' loss in INPV. The positive LCC savings—a different way of quantifying consumer benefits—reinforces this conclusion. The standard levels at TSL 3 are economically justified even without weighing the estimated monetary value of emissions reductions. When those monetized climate benefits from GHG emissions reductions and health benefits from SO_2 and NO_X emissions reductions are included—representing $2.39 billion in climate benefits (associated with the average SC–GHG at a 3-percent discount rate), and $4.14 billion (using a 3-percent discount rate) or $1.82 billion (using a 7-percent discount rate) in health benefits—the rationale becomes stronger still.

As stated, DOE conducts a ''walk-down'' analysis to determine the TSL that represents the maximum improvement in energy efficiency that is technologically feasible and economically justified as required under EPCA. The walk-down is not a comparative analysis, as a comparative analysis would result in the maximization of net benefits instead of energy savings that are technologically feasible and economically justified and would be contrary to the statute. 86 FR 70892, 70908. Although DOE has not conducted a comparative analysis to select the proposed energy conservation standards, DOE notes that as compared to TSL 4 and TSL 5, TSL 3 has higher average LCC savings, smaller percentages of consumer experiencing a net cost, a lower maximum decrease in INPV, and lower manufacturer conversion costs.

Accordingly, the Secretary has tentatively concluded that TSL 3 would offer the maximum improvement in efficiency that is technologically feasible and economically justified and would result in the significant conservation of energy. Although results are presented here in terms of TSLs, DOE analyzes and evaluates all possible ELs for each product class in its

analysis. For room ACs with cooling capacities greater than or equal to 8,000 Btu/h, TSL 3 corresponds to EL 4, the highest efficiency level below max-tech, incorporating commercially available variable-speed compressors. The variable-speed compressor required to achieve the max-tech efficiency level is currently available from only a single manufacturer, leading to the likelihood there may not be sufficient supply at that efficiency level to meet the demand of the market for the full range of cooling capacities for room ACs. For room ACs with cooling capacities less than 8,000 Btu/h, TSL 3 corresponds to EL 3, incorporating the maximum available energy efficient single-speed compressors. Both EL 4 and EL 5 for room ACs with cooling capacities less than 8,000 Btu/h incorporate variable-speed compressors based off of modeling of available compressors for models with cooling capacities greater than or equal to 8,000 Btu/h. Uncertainties exist at those efficiency levels regarding both the availability of variable-speed compressors that can be integrated into these smaller-size units and the feasibility of incorporating these variable-speed compressors with related components into a more space-constrained chassis than for larger-capacity room ACs. There are no models commercially available that incorporate variable-speed compressors for cooling capacities less than 8,000 Btu/h. The proposed standard levels at TSL 3 results in positive LCC savings for all product classes, significantly reduce the number of consumers experiencing a net cost, and reduce the decrease in INPV and conversion costs to the point where DOE has tentatively concluded they are economically justified, as discussed for TSL 3 in the preceding paragraphs.

Therefore, based on the previous considerations, DOE proposes to adopt the energy conservation standards for room ACs at TSL 3. The proposed amended energy conservation standards for room ACs, which are expressed as CEER and include the rounded cooling capacity product class descriptions discussed in section IV.A.1 of this document, are shown in Table V.58.

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Table V.58 Proposed Amended Energy Conservation Standards for Room Air Conditioners for TSL 3

Product Class	Proposed Standard CEER (Btu/h)
Room AC without reverse cycle, with louvered sides	
<6,000 Btu/h (1)	13.1
6,000 to 7,900 Btu/h (2)	13.7
8,000 to 13,900 Btu/h (3)	16.0
14,000 to 19,900 Btu/h (4)	16.0
20,000 to 27,900 Btu/h (5a)	13.8
≥28,000 Btu/h (5b)	13.2
Room AC without reverse cycle, without louvered sides	
<6,000 Btu/h (6)	12.8
6,000 to 7,900 Btu/h (7)	12.8
8,000 to 10,900 Btu/h (8a)	14.1
11,000 to 13,900 Btu/h (8b)	13.9
14,000 to 19,900 Btu/h (9)	13.7
≥20,000 Btu/h (10)	13.8
Room AC with reverse cycle, with louvered sides	
<20,000 Btu/h (11)	14.4
≥20,000 Btu/h (13)	13.7
Room AC with reverse cycle, without louvered sides	
<14,000 Btu/h (12)	13.7
≥14,000 Btu/h (14)	12.8
Casement	
Casement-Only (15)	13.9
Casement-Slider (16)	15.3

2. Annualized Benefits and Costs of the Proposed Standards

The benefits and costs of the proposed standards can also be expressed in terms of annualized values. The annualized net benefit is (1) the annualized national economic value (expressed in 2020$) of the benefits from operating products that meet the proposed standards (consisting primarily of operating cost savings from using less energy, minus increases in product purchase costs, and (2) the annualized monetary value of the

benefits of GHGs, NO_X, and SO_2 emission reductions.

Table V.59 shows the annualized values for room ACs under TSL 3, expressed in 2020$. The results under the primary estimate are as follows.

Using a 7-percent discount rate for consumer benefits and costs and health benefits from reduced SO_2 and NO_X, and the 3-percent discount rate case for climate benefits from reduced GHG emissions, the estimated cost of the proposed standards for room ACs is $216.9 million per year in increased equipment costs, while the estimated annual benefits are $727.5 million in reduced operating costs, $137.5 million in climate benefits, and $192.1 million in monetized health benefits. In this case, the net monetized benefit amounts to $840.2 million per year.

Using a 3-percent discount rate for all benefits and costs, the estimated cost of the proposed standards for room ACs is $190.1 million per year in increased equipment costs, while the estimated annual benefits are $796.7 million in reduced operating costs, $137.5 million in climate benefits, and $237.9 million in monetized health benefits. In this case, the net monetized benefit amounts to $982.0 million per year.

Table V.59 Annualized Benefits and Costs of Proposed Energy Conservation Standards for Room Air Conditioners (TSL 3)

	Million 2020$/year		
	Primary Estimate	Low-Net-Benefits Estimate	High-Net-Benefits Estimate
3% discount rate			
Consumer Operating Cost Savings	796.7	751.9	847.8
Climate Benefits*	137.5	134.2	140.4
Health Benefits**	237.9	232.3	242.7
Total Benefits†	1,172.0	1,118.4	1,230.9
Consumer Incremental Product Costs‡	190.1	213.2	163.1
Net Benefits	982.0	905.2	1,067.7
7% discount rate			
Consumer Operating Cost Savings	727.5	693.3	768.4
Climate Benefits*	137.5	134.2	140.4
Health Benefits**	192.1	188.1	195.7
Total Benefits†	1,057.1	1,015.6	1,104.4
Consumer Incremental Product Costs‡	216.9	240.0	190.0
Net Benefits	840.2	775.7	914.5

Note: This table presents the costs and benefits associated with room ACs shipped in 2026–2055. These results include benefits to consumers which accrue after 2055 from the products shipped in 2026–2055.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC-CO_2), methane (SC-CH_4), and nitrous oxide (SC-N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the global social cost of greenhouse gases (SC-GHG). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC-GHG point estimate, and it emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates. See section IV.L of this document for more details.

** Health benefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. The health benefits are presented at real discount rates of 3 and 7 percent. See section IV.L of this document for more details.

† Total and net benefits include consumer, climate, and health benefits. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate, but the Department does not have a single central SC-GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22-30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana v. Biden*, No. 21-cv-1074-JDC-KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from "adopting, employing, treating as binding, or relying upon" the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

‡ Costs include incremental equipment costs as well as installation costs.

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VI. Cooling Capacity Verification

DOE is proposing to add the cooling capacity of room ACs to 10 CFR 429.134 to help regulated entities understand how DOE will determine the product class that applies to a given basic model in the context of an enforcement investigation. DOE is proposing a similar approach that it has adopted for portable air conditioners, packaged terminal air conditioners and heat pumps, and dehumidifiers. More specifically, DOE is going to compare the mean of the tested cooling capacity from the units of a given basic model that DOE has tested for enforcement rounded to the nearest hundred to the certified cooling capacity by the manufacturer. DOE will use the certified cooling capacity of the manufacturer if the mean of the DOE tested units is within 5 percent of the certified cooling capacity. If the manufacturer does not have a valid certification, including if the certified cooling capacity was incorrectly certified, or the certified cooling capacity is found to be outside of the 5 percent tolerance, DOE will use the rounded mean of the DOE tested units within the enforcement sample to determine the applicable product class and energy conservation standard for this particular basic model. DOE believes these proposed provisions provide additional clarity and transparency to the enforcement process. The proposal can be found in 10 CFR 429.134 and DOE seeks comment on this approach.

VII. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Section 1(b)(1) of Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993), requires each agency to identify the problem that it intends to address, including, where applicable, the failures of private markets or public institutions that warrant new agency action, as well as to assess the significance of that problem. The problems that the proposed standards set forth in this NOPR are intended to address are as follows:

(1) Insufficient information and the high costs of gathering and analyzing relevant information leads some consumers to miss opportunities to make cost-effective investments in energy efficiency.

(2) In some cases, the benefits of more-efficient equipment are not realized due to misaligned incentives between purchasers and users. An example of such a case is when the equipment purchase decision is made by a building contractor or building owner who does not pay the energy costs.

(3) There are external benefits resulting from improved energy efficiency of appliances and equipment that are not captured by the users of such products. These benefits include externalities related to public health, environmental protection, and national energy security that are not reflected in energy prices, such as reduced emissions of air pollutants and greenhouse gases that impact human health and global warming.

The Administrator of the Office of Information and Regulatory Affairs (''OIRA'') in the OMB has determined that the proposed regulatory action is a significant regulatory action under section (3)(f) of Executive Order 12866. Accordingly, pursuant to section 6(a)(3)(B) of the Order, DOE has provided to OIRA: (i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and (ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate. DOE has included these documents in the rulemaking record.

In addition, the Administrator of OIRA has determined that the proposed regulatory action is an ''economically'' significant regulatory action under section (3)(f)(1) of E.O. 12866. Accordingly, pursuant to section 6(a)(3)(C) of the Order, DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs anticipated from the regulatory action, together with, to the extent feasible, a quantification of those costs; and an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. These assessments can be found in the technical support document for this proposed rulemaking.

DOE has also reviewed this regulation pursuant to E.O. 13563, issued on January 18, 2011. 76 FR 3281 (Jan. 21, 2011). E.O. 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866. To the extent permitted by law, agencies are required by E.O. 13563 to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, OIRA has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this NOPR is consistent with these principles, including the requirement that, to the extent permitted by law, benefits justify costs and that net benefits are maximized.

B. Review Under the Regulatory Flexibility Act

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

DOE reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE certifies that the proposed

rule, if adopted, would not have significant economic impact on a substantial number of small entities. The factual basis of this certification is set forth in the following paragraphs.

In accordance with EPCA, DOE is publishing this NOPR as part of the legislated 6-year review of energy conservation standards for room ACs. (42 U.S.C. 6295(m)) The current room AC energy conservation standards were implemented by a direct final rule published on April 21, 2011 (76 FR 22454) and subsequently confirmed on August 24, 2011. 76 FR 52854. Compliance with those standards has been required since June 1, 2014. 76 FR 52852. Pursuant to EPCA, any new or amended energy conservation standard must be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in a significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) EPCA also provides that not later than 6 years after issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a notice of proposed rulemaking including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m))

For manufacturers of room ACs, the Small Business Administration (''SBA'') has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. (*See* 13 CFR part 121.) The size standards are listed by North American Industry Classification System (''NAICS'') code and industry description and are available at *www.sba.gov/document/support--table-size-standards.* Manufacturing of room ACs is classified under NAICS 333415, ''Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.'' The SBA sets a threshold of 1,250 employees or fewer for an entity to be considered as a small business for this category.

To estimate the number of companies that could be small business manufacturers of products covered by this proposed rulemaking, DOE conducted a market survey using public information and subscription-based company reports to identify potential small manufacturers. DOE's research involved DOE's Compliance Certification Database (''CCD''),[78] California Energy Commission's Modernized Appliance Efficiency Database System (''MAEDbS''),[79] ENERGY STAR Product Finder,[80] individual company websites, and market research tools (*e.g.,* reports from Dun & Bradstreet [81]) to create a list of companies that manufacture, produce, import, or assemble the products covered by this rulemaking. DOE also asked stakeholders and industry representatives if they were aware of any other small manufacturers during manufacturer interviews and at DOE public meetings.

DOE identified eight OEMs of room AC products sold in the United States. Upon initial review, one OEM was identified as a small manufacturer based in the United States. However, in August 2021, a large manufacturer acquired the small manufacturer.[82] Following that acquisition, no domestic room AC OEMs qualify as a small business. Given the lack of small entities with a direct compliance burden, DOE certifies that the proposed rule would not have ''a significant economic impact on a substantial number of small entities.'' DOE requests comment on this certification conclusion.

DOE has submitted a certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act

Manufacturers of room ACs must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for room ACs, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including room ACs. 76 FR 12422 (Mar. 7, 2011); 80 FR 5099 (Jan. 30, 2015). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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

D. Review Under the National Environmental Policy Act of 1969

DOE is analyzing this proposed regulation in accordance with the National Environmental Policy Act of 1969 (''NEPA'') and DOE's NEPA implementing regulations (10 CFR part 1021). DOE's regulations include a categorical exclusion for rulemakings that establish energy conservation standards for consumer products or industrial equipment. 10 CFR part 1021, subpart D, appendix B5.1. DOE anticipates that this rulemaking qualifies for categorical exclusion B5.1 because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, none of the exceptions identified in categorical exclusion B5.1(b) apply, no extraordinary circumstances exist that require further environmental analysis, and it otherwise meets the requirements for application of a categorical exclusion. See 10 CFR 1021.410. DOE will complete its NEPA review before issuing the final rule.

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE

[78] *regulations.doe.gov/certification-data/#q=Product_Group_s%3A*.*

[79] *cacertappliances.energy.ca.gov/Pages/ApplianceSearch.aspx.*

[80] *energystar.gov/productfinder/.*

[81] *app.dnbhoovers.com.*

[82] *https://www.rheem.com/about/news-releases/rheem-acquires-friedrich-air-conditioning (published August 30, 2021).*

published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has tentatively determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of E.O. 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, section 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.*

Although this proposed rule does not contain a Federal intergovernmental mandate, it may require expenditures of $100 million or more in any one year by the private sector. Such expenditures may include: (1) Investment in research and development and in capital expenditures by room AC manufacturers in the years between the final rule and the compliance date for the new standards and (2) incremental additional expenditures by consumers to purchase higher-efficiency room ACs, starting at the compliance date for the applicable standard.

Section 202 of UMRA authorizes a Federal agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies the proposed rule. (2 U.S.C. 1532(c)) The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA and Executive Order 12866. The **SUPPLEMENTARY INFORMATION** section of this NOPR and the TSD for this proposed rule respond to those requirements.

Under section 205 of UMRA, the Department is obligated to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under section 202 is required. (2 U.S.C. 1535(a)) DOE is required to select from those alternatives the most cost-effective and least burdensome alternative that achieves the objectives of the proposed rule unless DOE publishes an explanation for doing otherwise, or the selection of such an alternative is inconsistent with law. As required by 42 U.S.C. 6295(m), this proposed rule would establish amended energy conservation standards for room ACs that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified, as required by 42 U.S.C. 6295(o)(2)(A) and 42 U.S.C. 6295(o)(3)(B). A full discussion of the alternatives considered by DOE is presented in chapter 17 of the TSD for this proposed rule.

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

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (Mar. 15, 1988), DOE has determined that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

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

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67

FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this NOPR under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has tentatively concluded that this regulatory action, which proposes amended energy conservation standards for room ACs, is not a significant energy action because the proposed standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on this proposed rule.

L. Information Quality

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (''OSTP''), issued its Final Information Quality Bulletin for Peer Review (''the Bulletin''). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are ''influential scientific information,'' which the Bulletin defines as ''scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions.'' 70 FR 2664, 2667.

In response to OMB's Bulletin, DOE conducted formal peer reviews of the energy conservation standards development process and the analyses that are typically used and has prepared a report describing that peer review.[83] Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. DOE has determined that the peer-reviewed analytical process continues to reflect current practice, and the Department followed that process for developing energy conservation standards in the case of the present rulemaking.

VIII. Public Participation

A. Attendance at the Webinar

The time, date, and location of the webinar are listed in the **DATES** and **ADDRESSES** sections at the beginning of this document. If no participants register for the webinar then it will be cancelled. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=52.* Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this document, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the webinar. Requests may be sent by email to the Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B 1000 Independence Avenue SW, Washington, DC 20585–0121, or *ApplianceStandardsQuestions@ee.doe.gov.* Persons who wish to speak should include with their request a computer file in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format that briefly describes the nature of their interest in this rulemaking and the topics they wish to discuss. Such persons should also provide a daytime telephone number where they can be reached.

Persons requesting to speak should briefly describe the nature of their interest in this rulemaking and provide a telephone number for contact. DOE requests persons selected to make an oral presentation to submit an advance copy of their statements at least two weeks before the webinar. At its discretion, DOE may permit persons who cannot supply an advance copy of their statement to participate, if those persons have made advance alternative arrangements with the Building Technologies Office. As necessary, requests to give an oral presentation should ask for such alternative arrangements.

C. Conduct of the Public Meeting

DOE will designate a DOE official to preside at the webinar/public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA. (42 U.S.C. 6306) A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the webinar/public meeting. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the webinar/public meeting, interested parties may submit further comments on the proceedings, as well as on any aspect of the rulemaking, until the end of the comment period.

The public meeting will be conducted in an informal, conference style. DOE will present summaries of comments received before the webinar/public meeting, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this proposed rulemaking. Each participant will be allowed to make a general statement (within time limits

[83] The 2007 ''Energy Conservation Standards Rulemaking Peer Review Report'' is available at the following website: *energy.gov/eere/buildings/downloads/energy-conservation-standards-rulemaking-peer-review-report-0.*

determined by DOE), before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the webinar/public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the previous procedures that may be needed for the proper conduct of the webinar/public meeting.

A transcript of the webinar/public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document and will be accessible on the DOE website. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via *www.regulations.gov.* The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email. Comments and documents submitted via email also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. No telefacsimiles (''faxes'') will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) DOE seeks comment on the proposal to not make any changes to room AC product classes. See section IV.A.1 of this document.

(2) DOE seeks comment on whether evaporator air recirculation should be included in the engineering analysis. See section IV.A.2.a of this document.

(3) DOE seeks comment on the updated single-speed compressor maximum efficiency estimates. See section IV.A.2.b of this document.

(4) DOE seeks comment on the approach to alternative refrigerants in this engineering analysis. See section IV.A.2.c of this document.

(5) DOE seeks comment on the technologies screened out in the NOPR screening analysis. See section IV.B.1 of this document.

(6) DOE requests comment on the new efficiency level (EL 4) in the engineering analysis. See section IV.C.1.b of this document.

(7) DOE seeks comment on the approach to design EL 3 as the level reached by the most efficient single-speed room ACs. See section IV.C.1.b of this document.

(8) DOE requests comment on the incremental MPCs from the NOPR engineering analysis. See section IV.C.3 of this document.

(9) DOE welcomes feedback on its approach to estimating fan-only use

operating hours and any additional data that can be provided to estimate the amount of time spent in fan-only mode. See section IV.E of this document.

(10) DOE requests feedback on its approach to calculating the energy-use of variable-speed compressors and would welcome field metered data to further investigate the varying amounts of energy use due to single-speed and variable-speed units. See section IV.E of this document.

(11) DOE requests comments on its assumption and methodology for determining equipment price trends. See section IV.F.1 of this document.

(12) DOE requests feedback on its approach to projecting the efficiency distribution in 2026. See section IV.F.8 of this document.

(13) DOE welcomes shipments data that include markets in addition to replacement and first-time user markets. See section IV.G of this document.

(14) DOE requests comment on its general methodology for estimating shipments. See section IV.G of this document.

(15) DOE requests comment its approach to projecting market share for variable-speed technologies over the course of the analysis period. See section IV.H.1 of this document.

(16) DOE requests comment on its approach to monetizing the impact of the rebound effect in standards cases. See section IV.H.3 of this document.

(17) DOE requests comment on the magnitude of costs associated with transitioning room AC models to low-GWP refrigerants, such as R–32, along with the associated UL costs that would be incurred between the publication of this NOPR and the proposed compliance date of amended standards. Quantification and categorization of associated costs, such as engineering efforts, test lab time, UL certification costs, and capital investments, would enable DOE to refine its analysis. See section V.B.2.d of this document.

(18) DOE requests information regarding the impact of cumulative regulatory burden on manufacturers of room ACs associated with multiple DOE standards or product-specific regulatory actions of other Federal agencies. See section V.B.2.d of this document.

(19) DOE requests comment on the percentage of room ACs manufactured outside of China and the countries of origin, as well as information on the country-specific fully-burdened labor rates and key raw material prices.

(20) DOE requests comment on the impact of tariffs on pricing at each step in the distribution chain, as well as the percentage change in retail price paid by the consumer as a result of Section 301 tariffs. See section V.B.2.e of this document.

(21) DOE requests comment on the certification conclusion.

Additionally, DOE welcomes comments on other issues relevant to the conduct of this rulemaking that may not specifically be identified in this document.

IX. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Small businesses.

Signing Authority

This document of the Department of Energy was signed on March 28, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, 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 March 31, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons set forth in the preamble, DOE proposes to amend parts 429 and 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Section 429.134 is amended by adding paragraph(s) to read as follows:

§ 429.134 Product-specific enforcement provisions.

* * * * *

(s) *Room air conditioners.* Verification of cooling capacity. DOE will measure the cooling capacity of each unit DOE tests pursuant to the test requirements of 10 CFR part 430. DOE will calculate the mean of the test results, rounded to the nearest hundred, and compare it to the value of cooling capacity certified by the manufacturer for the basic model. The certified cooling capacity will be considered valid only if the basic model is properly certified pursuant to this part, and the rounded mean from testing pursuant to this section is within five percent of the cooling capacity reported in the manufacturer's most recent valid certification report at the time of DOE's assessment test.

(1) If the certified cooling capacity is valid, DOE will use the certified cooling capacity as the basis for identifying the correct product class for the basic model and the minimum combined energy efficiency ratio allowed for the basic model.

(2) If the certified cooling capacity is not valid, DOE will use the mean measured cooling capacity of the units in the sample, rounded to the nearest hundred, as the basis for identifying the correct product class for the basic model and the minimum combined energy efficiency ratio allowed for the basic model.

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 3. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 4. Section 430.32 is amended by revising paragraph (b) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(b) *Room air conditioners.*

The following standards remain in effect from June 1, 2014 until [*date 3 years after publication of the final rule*]:

Equipment class	Combined energy efficiency ratio
(1) Without reverse cycle, with louvered sides, and with a certified cooling capacity* less than 6,000 Btu/h	11.0
(2) Without reverse cycle, with louvered sides and with a certified cooling capacity of 6,000 to 7,999 Btu/h	11.0
(3) Without reverse cycle, with louvered sides and with a certified cooling capacity of 8,000 to 13,999 Btu/h	10.9
(4) Without reverse cycle, with louvered sides and with a certified cooling capacity of 14,000 to 19,999 Btu/h	10.7
(5)(A) Without reverse cycle, with louvered sides and with a certified cooling capacity of 20,000 Btu/h to 27,999 Btu/h	9.4
(5)(B) Without reverse cycle, with louvered sides and with a certified cooling capacity of 28,000 Btu/h or more	9.0
(6) Without reverse cycle, without louvered sides, and with a certified cooling capacity less than 6,000 Btu/h	10.0
(7) Without reverse cycle, without louvered sides and with a certified cooling capacity of 6,000 to 7,999 Btu/h	10.0
(8)(A) Without reverse cycle, without louvered sides and with a certified cooling capacity of 8,000 to 10,999 Btu/h	9.6
(8)(B) Without reverse cycle, without louvered sides and with a certified cooling capacity of 11,000 to 13,999 Btu/h	9.5
(9) Without reverse cycle, without louvered sides and with a certified cooling capacity of 14,000 to 19,999 Btu/h	9.3
(10) Without reverse cycle, without louvered sides and with a certified cooling capacity of 20,000 Btu/h or more	9.4
(11) With reverse cycle, with louvered sides, and with a certified cooling capacity less than 20,000 Btu/h	9.8
(12) With reverse cycle, without louvered sides, and with a certified cooling capacity less than 14,000 Btu/h	9.3
(13) With reverse cycle, with louvered sides, and with a certified cooling capacity of 20,000 Btu/h or more	9.3
(14) With reverse cycle, without louvered sides, and with a certified cooling capacity of 14,000 Btu/h or more	8.7
(15) Casement-Only	9.5
(16) Casement-Slider	10.4

* The certified cooling capacity is determined by the manufacturer in accordance with 10 CFR 429.15(a)(3).

The following standards apply to products manufactured starting [*Date* 3 *years after publication of the final rule*]:

Equipment class	Combined energy efficiency ratio
(1) Without reverse cycle, with louvered sides, and with a certified cooling capacity* less than 6,000 Btu/h	13.1
(2) Without reverse cycle, with louvered sides and with a certified cooling capacity of 6,000 to 7,900 Btu/h	13.7
(3) Without reverse cycle, with louvered sides and with a certified cooling capacity of 8,000 to 13,900 Btu/h	16.0
(4) Without reverse cycle, with louvered sides and with a certified cooling capacity of 14,000 to 19,900 Btu/h	16.0
(5)(A) Without reverse cycle, with louvered sides and with a certified cooling capacity of 20,000 Btu/h to 27,900 Btu/h	13.8
(5)(B) Without reverse cycle, with louvered sides and with a certified cooling capacity of 28,000 Btu/h or more	13.2
(6) Without reverse cycle, without louvered sides, and with a certified cooling capacity less than 6,000 Btu/h	12.8
(7) Without reverse cycle, without louvered sides and with a certified cooling capacity of 6,000 to 7,900 Btu/h	12.8
(8)(A) Without reverse cycle, without louvered sides and with a certified cooling capacity of 8,000 to 10,900 Btu/h	14.1
(8)(B) Without reverse cycle, without louvered sides and with a certified cooling capacity of 11,000 to 13,900 Btu/h	13.9
(9) Without reverse cycle, without louvered sides and with a certified cooling capacity of 14,000 to 19,900 Btu/h	13.7
(10) Without reverse cycle, without louvered sides and with a certified cooling capacity of 20,000 Btu/h or more	13.8
(11) With reverse cycle, with louvered sides, and with a certified cooling capacity less than 20,000 Btu/h	14.4
(12) With reverse cycle, without louvered sides, and with a certified cooling capacity less than 14,000 Btu/h	13.7
(13) With reverse cycle, with louvered sides, and with a certified cooling capacity of 20,000 Btu/h or more	13.7
(14) With reverse cycle, without louvered sides, and with a certified cooling capacity of 14,000 Btu/h or more	12.8
(15) Casement-Only	13.9
(16) Casement-Slider	15.3

* The certified cooling capacity is determined by the manufacturer in accordance with 10 CFR 429.15(a)(3).

* * * * *

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