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DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2020–BT–TP–0012]

RIN 1904–AE49

Energy Conservation Program: Test Procedure for Battery Chargers; Correction

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

ACTION: Final rule; correction.

SUMMARY: The U.S. Department of Energy (''DOE'') is correcting a final rule that appeared in the **Federal Register** on September 8, 2022. The document amended test procedures for battery chargers. This document corrects amendatory errors in that final rule.

DATES: Effective October 11, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Nolan Brickwood, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–5709. Email: *nolan.brickwood@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

DOE published a final rule in the **Federal Register** on September 8, 2022 (September 2022 Final Rule), amending the test procedure for battery chargers. 87 FR 55090. This correction addresses numbering errors in the amendatory language in that final rule.

First, DOE noted in the amendatory instructions that it was replacing the text ''appendix Y'' with the text ''appendices Y and Y1'' in paragraph (p)(3) of 10 CFR 430.3 and replacing the text ''Y, Z'' with the text ''Y, Y1, Z'' in paragraph (p)(6) of 10 CFR 430.3. However, these paragraphs have recently been redesignated to paragraphs (p)(4) and (p)(7), respectively. Second, the instruction amending the introductory text of appendix Y to subpart B instructs to revise a note that does not currently exist. Instead, the instruction should have said to ''add a note before the introductory text and revise the introductory paragraph''. Finally, the instruction to revise the definition of C-Rate in appendix Y erroneously refers to amending section 2.1.0 when the instruction should have stated to amend section 2.10. of appendix Y to subpart B of part 430.

II. Need for Correction

As published, the regulatory text in September 2022 Final Rule may result in confusion due to incorrect section references. Because this final rule would simply correct errors in the text without making substantive changes in the September 2022 Final Rule, the changes addressed in this document are technical in nature.

III. Procedural Issues and Regulatory Review

DOE has concluded that the determinations made pursuant to the various procedural requirements applicable to the September 2022 Final Rule remain unchanged for this final rule technical correction. These determinations are set forth in the September 2022 Final Rule. 87 FR 55090, 55117–55122.

Pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b), DOE finds that there is good cause to not issue a separate notice to solicit public comment on the changes contained in this document. Issuing a separate notice to solicit public comment would be impracticable, unnecessary, and contrary to the public interest. Neither the errors nor the corrections in this document affect the substance of the September 2022 Final Rule or any of the conclusions reached in support of the final rule. Providing prior notice and an opportunity for public comment on correcting objective, typographical errors that do not change the substance of the test procedure serves no useful purpose.

Further, this rule correcting typographical errors makes non-substantive changes to the test procedure. As such, this rule is not subject to the 30-day delay in effective date requirement of 5 U.S.C. 553(d) otherwise applicable to rules that make substantive changes.

In final rule FR Doc. 2022–18717, published in the issue of Thursday, September 8, 2022, (87 FR 55090), the following corrections are made:

§ 430.3 [Corrected]

■ 1. On page 55122, second column, amendatory instructions 4.b. and 4.c. are corrected to read as follows:

■ b. In paragraph (p)(4) introductory text, removing the text ''appendix Y'', and adding in its place the text ''appendices Y and Y1''; and

■ c. In paragraph (p)(7), removing the text ''Y, Z,'', and adding in its place the text ''Y, Y1, Z''.

■ 2. On page 55122, third column, amendatory instructions 6.a. and 6.b. are corrected to read as follows:

■ a. Adding a note before the introductory text and revising the introductory paragraph;

■ b. Revising sections 2.10., 3.1.4.(b), 3.2.5.(f), 3.3.4, 3.3.6.(c)(5), and 3.3.8.

Signing Authority

This document of the Department of Energy was signed on September 28, 2022, by Francisco Alejandro Moreno, Acting 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 September 30, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–21695 Filed 10–6–22; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 201

[Docket No. R–1780]

RIN 7100–AG38

Regulation A: Extensions of Credit by Federal Reserve Banks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (''Board'') has adopted final amendments to its Regulation A to reflect the Board's approval of an increase in the rate for primary credit at each Federal Reserve Bank. The secondary credit rate at each Reserve Bank automatically increased by formula as a result of the Board's primary credit rate action.

DATES:

Effective date: The amendments to part 201 (Regulation A) are effective October 7, 2022.

Applicability date: The rate changes for primary and secondary credit were applicable on September 22, 2022.

FOR FURTHER INFORMATION CONTACT: M. Benjamin Snodgrass, Senior Counsel (202–263–4877), Legal Division, or Kristen Payne, Lead Financial Institution & Policy Analyst (202–452–2872), or Margaret DeBoer, Senior Associate Director (202–452–3139), Division of Monetary Affairs; for users of telephone systems via text telephone (TTY) or any TTY-based Telecommunications Relay Services (TRS), please call 711 from any telephone, anywhere in the United States; Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The Federal Reserve Banks make primary and secondary credit available to depository institutions as a backup source of funding on a short-term basis, usually overnight. The primary and secondary credit rates are the interest rates that the twelve Federal Reserve Banks charge for extensions of credit under these programs. In accordance with the Federal Reserve Act, the primary and secondary credit rates are established by the boards of directors of the Federal Reserve Banks, subject to review and determination of the Board.

On September 21, 2022, the Board voted to approve a 0.75 percentage point increase in the primary credit rate, thereby increasing the primary credit rate from 2.50 percent to 3.25 percent. In addition, the Board had previously approved the renewal of the secondary credit rate formula, the primary credit rate plus 50 basis points. Under the formula, the secondary credit rate increased by 0.75 percentage points as a result of the Board's primary credit rate action, thereby increasing the secondary credit rate from 3.00 percent to 3.75 percent. The amendments to Regulation A reflect these rate changes.

The 0.75 percentage point increase in the primary credit rate was associated with a 0.75 percentage point increase in the target range for the federal funds rate (from a target range of 2¼ percent to 2½ percent to a target range of 3 percent to 3¼ percent) announced by the Federal Open Market Committee on September 21, 2022, as described in the Board's amendment of its Regulation D published elsewhere in today's **Federal Register**.

Administrative Procedure Act

In general, the Administrative Procedure Act (''APA'') [1] imposes three principal requirements when an agency promulgates legislative rules (rules made pursuant to Congressionally-delegated authority): (1) publication with adequate notice of a proposed rule; (2) followed by a meaningful opportunity for the public to comment on the rule's content; and (3) publication of the final rule not less than 30 days before its effective date. The APA provides that notice and comment procedures do not apply if the agency for good cause finds them to be ''unnecessary, impracticable, or contrary to the public interest.'' [2] Section 553(d) of the APA also provides that publication at least 30 days prior to a rule's effective date is not required for (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) a rule for which the agency finds good cause for shortened notice and publishes its reasoning with the rule.[3] The APA further provides that the notice, public comment, and delayed effective date requirements of 5 U.S.C. 553 do not apply ''to the extent that there is involved . . . a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.'' [4]

Regulation A establishes the interest rates that the twelve Reserve Banks charge for extensions of primary credit and secondary credit. The Board has determined that the notice, public comment, and delayed effective date requirements of the APA do not apply to these final amendments to Regulation A. The amendments involve a matter relating to loans and are therefore exempt under the terms of the APA. Furthermore, because delay would undermine the Board's action in responding to economic data and conditions, the Board has determined that ''good cause'' exists within the meaning of the APA to dispense with the notice, public comment, and delayed effective date procedures of the APA with respect to the final amendments to Regulation A.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (''RFA'') does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[5] As noted previously, a general notice of proposed rulemaking is not required if the final rule involves a matter relating to loans. Furthermore, the Board has determined that it is unnecessary and contrary to the public interest to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (''PRA'') of 1995,[6] the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget. The final rule contains no requirements subject to the PRA.

List of Subjects in 12 CFR Part 201

Banks, banking, Federal Reserve System, Reporting and recordkeeping.

Authority and Issuance

For the reasons set forth in the preamble, the Board is amending 12 CFR Chapter II to read as follows:

[1] 5 U.S.C. 551 *et seq.*

[2] 5 U.S.C. 553(b)(3)(A).

[3] 5 U.S.C. 553(d).

[4] 5 U.S.C. 553(a)(2) (emphasis added).

[5] 5 U.S.C. 603, 604.

[6] 44 U.S.C. 3506; see 5 CFR part 1320 Appendix A.1.

PART 201—EXTENSIONS OF CREDIT BY FEDERAL RESERVE BANKS (REGULATION A)

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 12 U.S.C. 248(i)–(j), 343 *et seq.,* 347a, 347b, 347c, 348 *et seq.,* 357, 374, 374a, and 461.

■ 2. In § 201.51, paragraphs (a) and (b) are revised to read as follows:

§ 201.51 Interest rates applicable to credit extended by a Federal Reserve Bank.[3]

(a) *Primary credit.* The interest rate at each Federal Reserve Bank for primary credit provided to depository institutions under § 201.4(a) is 3.25 percent.

(b) *Secondary credit.* The interest rate at each Federal Reserve Bank for secondary credit provided to depository institutions under § 201.4(b) is 3.75 percent.

* * * * *

By order of the Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2022–21830 Filed 10–6–22; 8:45 am]

BILLING CODE 6210–02–P

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Docket No. R–1781; RIN 7100–AG39]

Regulation D: Reserve Requirements of Depository Institutions

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (''Board'') has adopted final amendments to its Regulation D to revise the rate of interest paid on balances (''IORB'') maintained at Federal Reserve Banks by or on behalf of eligible institutions. The final amendments specify that IORB is 3.15 percent, a 0.75 percentage point increase from its prior level. The amendment is intended to enhance the role of IORB in maintaining the federal funds rate in the target range established by the Federal Open Market Committee (''FOMC'' or ''Committee'').

DATES:

Effective date: The amendments to part 204 (Regulation D) are effective October 7, 2022.

Applicability date: The IORB rate change was applicable on September 22, 2022.

FOR FURTHER INFORMATION CONTACT: M. Benjamin Snodgrass, Senior Counsel (202–263–4877), Legal Division, or Kristen Payne, Lead Financial Institution & Policy Analyst (202–452–2872), or Margaret DeBoer, Senior Associate Director (202–452–3139), Division of Monetary Affairs; for users of telephone systems via text telephone (TTY) or any TTY-based Telecommunications Relay Services (TRS), please call 711 from any telephone, anywhere in the United States; Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

For monetary policy purposes, section 19 of the Federal Reserve Act (''Act'') imposes reserve requirements on certain types of deposits and other liabilities of depository institutions.[1] Regulation D, which implements section 19 of the Act, requires that a depository institution meet reserve requirements by holding cash in its vault, or if vault cash is insufficient, by maintaining a balance in an account at a Federal Reserve Bank (''Reserve Bank'').[2] Section 19 also provides that balances maintained by or on behalf of certain institutions in an account at a Reserve Bank may receive earnings to be paid by the Reserve Bank at least once each quarter, at a rate or rates not to exceed the general level of short-term interest rates.[3] Institutions that are eligible to receive earnings on their balances held at Reserve Banks (''eligible institutions'') include depository institutions and certain other institutions.[4] Section 19 also provides that the Board may prescribe regulations concerning the payment of earnings on balances at a Reserve Bank.[5] Prior to these amendments, Regulation D established IORB at 2.40 percent.[6]

II. Amendment to IORB

The Board is amending § 204.10(b)(1) of Regulation D to establish IORB at 3.15 percent. The amendment represents a 0.75 percentage point increase in IORB. This decision was announced on September 21, 2022, with an effective date of September 22, 2022, in the Federal Reserve Implementation Note that accompanied the FOMC's statement on September 21, 2022. The FOMC statement stated that the Committee decided to raise the target range for the federal funds rate to 3 to 3¼ percent.

The Federal Reserve Implementation Note stated:

> The Board of Governors of the Federal Reserve System voted unanimously to raise the interest rate paid on reserve balances to 3.15 percent, effective September 22, 2022.

As a result, the Board is amending § 204.10(b)(1) of Regulation D to establish IORB at 3.15 percent.

III. Administrative Procedure Act

In general, the Administrative Procedure Act (''APA'')[7] imposes three principal requirements when an agency promulgates legislative rules (rules made pursuant to Congressionally-delegated authority): (1) publication with adequate notice of a proposed rule; (2) followed by a meaningful opportunity for the public to comment on the rule's content; and (3) publication of the final rule not less than 30 days before its effective date. The APA provides that notice and comment procedures do not apply if the agency for good cause finds them to be ''unnecessary, impracticable, or contrary to the public interest.''[8] Section 553(d) of the APA also provides that publication at least 30 days prior to a rule's effective date is not required for (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) a rule for which the agency finds good cause for shortened notice and publishes its reasoning with the rule.[9]

The Board has determined that good cause exists for finding that the notice, public comment, and delayed effective date provisions of the APA are unnecessary, impracticable, or contrary to the public interest with respect to these final amendments to Regulation D. The rate change for IORB that is reflected in the final amendment to Regulation D was made with a view towards accommodating commerce and business and with regard to their bearing upon the general credit situation of the country. Notice and public comment would prevent the Board's action from being effective as promptly as necessary in the public interest and would not otherwise serve any useful purpose. Notice, public comment, and a delayed effective date would create

[3] The primary, secondary, and seasonal credit rates described in this section apply to both advances and discounts made under the primary, secondary, and seasonal credit programs, respectively.

[1] 12 U.S.C. 461(b). In March 2020, the Board set all reserve requirement ratios to zero percent. See Interim Final Rule, 85 FR 16525 (Mar. 24, 2020); Final Rule, 86 FR 8853 (Feb. 10, 2021).

[2] 12 CFR 204.5(a)(1).

[3] 12 U.S.C. 461(b)(1)(A) and (b)(12)(A).

[4] See 12 U.S.C. 461(b)(1)(A) & (b)(12)(C); see also 12 CFR 204.2(y).

[5] See 12 U.S.C. 461(b)(12)(B).

[6] See 12 CFR 204.10(b)(1).

[7] 5 U.S.C. 551 *et seq.*

[8] 5 U.S.C. 553(b)(3)(A).

[9] 5 U.S.C. 553(d).

uncertainty about the finality and effectiveness of the Board's action and undermine the effectiveness of that action. Accordingly, the Board has determined that good cause exists to dispense with the notice, public comment, and delayed effective date procedures of the APA with respect to this final amendment to Regulation D.

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (''RFA'') does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[10] As noted previously, the Board has determined that it is unnecessary and contrary to the public interest to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

V. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (''PRA'') of 1995,[11] the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget. The final rule contains no requirements subject to the PRA.

List of Subjects in 12 CFR Part 204

Banks, Banking, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons set forth in the preamble, the Board amends 12 CFR part 204 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS (REGULATION D)

■ 1. The authority citation for part 204 continues to read as follows:

Authority: 12 U.S.C. 248(a), 248(c), 461, 601, 611, and 3105.

■ 2. Section 204.10 is amended by revising paragraph (b)(1) to read as follows:

§ 204.10 Payment of interest on balances.

* * * * *

(b) * * *

(1) For balances maintained in an eligible institution's master account, interest is the amount equal to the interest on reserve balances rate (''IORB rate'') on a day multiplied by the total balances maintained on that day. The IORB rate is 3.15 percent.

* * * * *

[10] 5 U.S.C. 603, 604.

[11] 44 U.S.C. 3506; see 5 CFR part 1320 Appendix A.1.

By order of the Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2022–21833 Filed 10–6–22; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

12 CFR Part 1102

[Docket No. AS22–06]

Appraisal Subcommittee; Appraiser Regulation; Temporary Waiver Requests

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Final rule.

SUMMARY: The Appraisal Subcommittee (ASC) of the Federal Financial Institutions Examination Council (FFIEC) is adopting a final rule to amend rules of practice and procedure governing temporary waiver proceedings which were promulgated in 1992 pursuant to Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended (Title XI).

DATES: This final rule is effective on December 6, 2022.

FOR FURTHER INFORMATION CONTACT: Lori Schuster, Management and Program Analyst, *lori@asc.gov,* or Alice M. Ritter, General Counsel, *alice@asc.gov,* ASC, 1325 G Street NW, Suite 500, Washington, DC 20005.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of Title XI[1] is ''to provide that Federal financial and public policy interests in real estate related transactions will be protected by requiring that real estate appraisals utilized in connection with federally related transactions [FRTs] are performed in writing, in accordance with uniform standards, by individuals whose competency has been demonstrated and whose professional conduct will be subject to effective supervision.''[2]

As directed by Title XI, the Federal financial institutions regulatory agencies' appraisal regulations require appraisals for FRTs to meet minimum appraisal standards as evidenced by the *Uniform Standards of Professional Appraisal Practice* (USPAP) promulgated by the Appraisal Standards Board (ASB) of the Appraisal Foundation.[3] Title XI also requires that certified and licensed appraisers meet the minimum qualification criteria as set forth in *The Real Property Appraiser Qualification Criteria* (AQB Criteria) issued by the Appraiser Qualifications Board (AQB) of the Appraisal Foundation.[4] The State appraiser regulatory agencies enforce these federal minimum requirements for credentialed appraisers in their respective States and are subject to federal oversight by the ASC.[5]

Section 1119(b) of Title XI authorizes the ASC to waive, on a temporary basis, subject to approval of the FFIEC any requirement relating to certification or licensing of a person to perform appraisals under Title XI if the ASC or a State appraiser regulatory agency makes a written determination that there is a scarcity of certified or licensed appraisers to perform appraisals in connection with FRTs in a State, or in any geographical political subdivision of a State, leading to significant delays in the performance of such appraisals. A waiver terminates when the ASC determines that such significant delays have been eliminated.[6]

Congress intended that the ASC exercise this waiver authority ''cautiously.''[7]

The ASC published rules of practice and procedure governing temporary waiver proceedings in 1992.[8] The ASC has ordered temporary waiver relief on two occasions. The first was for the Commonwealth of the Northern Mariana

[1] Title XI established the ASC. The ASC Board consists of seven members. Five members are designated by the heads of the FFIEC federal member agencies (Board of Governors of the Federal Reserve System [Board], Bureau of Consumer Financial Protection [Bureau], Federal Deposit Insurance Corporation [FDIC], Office of the Comptroller of the Currency [OCC], and National Credit Union Administration [NCUA]). The other two members are designated by the heads of the Department of Housing and Urban Development (HUD) and the Federal Housing Finance Agency (FHFA).

[2] Title XI section 1101. *See also,* 12 U.S.C. 3331.

[3] Title XI section 1110, 12 U.S.C. 3339, implemented by the Office of the Comptroller of the Currency: 12 CFR 34.44; Federal Reserve Board: 12 CFR 225.64; Federal Deposit Insurance Corporation: 12 CFR 323.4; and National Credit Union Administration: 12 CFR 722.4.

[4] Title XI section 1116(a) and (c). *See also,* 12 U.S.C. 3345(a) and (c).

[5] Title XI section 1118. *See also,* 12 U.S.C. 3347. ''State appraiser regulatory agencies'' are referred to in the final rule as ''State Appraisal Agencies.''

[6] Title XI section 1119(b). *See also,* 12 U.S.C. 3348(b).

[7] House Comm. on Banking, Finance and Urban Affairs, Report Together with Additional Supplemental, Minority, Individual, and Dissenting Views, Financial Institutions Reform, Recovery, and Enforcement Act of 1989, H.R. Rep. No. 101–54 Part 1, 101st Cong., 1st Sess., at 482–83.

[8] 12 CFR part 1102, subpart A.

Islands in February 1993 (preceded by an interim order for relief issued in December 1992). The second was in August 2019 for the State of North Dakota (which was extended in part for one additional year in 2020).

Application of the rules of practice and procedure in the present day have led the ASC to recognize advantages to revising the rules to provide greater clarity, define certain terms and amend timeframes in the procedural process to be more conducive to deliberation by the ASC, and in the event of approval, deliberation by the FFIEC. The ASC is also adopting interpretations of several terms used in section 1119(b) of Title XI. These interpretations are included in the ''definitions'' section of the final rule.

Though neither procedural rules nor published agency interpretations of their statutory authority require notice and comment under the Administrative Procedure Act (APA),[9] the ASC voluntarily submitted the proposed rule and interpretations for public comment in order to seek feedback from interested parties. On January 13, 2022, the ASC published a proposed rule to amend the rules of practice and procedure governing temporary waiver proceedings with a 60-day public comment period.[10]

II. The Final Rule

The final rule amends rules of practice and procedure governing temporary waiver proceedings which were promulgated in 1992 pursuant to section 1119(b) of Title XI.[11] For the reasons discussed in section III of this **SUPPLEMENTARY INFORMATION**, the final rule adopts and amends the rules of practice and procedure substantially as proposed, with the following modifications:

(1) definition of ''Petition'' to include State financial institutions regulatory agencies as potential petitioners; and

(2) clarification that either a mandatory or discretionary waiver termination requires publication in the **Federal Register**, and that a discretionary waiver termination requires such publication with a 30-day comment period.

[9] 5 U.S.C. 553(b).

[10] 87 FR 2079.

[11] The flow chart included in the preamble of the proposed rule also applies to the final rule and can be accessed here: *https://www.asc.gov/Documents/FedralRegisterDocuments/2022.07.25%20Temporary%20Waiver%20Flow%20Chart%20for%20Final.pdf.* This is for reference purposes only and is not part of this final rule.

III. The Final Rule and Public Comments on the Proposed Rule

The following is a section-by-section review and discussion of the public comments received by the ASC concerning the proposal. The ASC requested comment on all aspects of the proposed amendments to the rules of practice and procedure governing temporary waiver proceedings. The ASC received four comment letters in response to the published proposal. These comment letters were received from appraiser trade associations, a state department of financial institutions, a national advocacy association for the credit union system and a national association of state bank supervisors.

A. Section 1102.1: Authority, Purpose, and Scope

Section 1102.1 finalizes proposed § 1102.1 without change and clarifies the distinction between: (1) a request from a State appraiser regulatory agency, referred to in the proposed rule as a ''Request for Temporary Waiver''; and (2) information received from other persons or entities (which could include a State appraiser regulatory agency), referred to in the proposed rule as a ''Petition.'' The procedures set forth in the final rule for ASC's consideration of a temporary waiver varies depending on whether the ASC has received a Request for Temporary Waiver or a Petition requesting that the ASC initiate a temporary waiver proceeding.

One commenter asserted that Title XI's temporary waiver provision was meant to support implementation of State program requirements enacted by Congress rather than to provide regulatory relief, which has caused confusion in the marketplace. The commenter did indicate general support for the proposed actions regarding the temporary waiver process but expressed concern over negative consequences and continued confusion. Although the ASC acknowledges this comment, there is no provision in Title XI that sunsets the temporary waiver provision.

Another commenter stated that the process is cumbersome, bureaucratic and did not offer any real assistance, and added that the proposed revisions to the rule are seemingly designed to ensure the process is burdensome to the point applications are not received or will be deemed incomplete. While the current rule and this final rule seek to obtain appropriate information to inform the ASC in potentially exercising this waiver authority which Congress intended that the ASC exercise cautiously,[12] the final rule clarifies the information to be submitted and the procedures to be followed to the extent the ASC can exercise such authority in a procedural rulemaking.

B. Section 1102.2: Definitions

Section 1102.2 finalizes proposed § 1102.2 with modification to the definition of ''Petition'' as discussed below. The following is a discussion of those definitions on which the ASC received public comment. Definitions on which the ASC did not receive comment are not discussed below.

One commenter noted that the proposed definition of ''Petition'' identified Federal financial institution regulators but failed to include State financial institution regulators. The ASC agrees, and therefore proposed § 1102.2(c) is adopted with modification to the definition of ''Petition'' to include State financial institutions regulatory agencies as a potential petitioner.

Several commenters asked for reconsideration of the proposed definitions of ''scarcity'' and ''delay'' to be measured or objectively determined as recommended in the report released in December 2021 by the Government Accountability Office (GAO).[13] The ASC appreciates the commenters' request for more precise definitions of these terms. The ASC has considered these comments and determined that ''scarcity'' and ''delay'' are best understood in the context of the individual State or geographical political subdivision of a State waiver applicant. Further, more precise definitions would limit the ASC's flexibility in making waiver determinations. However, the ASC has included new or revised definitions and interpretations of terms in the final rule in order to provide more clarity on the processing of a Request or Petition.

Another commenter asserted that having geographic location as a factor to consider in determining if a delay is out of the ordinary and opens the door to government-sanctioned discrimination. The acknowledgement of geographic location is built into the statute in section 1119(b) of Title XI, which references a finding of scarcity of certified or licensed appraisers to perform appraisals in connection with FRTs in a State, or in any geographical political subdivision of a State, leading to significant delays in the performance of such appraisals. The language in the current rule and this final rule reflects that language and recognizes varying circumstances in political subdivisions

[12] *Supra* note 7.

[13] *https://www.gao.gov/products/gao-22-104472.*

within a State. The ASC agrees it should not be applied to deprive anyone of equal access to credit.

C. Section 1102.3: Request for Temporary Waiver

Section 1102.3 finalizes proposed § 1102.3 without change. Section 1102.3(a) states that the State Appraisal Agency for the State in which temporary waiver relief is sought may file a Request for Temporary Waiver. Section 1102.3(b) provides that a Request for Temporary Waiver will not be deemed to have been received by the ASC unless it fully and accurately sets out:

- a written determination by the State Appraisal Agency that there is a scarcity of certified or licensed appraisers leading to significant delays in the performance of appraisals for FRTs or a specified class of FRTs within either a portion of, or the entire State;
- the requirement(s) of State law from which relief is being sought;
- the nature of the scarcity of certified or licensed appraisers (including supporting documentation, statistical or otherwise verifiable);
- the extent of the delays anticipated or experienced in the performance of appraisals by certified or licensed appraisers (including supporting documentation, statistical or otherwise verifiable);
- how complaints concerning appraisals by persons who are not certified or licensed would be processed in the event a temporary waiver is granted; and
- meaningful suggestions and recommendations for remedying the situation.

The amendments to paragraph (b) provide clarity on information that should be included in a Request for Temporary Waiver. The amendments also modify the requirement for a State Appraisal Agency to provide ''a specific plan for expeditiously alleviating the scarcity and service delays'' to ''meaningful suggestions and recommendations for remedying the situation'' recognizing that the situation creating scarcity and delay may be completely outside the control of the State Appraisal Agency.

The amendments include the phrase ''supporting documentation, statistical or otherwise verifiable.'' A Request for Temporary Waiver should include clear and specific data to support a claim that there is a scarcity of appraisers leading to significant delays in the performance of appraisals for FRTs, or a specified class of FRTs, for either a portion of, or the entire State. The data supporting such a claim may vary from location to location and situation to situation. Information about the following could assist the ASC in reviewing a Request for Temporary Waiver:

(1) Geography—location(s) of the scarcity leading to significant delay.

(2) Transactions—types of FRTs impacted (*i.e.,* property and transaction type(s) and transaction amount(s)).

(3) Time—length of time for waiver requested.

Section 1102.3(b) includes that a Request for Temporary Waiver address how complaints concerning appraisals by persons who are not certified or licensed would be processed in the event a temporary waiver is granted. Section 1102.3(c) clarifies that a Request for Temporary Waiver will be deemed received for purposes of publication in the **Federal Register** for notice and comment if the ASC determines that the information submitted meets the requirements of § 1102.3(b). Section 1102.3(d) sets forth what the process is in the event a Request for Temporary Waiver is not deemed to be received; written notice from the ASC would be required with an explanation for such a determination.

One commenter expressed concern over the requirement for a Request for Temporary Waiver to include ''the extent of the delays anticipated or experienced in the performance of appraisals,'' stating that granting a request based solely on anticipated delays is troubling. The commenter suggested requiring clear, convincing and specific evidence. While the ASC acknowledges the basis for this concern, this is language carried over from the current rule, and was helpful information for the ASC in considering more recent temporary waiver requests. The ASC would not consider ''anticipated delay'' alone, but rather would take this into account with all other information received.

The commenter addressed the need for applicants to understand the limited scope of temporary waivers to FRTs, that a temporary waiver does not remove the requirement for an appraisal for FRTs, and that many mortgage transactions are guided by underwriting requirements of an entity not covered under the FRT definition. The ASC agrees with the commenter's observations. The commenter also expressed concern that all available options should be exhausted prior to temporary waivers being considered, such as temporary practice permits and reciprocal licensing, and that States should be required to do so. While the ASC agrees that such options may be useful to minimize appraiser shortages, imposing such a requirement would be outside of the scope of this rulemaking, which is to amend existing rules of practice and procedure for temporary waivers.

The commenter also asserted that the ASC should afford great deference to the State appraiser regulatory agency in the processing of a Request for Temporary Waiver, and that the ASC should have clear and convincing evidence if it proceeds contrary to the State's position. The final rule has deference built into the process for a State's Request for Temporary Waiver. If all information is properly submitted, it is promptly published in the **Federal Register**. Even in the case of a Petition requesting the ASC exercise its discretionary authority to initiate a temporary waiver proceeding, the final rule incorporates the option for ASC referral and consultation with the State, while at the same time, maintaining the statutory responsibility for the ASC to make the determination, which would require FFIEC approval in the case of a temporary waiver being granted.

One commenter asked for reconsideration of the new requirement to address how complaints concerning appraisals by persons who are not credentialed would be processed stating that it is unnecessary since State regulators would continue to review and process complaints. Another commenter questioned this requirement stating that it is unnecessary since transactions would be governed by FFIEC agencies chartering or licensing the lender. While State appraiser regulatory agencies are charged with effective supervision of credentialed appraisers, some States may not have the authority to process complaints about unlicensed or uncredentialed individuals. The ASC found this to be a void when a temporary waiver was granted, and therefore review and processing of complaints should be addressed proactively in considering a Request for Temporary Waiver. If a State regulator would indeed continue to review and process such complaints, it would merely need to state that in the Request for Temporary Waiver. If the State lacks authority to do so, other options could be explored in a proactive manner.

A commenter stated that the ASC's request for documentation, statistical or otherwise verifiable, is a request for something that does not exist due to lack of a centralized reporting or gathering mechanism for such data. The final rule includes the phrase ''supporting documentation, statistical or otherwise verifiable.'' This is to provide clarification, without being overly prescriptive, as to what a Request or Petition for temporary waiver should include to support the existence of a

scarcity and delay, and what the ASC will consider in determining receipt of a Request or Petition. This leaves options open for a requester or petitioner to provide clear and specific data to support a claim that there is a scarcity of appraisers leading to significant delays in the performance of covered appraisals, while recognizing the data supporting such a claim may vary from location to location and situation to situation.

D. Section 1102.4: Petition Requesting the ASC Initiate a Temporary Waiver Proceeding

Section 1102.4 finalizes proposed § 1102.4 with modification to § 1102.4(a) to include State financial institutions regulatory agencies as a potential petitioner, consistent with the modification to the definition of ''Petition'' in § 1102.2(c).

Section 1102.4 clarifies that a Petition is a request for the ASC to exercise its discretionary authority to initiate a temporary waiver proceeding. Section 1102.4(a), as modified, states that a Petition may be filed by the Federal or State financial institutions regulatory agencies, their respective regulated financial institutions, or other persons or institutions with a demonstrable interest in appraiser regulation, including a State Appraisal Agency.

Section 1102.4(b) provides that a Petition should include:

- information (statistical or otherwise verifiable) to support the existence of a scarcity of certified or licensed appraisers leading to significant delays in the performance of appraisals for FRTs or a specified class of FRTs for either a portion of, or the entire State; and
- the extent of the delays anticipated or experienced in the performance of appraisals by certified or licensed appraisers (including supporting documentation, statistical or otherwise verifiable).

A Petition may also include meaningful suggestions and recommendations for remedying the situation. The amendments to this subsection provide clarity on information that should be included in a Petition while easing the expectation that a Petition contain the specificity of a Request for Temporary Waiver from a State Appraisal Agency.

The amendments include the phrase ''supporting documentation, statistical or otherwise verifiable.'' A Petition should include data to support a claim that there is a scarcity of appraisers leading to significant delays in the performance of appraisals for FRTs, or a specified class of FRTs, for either a portion of, or the entire State. Section 1102.4(c) clarifies the requirement for a petitioner to provide a copy of their Petition to the State Appraisal Agency, unless the Party filing the Petition is the State Appraisal Agency.

Section 1102.4(d) provides that a Petition may be processed for further action if the ASC determines that the information submitted meets the requirements of § 1102.4(b) and that further action should be taken to determine whether a scarcity of appraisers exists and that the scarcity is leading to significant delays in the performance of appraisals for FRTs or a specified class of FRTs within either a portion of, or the entire State. Section 1102.4(e) sets forth what is required in the event a Petition does not meet the requirements of § 1102.4(b) and thereby is either denied or referred back to the petitioner. In either case, written notice from the ASC would be required with an explanation for such a determination.

Section 1102.4(f) states that if a Petition is processed for further action, the ASC may initially refer a Petition to the State Appraisal Agency where temporary waiver relief is sought for evaluation and further study, or the ASC may take further action without referring a Petition to the State Appraisal Agency. If the ASC refers a Petition to the State Appraisal Agency, § 1102.4(g) states that in the event the State Appraisal Agency opts to conduct evaluation and further study on a Petition, the State Appraisal Agency may issue a written determination that there is a scarcity of certified or licensed appraisers leading to significant delays in the performance of appraisals for FRTs or a class of FRTs within either a portion of, or the entire State. Assuming the State Appraisal Agency has addressed the items that would be included in a Request for Temporary Waiver as set forth in § 1102.3(b), the Petition would now be subject to the procedures and requirements for a Request for Temporary Waiver.

The State Appraisal Agency could alternatively recommend that the ASC take no further action on the Petition, or simply decline to conduct evaluation and further study on a Petition. In either case, the ASC may exercise its discretion in determining whether to issue an Order initiating a temporary waiver proceeding.

One commenter stated that the proposed option to refer a Petition to the State appraiser regulatory agency may cause delay and that there is no statutory requirement for such a referral. Another commenter asserted that the option to refer a Petition to the State appraiser regulatory agency results in a delegation to the State appraiser regulatory agency and will create inconsistencies between States. The final rule incorporates the option for referral with the State while at the same time maintaining the statutory responsibility for the ASC to make a determination. It is important to note that the decision-making authority is with the ASC with approval from the FFIEC in the case of a temporary waiver being granted. However, given State regulators may be the most knowledgeable concerning any scarcity or delay within their borders, the ASC believes it appropriate to include the option to refer or consult with State regulators in the event of a Petition being filed.

Another commenter stated that the rule as proposed creates two classes of applicants, and that governmental agencies such as State bank regulators need the ability to directly apply for a waiver without being referred to State appraiser regulatory agencies. Section 1102.3(a) states that the State appraiser regulatory agency for the State in which temporary waiver relief is sought may file a Request for Temporary Waiver as distinguished from a Petition from other persons or entities as proposed in § 1102.4. Alternatively, a State appraiser regulatory agency may submit a Petition as set forth in proposed § 1102.4. The ASC believes this is consistent with the intent of the current rule [14] and agrees with the rationale set forth in the preamble of the current rule. The State appraiser regulatory agencies have always been given a more direct path to seek temporary waiver relief. Referral of a Petition from other persons or entities is an option the ASC may exercise but is not required as the commenter seems to suggest.

The commenter added that the rule as proposed requires applicants to provide meaningful suggestions and recommendations for remedying the situation, and that the cause is often complex, and the applicant may not be in a position to understand the greater political, legal or socioeconomic forces causing the shortage. As clarification, and as proposed, the final rule states that a Petition ''may'' include meaningful suggestions and recommendations for remedying the situation. This is not new and was

[14] ''The rules provide persons other than the State appraisal regulatory agencies ('State agencies') with the opportunity to submit informational submissions to the ASC. They also may request that the ASC exercise its discretionary authority to provide temporary waiver relief. The ASC will consider such submissions and requests in determining whether it should initiate a temporary waiver proceeding.'' *See* 57 FR 10980 (April 1992).

carried over from the current rule. The ASC has acknowledged this is not a problem for the applicant alone to resolve. Particularly in the North Dakota temporary waiver process, the complexity of the problem was recognized, which was the basis for the condition to the Order granting a temporary waiver: ''During the one-year period, the Requester is expected to develop a plan through continued dialogue with North Dakota stakeholders, including the Appraiser Board, to identify potential solutions to address appraiser scarcity and appraisal delay.'' [15]

One commenter expressed concern about availability of appraisal services, especially in rural areas, and the difficulty in securing timely appraisals. While recognizing multiple reasons for scarcity in areas, the commenter expressed support for revision of minimum credentialing requirements as established by the Appraisal Foundation's Appraiser Qualifications Board (AQB) to ensure new entrants into the profession and increase diversity. While the ASC supports a review of minimum credentialing requirements as established by the AQB to ensure they do not impose a barrier to entry into the profession and promote diversity, revisions to minimal credentialing requirements is outside the scope of this procedural rulemaking.[16]

The commenter asked for reconsideration of what they understood to be a new requirement for a written determination by the State appraiser regulatory agency. That requirement is only in the case of a Request for Temporary Waiver and is not required in the case of a Petition. Moreover, the requirement is part of the statute and the current rule: section 1119(b) of Title XI authorizes the ASC to waive, on a temporary basis, subject to approval of the FFIEC ''any requirement relating to certification or licensing of a person to perform appraisals under [Title XI] if the [ASC] or a [State appraiser regulatory agency] makes a written determination that there is a scarcity of certified or licensed appraisers to perform appraisals in connection with [FRTs] in a State. . . .'' The final rule clarifies the application of this statutory requirement.

E. Section 1102.5: Order Initiating a Temporary Waiver Proceeding

Section 1102.5 finalizes proposed § 1102.5 without change. Section 1102.5 clarifies that an Order initiating a temporary waiver proceeding may be in response to a Petition or may be initiated by the ASC without a Petition having been submitted. In either event, such an Order would include consideration of certain items that would be addressed in a Request for Temporary Waiver. (*See, e.g.,* § 1102.3(b)(2) through (6), *Contents and Receipt of a Request for Temporary Waiver.*) If such an Order is issued, the ASC shall publish a **Federal Register** notice in accordance with § 1102.6(b).

F. Section 1102.6: Notice and Comment

Section 1102.6 finalizes proposed § 1102.6 without change and does not vary in substance from § 1102.4 of the current rule, which provides for a 30-day notice and comment period on either a Request for Temporary Waiver or an Order initiating a temporary waiver proceeding.

G. Section 1102.7: ASC Determination

Section 1102.7 finalizes proposed § 1102.7 without change. Section 1102.7 expands the current 45-day deadline for the ASC to make a determination. Section 1102.7 also, for reasons set forth in the proposed rule, eliminates the interim Order from the rules of practice and procedure. With respect to recent requests for temporary waivers, or other information submissions requesting the ASC initiate a proceeding, the 45-day turnaround limited the time available to process and evaluate information submitted, including comments received during the notice and comment period. The timeframe for an ASC determination, on either a Request for Temporary Waiver or an Order initiating a temporary waiver proceeding, is expanded from 45 calendar days to 90 calendar days from the date of publication in the **Federal Register** to allow sufficient time for thorough processing and consideration. Section 1102.7 also clarifies that in the event the ASC issues an Order approving a temporary waiver, which is only effective upon FFIEC approval of the waiver, the FFIEC's consideration of the waiver is not subject to the ASC's 90-day timeframe for a determination.

One commenter asked for reconsideration of extending the ASC's timeframe for action on temporary waivers. The final rule provides clarity on what is expected to avoid delays in submitting proper information to the ASC. The ASC found the 45-day turnaround period, which allows only 15 days for consideration of comments received during the notice and comment period, to be a constraint on proper deliberation.

Another commenter expressed concern over removing the 45-day requirement for the ASC to take action stating that the ASC may deem a Request or Petition incomplete which may result in further delay. Under either the current rule or this final rule, the timeframe for taking action would not commence in either event until a Petition or Request is deemed received. Incomplete information submitted by an applicant would be the cause of delay in either circumstance. The final rule provides more clarity, particularly regarding the type of information that is expected in a Petition or a Request. This degree of specificity is intended to avoid rejection or supplementation of a Request or Petition, which was the case in the North Dakota request, resulting in a delay of nearly one year.

H. Section 1102.8: Waiver Extension

Section 1102.8 finalizes proposed § 1102.8 without change and does not vary in substance from § 1102.6 of the current rule.

I. Section 1102.9: Waiver Termination

Section 1102.9 finalizes proposed § 1102.9 with clarification that either a mandatory or discretionary waiver termination requires publication in the **Federal Register**, and that a discretionary waiver termination requires such publication with a 30-day comment period. Section 1102.9 distinguishes between mandatory waiver termination versus discretionary waiver termination. Section 1119(b) of Title XI states, ''[t]he waiver terminates when the [ASC] determines that such significant delays have been eliminated.'' Therefore, § 1102.9(a) requires termination in the event of such a finding by the ASC. Section 1102.9(b) retains the provision for a discretionary waiver termination in the event the ASC finds that the terms and conditions of the waiver Order are not being satisfied. Section 1102.9(c) requires publication in the **Federal Register** of either a mandatory or discretionary waiver termination, and Section 1102.9 finalizes proposed § 1102.9 with clarification that either a mandatory or discretionary waiver termination requires publication in the **Federal Register**, and that a discretionary waiver termination requires such publication with a 30-day comment period. In the absence of

[15] 84 FR 38630, 38633 (Aug. 7, 2019).

[16] *See* Agency Actions to Advance Valuation Equity; Building a well-trained, accessible, and diverse appraiser workforce 3.1: ''Update appraiser qualification criteria related to appraiser education, experience, and examination requirements to lower barriers to entry in the appraiser profession.'' *Action Plan to Advance Property Appraisal and Valuation Equity; Closing the Racial Wealth Gap by Addressing Mis-valuations for Families and Communities of Color* at 5 (March 2022).

further ASC action to the contrary, a discretionary waiver termination automatically becomes final 21 calendar days after the close of the comment period. Consistent with statute, a mandatory waiver termination is final upon such a determination being made by the ASC.

IV. Regulatory Requirements

The ASC has concluded that the final rule constitutes a rule of agency organization, procedure, or practice, and is therefore exempt from the notice-and-comment rulemaking requirements of the APA.[17] For the same reason, the amendments are not subject to the 30-day delayed effective date for substantive rules under the APA.[18] Moreover, agency interpretations of terms used in their statutory authority are exempt from the notice and comment requirement. Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[19]

Paperwork Reduction Act

There is no collection of information required by this final rule that would be subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* The Paperwork Reduction Act of 1995 [20] (PRA) states that no agency may conduct or sponsor, nor is the respondent required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The ASC has reviewed this final rule and determined that it does not contain any information collection requirements subject to the PRA. Accordingly, no submissions to OMB will be made with respect to this final rule.

Unfunded Mandates Reform Act of 1995 Determination

This final rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. This final rule amends the current rule to provide definitions of terms and greater clarity on the proceedings for a temporary waiver. A statement containing the information required by the Unfunded Mandates Reform Act, 2 U.S.C. 1531 *et seq.* is not required.

List of Subjects in 12 CFR Part 1102

Administrative practice and procedure, Appraisal management company registry fees, Appraisers, Banks, Banking, Freedom of information, Mortgages, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons set forth in the preamble, the ASC amends 12 CFR part 1102 as follows:

PART 1102—APPRAISER REGULATION

■ 1. The authority for part 1102 continues to read as follows:

Authority: 12 U.S.C. 3348(a), 3332, 3335, 3338 (a)(4)(B), 3348(c), 5 U.S.C. 552a, 553(e); Executive Order 12600, 52 FR 23781 (3 CFR, 1987 Comp., p. 235).

■ 2. Subpart A is revised to read as follows:

Subpart A—Temporary Waiver Requests

Sec.

Authority: 12 U.S.C. 3348(b).

§ 1102.1 Authority, purpose, and scope.

(a) *Authority.* This subpart is issued under section 1119(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (Title XI; 12 U.S.C. 3348(b)).

(b) *Purpose and scope.* This subpart prescribes rules of practice and procedure governing temporary waiver proceedings under section 1119(b) of Title XI (12 U.S.C. 3348(b)). These procedures apply whenever a Request for Temporary Waiver is submitted to the Appraisal Subcommittee (ASC) of the Federal Financial Institutions Examination Council (FFIEC) for a temporary waiver of any requirement relating to State certification or licensing (credentialing requirements) of persons eligible to perform appraisals for federally related transactions (FRTs) under Title XI. These procedures also apply in the event the ASC receives a Petition requesting the ASC initiate a temporary waiver proceeding. This subpart also contains the ASC's interpretations of terms used in section 1119(b) of Title XI.

§ 1102.2 Definitions.

For purposes of this subpart:

(a) *Federally related transaction (FRT)* means any real estate-related financial transaction which:

(1) A Federal financial institutions regulatory agency engages in, contracts for, or regulates; and

(2) Requires the services of an appraiser under the interagency appraisal rules. ((Title XI, section 1121(4), 12 U.S.C. 3350), implemented by the Office of the Comptroller of the Currency: 12 CFR 34.42(g) and 34.43(a); Federal Reserve Board: 12 CFR 225.62 and 225.63(a); Federal Deposit Insurance Corporation: 12 CFR 323.2(f) and 323.3(a); and National Credit Union Administration: 12 CFR 722.2(f) and 722.3(a).)

(b) *Performance of appraisals* means the appraisal service requested of an appraiser is provided to the lender or appraisal management company (AMC).

(c) *Petition* means information submitted to the ASC by the Federal or State financial institutions regulatory agencies, their respective regulated financial institutions, or other persons or institutions with a demonstrable interest in appraiser regulation, including a State Appraisal Agency, asking the ASC to exercise its discretionary authority to initiate a temporary waiver proceeding, and that meets the requirements, as determined by the ASC, set forth in § 1102.4.

(d) *Request for Temporary Waiver* means information submitted to the ASC by a State Appraisal Agency with a written determination requesting a temporary waiver that meets the requirements, as determined by the ASC, set forth in § 1102.3.

(e) *Scarcity of certified or licensed appraisers* means the number of active certified or licensed appraisers within a State or a specified geographical political subdivision is insufficient to meet the demand for appraisal services and such appraisers are difficult to retain.

(f) *Significant delays in the performance of appraisals* means delays that are substantially out of the ordinary when compared to performance of appraisals for similarly situated FRTs based on factors such as geographic location (*e.g.,* rural versus urban) and assignment type, and the delay is not the result of intervening circumstances outside the appraiser's control or brought about by the appraiser's client (*e.g.,* inability to access the subject property).

(g) *State Appraisal Agency* means the State appraiser certifying and licensing agency (Title XI, section 1121(1); *see also* 12 U.S.C. 3350(1)).

(h) *Temporary waiver* means a waiver of any or all credentialing requirements

[17] 5 U.S.C. 553(b).

[18] 5 U.S.C. 553(d).

[19] 5 U.S.C. 603(a) and 604(a).

[20] 44 U.S.C. 3501–3521.

for persons eligible to perform appraisals for FRTs; if granted, a temporary waiver does not waive the requirement for a *Uniform Standards of Professional Appraisal Practice* (USPAP)-compliant appraisal.

§ 1102.3 Request for Temporary Waiver.

(a) *Who can file a Request for Temporary Waiver.* The State Appraisal Agency for the State in which the temporary waiver relief is sought may file a Request for Temporary Waiver.

(b) *Contents and receipt of a Request for Temporary Waiver.* A Request for Temporary Waiver from a State Appraisal Agency will not be deemed received by the ASC unless it fully and accurately sets out:

(1) A written determination by the State Appraisal Agency that there is a scarcity of certified or licensed appraisers leading to significant delays in the performance of appraisals for FRTs or a specified class of FRTs within either a portion of, or the entire State;

(2) The requirement(s) of State law from which relief is being sought;

(3) The nature of the scarcity of certified or licensed appraisers (including supporting documentation, statistical or otherwise verifiable);

(4) The extent of the delays anticipated or experienced in the performance of appraisals by certified or licensed appraisers (including supporting documentation, statistical or otherwise verifiable);

(5) How complaints concerning appraisals by persons who are not certified or licensed would be processed in the event a temporary waiver is granted; and

(6) Meaningful suggestions and recommendations for remedying the situation.

(c) *Receipt of a Request for Temporary Waiver.* A Request for Temporary Waiver shall be deemed received for purposes of publication in the **Federal Register** for notice and comment if the ASC determines that the information submitted meets the requirements of paragraph (b) of this section to support that a scarcity of appraisers exists and that the scarcity is leading to significant delays in the performance of appraisals for FRTs or a specified class of FRTs within either a portion of, or the entire State.

(d) *Deny or refer back.* In the event the Request for Temporary Waiver is not deemed received, it may be denied in its entirety or referred back to the State Appraisal Agency for further action. In either case, the ASC shall provide written notice to the State Appraisal Agency providing an explanation for the determination.

§ 1102.4 Petition requesting the ASC initiate a temporary waiver proceeding.

(a) *Who can file a Petition requesting the ASC initiate a temporary waiver proceeding.* The Federal or State financial institutions regulatory agencies, their respective regulated financial institutions, and other persons or institutions with a demonstrable interest in appraiser regulation, including a State Appraisal Agency, may petition the ASC to exercise its discretionary authority to initiate a temporary waiver proceeding.

(b) *Contents of a Petition.* (1) A Petition should include:

(i) Information (statistical or otherwise verifiable) to support the existence of a scarcity of certified or licensed appraisers leading to significant delays in the performance of appraisals for FRTs or a specified class of FRTs for either a portion of, or the entire State; and

(ii) The extent of the delays anticipated or experienced in the performance of appraisals by certified or licensed appraisers (including supporting documentation, statistical or otherwise verifiable).

(2) A Petition may also include meaningful suggestions and recommendations for remedying the situation.

(c) *Copy of Petition to State Appraisal Agency.* In the case of a Petition from a party other than a State Appraisal Agency, the party must promptly provide a copy of its Petition to the State Appraisal Agency.

(d) *ASC review of a Petition.* A Petition may be processed for further action if the ASC determines that the information submitted meets the requirements of paragraph (b) of this section and that further action should be taken to determine whether a scarcity of appraisers exists and that the scarcity is leading to significant delays in the performance of appraisals for FRTs or a specified class of FRTs within either a portion of, or the entire State.

(e) *Deny or refer back.* In the event a Petition does not meet the requirements of paragraph (b) of this section it may be denied in its entirety or referred back to the petitioner for further action. In either event, the ASC shall provide written notice to the petitioner providing an explanation for the determination.

(f) *Further action on a Petition.* If the ASC determines that a Petition should be processed for further action, at its discretion the ASC may:

(1) Refer a Petition to the State Appraisal Agency where temporary waiver relief is sought for further evaluation and study, to include items that would be addressed in a Request for Temporary Waiver (*see* § 1102.3(b)); or

(2) Take further action without referring the Petition to the State Appraisal Agency.

(g) *State Appraisal Agency action.* (1) In the event the State Appraisal Agency opts to conduct further evaluation and study on a Petition, the State Appraisal Agency may:

(i) Issue a written determination that there is a scarcity of certified or licensed appraisers leading to significant delays in the performance of appraisals for FRTs or a class of FRTs within either a portion of, or the entire State (or request that the ASC issue such a written determination), in which case, the procedures and requirements of §§ 1102.3 and 1102.6(a) shall apply; or

(ii) Recommend that the ASC take no further action.

(2) In the event the State Appraisal Agency either recommends no further action or declines to conduct further evaluation and study on a Petition, the ASC may exercise its discretion in determining whether to issue an Order initiating a temporary waiver proceeding in accordance with § 1102.5(a).

§ 1102.5 Order initiating a temporary waiver proceeding.

The ASC may exercise discretion in determining whether to issue an Order initiating a temporary waiver proceeding in response to a Petition, or alternatively, the ASC may exercise discretion to initiate a temporary waiver proceeding on its own initiative without a Petition being submitted. In either event, such an Order would include consideration of certain items that would be addressed in a Request for Temporary Waiver. (*See, e.g.,* § 1102.3(b)(2) through (6).) If such an Order is issued, the ASC shall publish a **Federal Register** notice in accordance with § 1102.6(b).

§ 1102.6 Notice and comment.

(a) The ASC shall publish promptly in the **Federal Register** a notice respecting:

(1) A received Request for Temporary Waiver (*see* § 1102.3(c)); or

(2) An ASC Order initiating a temporary waiver proceeding (*see* § 1102.5).

(b) The notice of a received Request for Temporary Waiver or ASC Order initiating a temporary waiver proceeding shall contain a concise statement of the nature and basis for the action and shall give interested persons 30 calendar days from its publication in which to submit written data, views, and arguments.

§ 1102.7 ASC determination.

(a) *Order by the ASC.* Within 90 calendar days of the date of publication of the notice in the **Federal Register**, the ASC, by Order, shall either grant or deny a waiver, in whole or in part, and upon specified terms and conditions, including provisions for waiver termination. The Order shall be published in the **Federal Register**, which in the case of an Order approving a waiver, shall only be published after FFIEC approval of the waiver (*see* paragraph (b) of this section). Such Order shall respond to comments received from interested members of the public and shall provide the reasons for the ASC's finding(s).

(b) *Approval by the FFIEC.* Any ASC Order approving a waiver shall be effective only upon FFIEC approval of the waiver. FFIEC consideration of a waiver is not subject to the ASC's 90-day timeframe for a determination.

§ 1102.8 Waiver extension.

The ASC may initiate an extension of temporary waiver relief and shall follow §§ 1102.6, 1102.7 and 1102.9. A State Appraisal Agency also may seek an extension of temporary waiver relief by forwarding an additional written Request for Temporary Waiver to the ASC. A request for an extension from a State Appraisal Agency shall be subject to all the requirements of this subpart.

§ 1102.9 Waiver termination.

(a) *Mandatory waiver termination.* The ASC shall terminate a temporary waiver Order when the ASC determines that significant delays in the performance of appraisals by certified or licensed appraisers no longer exist.

(b) *Discretionary waiver termination.* The ASC at any time may terminate a waiver Order on the finding that the terms and conditions of the waiver Order are not being satisfied.

(c) *Publication in the* ***Federal Register****.* The ASC shall publish either a mandatory or discretionary waiver termination in the **Federal Register**, and a discretionary waiver termination requires such publication with a 30-day comment period. In the absence of further ASC action to the contrary, a discretionary waiver termination automatically becomes final 21 calendar days after the close of the comment period. A mandatory waiver termination is final upon such a determination being made by the ASC.

By the Appraisal Subcommittee.

Dated: September 29, 2022.

Zixta Martinez,

Chairperson.

[FR Doc. 2022–21606 Filed 10–6–22; 8:45 am]

BILLING CODE 6700–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0875; Project Identifier MCAI–2022–00640–R; Amendment 39–22185; AD 2022–20–01]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (AHD) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 C–2 helicopters. This AD was prompted by reports of excessively worn bolts that connect the cardan-pivot joint with the piston rod of the tail rotor actuator (TRA) assembly. This AD requires repetitively inspecting certain TRA assemblies, and depending on the results, replacing or repairing parts, or accomplishing additional inspections. This AD also prohibits installing an affected TRA assembly unless it passes required inspections. Lastly, this AD provides terminating actions for certain inspections, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 14, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 14, 2022.

ADDRESSES: For EASA material that is incorporated by reference (IBR) in this final rule, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.* For Airbus Helicopters service information identified in this final rule, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *airbus.com/helicopters/services/technical-support.html.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0875.

Examining the AD Docket

You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0875; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the EASA AD, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email *hal.jensen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued a series of EASA ADs, with the most recent being EASA AD 2022–0086, dated May 13, 2022 (EASA AD 2022–0086), to correct an unsafe condition for Airbus Helicopters Deutschland GmbH (AHD), formerly Eurocopter Deutschland GmbH; and Airbus Helicopters Inc., formerly American Eurocopter LLC, Model MBB–BK117 C–2 helicopters. EASA issued EASA AD 2022–0086 to supersede EASA AD 2019–0313, dated December 20, 2019.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 C–2 helicopters. The NPRM published in the **Federal Register** on July 14, 2022 (87 FR 42106). The NPRM was prompted by reports of excessively worn bolts that connect the cardan-pivot joint with the piston rod of the TRA assembly. According to Airbus Helicopters, manufacturer investigations of affected TRAs have revealed improperly assembled cardan-pivot joints as the main cause of the

excessively worn bolts. Additionally, incorrect washers as well as improperly shimmed laminated washers contribute to axial play and increased wear of the bolt. The NPRM proposed to require repetitively inspecting certain TRA assemblies, and depending on the results, replacing or repairing parts, or accomplishing additional inspections. The NPRM also proposed to prohibit installing an affected TRA assembly unless it passed required inspections. Lastly, the NPRM proposed terminating actions for certain inspections, as specified in EASA AD 2022–0086.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0086 requires, for certain TRAs with a steel or aluminum cardan-pivot joint, repetitively measuring the minimum diameter of the cardan-pivot joint assembly bolt. Depending on the results, EASA AD 2022–0086 requires replacing the bolt and laminated washers of the affected TRA or repetitively measuring the minimum diameter of the cardan-pivot joint assembly bolt at a reduced compliance time; or contacting AHD for approved repair instructions and compliance time or measuring the maximum diameter of the TRA piston rod bore hole. Depending on the results of measuring the maximum diameter of the TRA piston rod bore hole, EASA AD 2022–0086 requires replacing the bolt and laminated washers of the affected TRA; or contacting AHD for approved repair instructions and compliance time or repetitively measuring the maximum diameter of the TRA piston rod bore hole at a reduced compliance time. EASA AD 2022–0086 also prohibits installing an affected TRA assembly unless it passes its required inspections. Lastly, EASA AD 2022–0086 specifies certain terminating actions for repetitively measuring the minimum diameter of the cardan-pivot joint assembly bolt.

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

Other Related Service Information

The FAA reviewed Airbus Helicopters Alert Service Bulletin MBB–BK117 C–2–67A–027, Revision 2, dated December 15, 2021. This service information specifies, for TRAs with a steel or aluminum cardan-pivot joint, procedures for measuring the minimum diameter of the cardan-pivot joint assembly bolt, measuring the maximum diameter of the TRA piston rod bore hole, replacing the bolt and laminated washers, and reassembling the TRA.

Differences Between This AD and the EASA AD

EASA AD 2022–0086 requires discarding certain parts, whereas this AD requires removing those parts from service instead. EASA AD 2022–0086 requires maintaining a removed bolt for possible investigation purposes for four weeks, whereas this AD does not require that action. EASA AD 2022–0086 requires contacting AHD for approved repair instructions and accomplishing those instructions within the compliance time specified therein, whereas this AD requires accomplishing a repair in accordance with certain approved methods before further flight.

Costs of Compliance

The FAA estimates that this AD affects 142 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Measuring the cardan-pivot joint assembly bolt takes about 2 work-hours and parts cost a nominal amount for an estimated cost of $170 per helicopter and $24,140 for the U.S. fleet, per inspection cycle. If required, measuring the TRA piston rod bore hole following the cardan-pivot joint assembly bolt inspection takes about an additional 0.5 work-hour for an estimated cost of $43 per helicopter, per inspection cycle. Replacing a bolt and the laminated washers following an inspection takes about an additional 0.25 work-hour and parts cost about $586 for an estimated cost of $607 per replacement.

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–20–01 Airbus Helicopters Deutschland GmbH (AHD): Amendment 39–22185; Docket No. FAA–2022–0875; Project Identifier MCAI–2022–00640–R.

(a) Effective Date

This airworthiness directive (AD) is effective November 14, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 C–2 helicopters, certificated in any category.

Note 1 to paragraph (c): Helicopters with an MBB–BK 117 C–2(e) designation are Model MBB–BK 117 C–2 helicopters.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6720, Tail Rotor Control System.

(e) Unsafe Condition

This AD was prompted by reports of excessively worn bolts that connect the cardan-pivot joint with the piston rod of the tail rotor actuator assembly. The FAA is issuing this AD to detect and prevent worn bolts. The unsafe condition, if not addressed, could result in helicopter oscillations on the yaw axis during flight, failure of a bolt resulting in loss of control of the tail rotor, and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0086, dated May 13, 2022 (EASA AD 2022–0086).

(h) Exceptions to EASA AD 2022–0086

(1) Where EASA AD 2022–0086 requires compliance in terms of flight hours, this AD requires using hours time-in-service (TIS).

(2) Where EASA AD 2022–0086 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where Note 1 of EASA AD 2022–0086 allows a non-cumulative tolerance of 10% to the repetitive inspection intervals specified in its paragraphs (1), (2.2), and (5.2), this AD requires the repetitive inspection intervals specified in paragraphs (h)(3)(i) through (iii) of this AD.

(i) For the repetitive inspection interval specified in paragraph (1) of EASA AD 2022–0086, within intervals not to exceed 330 hours TIS.

(ii) For the repetitive inspection interval specified in paragraph (2.2) of EASA AD 2022–0086, within intervals not to exceed 165 hours TIS.

(iii) For the repetitive inspection interval specified in paragraph (5.2) of EASA AD 2022–0086, within intervals not to exceed 55 hours TIS.

(4) Where the service information referenced in EASA AD 2022–0086 specifies discarding parts, this AD requires removing those parts from service.

(5) Where the service information referenced in EASA AD 2022–0086 specifies maintaining a removed bolt for possible investigation purposes for four weeks, this AD does not require that action.

(6) Where paragraphs (3.1) and (5.1) of EASA AD 2022–0086 specify contacting AHD for approved repair instructions and accomplishing those instructions within the compliance time specified therein, this AD requires, before further flight, repair done in accordance with a method approved by the Manager, General Aviation & Rotorcraft Section, International Validation Branch, FAA; EASA; or Airbus Helicopters Deutschland GmbH EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(7) This AD does not mandate compliance with the ''Remarks'' section of EASA AD 2022–0086.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0086 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Special Flight Permit

A special flight permit may be issued in accordance with 14 CFR 21.197 and 21.199, provided that there are no passengers onboard.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(l) Related Information

For more information about this AD, contact Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email *hal.jensen@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2022–0086, dated May 13, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0086, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0875.

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

Issued on September 12, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–21884 Filed 10–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31453; Amdt. No. 568]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: Effective 0901 UTC, November 3, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures

and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29 Room 104, Oklahoma City, OK 73125. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

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

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC, on September 30, 2022.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, November 03, 2022.

PART 95—IFR ALTITUDES

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113 and 14 CFR 11.49(b)(2)

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

[Amendment 568 Effective Date, November 03, 2022]

From	To	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes			
§ 95.3227 RNAV Route T227 Is Amended By Adding			
BINAL, AK FIX	WIXER, AK WP	*3800	17500
*3000—MOCA			
WIXER, AK WP	CULTI, AK WP	3400	17500
CULTI, AK WP	*ZAFPO, AK WP	4300	17500
*4600—MCA ZAFPO, AK WP, NE BND			
ZAFPO, AK WP	BATTY, AK FIX	5600	17500
BATTY, AK FIX	GAMIC, AK WP	5700	17500
GAMIC, AK WP	FEDGI, AK WP	5000	17500
FEDGI, AK WP	*WEZZL, AK WP	*6300	17500
*2700—MCA WEZZL, AK WP, SW BND			
WEZZL, AK WP	AMOTT, AK FIX	*2100	17500
*1500—MOCA			
GLOWS, AK FIX	PERZO, AK WP	*3600	17500
*2300—MOCA			
PERZO, AK WP	*FAIRBANKS, AK VORTAC	3400	17500
*3600—MCA FAIRBANKS, AK VORTAC, N BND			
PESGE, AK WP	*JIFFS, AK WP	5000	17500
*8400—MCA JIFFS, AK WP, N BND			
JIFFS, AK WP	FIPSU, AK WP	*11000	17500
*8400—MOCA			
Is Amended To Delete			
BINAL, AK FIX	PORT HEIDEN, AK NDB/DME	*3800	17500
PORT HEIDEN, AK NDB/DME	CULTI, AK WP	*3700	17500
*1900—MOCA			
BATTY, AK FIX AMOTT, AK FIX	**13000	17500	.....
*5200—MCA AMOTT, AK FIX, SW BND			
*12300—MOCA			

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT—Continued

[Amendment 568 Effective Date, November 03, 2022]

From	To	MEA	MAA
Is Amended To Read In Part			
MORDI, AK FIX	GENFU, AK FIX	*4900	17500
*4000—MOCA			
GENFU, AK FIX	BINAL, AK FIX	**4000	17500
*3300—MCA BINAL, AK FIX, SW BND			
AMOTT, AK FIX	BIG LAKE, AK VORTAC	**2300	17500
*2700—MCA BIG LAKE, AK VORTAC, N BND			
FAIRBANKS, AK VORTAC	PESGE, AK WP	**5400	17500
*5100—MCA PESGE, AK WP, S BND			
§ 95.3229 RNAV Route T229 Is Amended By Adding			
KOTZEBUE, AK VOR/DME	SUGRE, AK FIX	4000	17500
SUGRE, AK FIX	VANTY, AK WP	3000	17500
Is Amended To Delete			
KOTZEBUE, AK VOR/DME	POINT HOPE, AK NDB	4000	17500
§ 95.3231 RNAV Route T231 Is Amended To Read in Part			
SELAWIK, AK VOR/DME	KOTZEBUE, AK VOR/DME	*3000	17500
*2500—MOCA			
§ 95.3232 RNAV Route T232 Is Amended By Adding			
BARROW, AK VOR/DME	BRONX, AK FIX	*4000	17500
*1900—MOCA			
BRONX, AK FIX	AKUMY, AK WP	9100	17500
AKUMY, AK WP	*OCOCU, AK FIX	**9000	17500
*5600—MCA OCOCU, AK FIX, NW BND			
**7800—MOCA			
OCOCU, AK FIX	BETTLES, AK VOR/DME	*9000	17500
*4100—MOCA			
BETTLES, AK VOR/DME	*FAIRBANKS, AK VORTAC	**6000	17500
*3600—MCA FAIRBANKS, AK VORTAC, NW BND			
**5400—MOCA			
FAIRBANKS, AK VORTAC	KRNKL, AK FIX	*3200	17500
*2900—MOCA			
KRNKL, AK FIX	IMARE, AK FIX	*2300	17500
*1900—MOCA			
IMARE, AK FIX	CUTUB, AK WP	*3900	17500
*3400—MOCA			
CUTUB, AK WP	*RIVOR, AK FIX	3700	17500
*2800—MCA RIVOR, AK FIX, W BND			
RIVOR, AK FIX	*BIG DELTA, AK VORTAC	3200	17500
*5100—MCA BIG DELTA, AK VORTAC, E BND			
BIG DELTA, AK VORTAC	MEYLE, AK FIX	6400	17500
MEYLE, AK FIX	NORTHWAY, AK VORTAC	8000	17500
Is Amended To Delete			
NORTHWAY, AK VORTAC	BIG DELTA, AK VORTAC	8000	17500
BIG DELTA, AK VORTAC	FAIRBANKS, AK VORTAC	*5000	17500
*4300—MOCA			
FAIRBANKS, AK VORTAC	BETTLES, AK VOR/DME	*6000	17500
*5200—MOCA			
BETTLES, AK VOR/DME	BRONX, AK FIX	*9000	17500
BRONX, AK FIX	BARROW, AK VOR/DME	*4000	17500
*1200—MOCA			
§ 95.3233 RNAV Route T233 Is Amended By Adding			
KOTZEBUE, AK VOR/DME	CIBDU, AK WP	2600	17500
CIBDU, AK WP	TOMPY, AK WP	4100	17500
TOMPY, AK WP	KORKY, AK WP	4900	17500
ENCOR, AK WP	BETTLES, AK VOR/DME	4700	17500
Is Amended To Delete			
AMBLER, AK NDB	KORKY, AK WP	*5000	17500

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT—Continued

[Amendment 568 Effective Date, November 03, 2022]

From	To	MEA	MAA
ENCOR, AK WP	EVANSVILLE, AK NDB	*5000	17500
Is Amended To Read in Part			
KORKY, AK WP *4900—MCA ENCOR, AK WP, W BND	*ENCOR, AK WP	6800	17500
§ 95.3235 RNAV Route T235 Is Amended By Adding			
FILEV, AK WP	ZISDU, AK WP	1800	17500
ZISDU, AK WP *1400—MOCA	WUPUV, AK WP	*2000	17500
WUPUV, AK WP *1500—MOCA	JATIL, AK WP	*3500	17500
JATIL, AK WP	ZADRO, AK WP	1800	17500
ZADRO, AK WP	DEADHORSE, AK VOR/DME	1900	17500
Is Amended To Delete			
ATQASUK, AK NDB *1300—MOCA	NUIQSUT VILLAGE, AK NDB	*3000	17500
§ 95.3267 RNAV Route T267 Is Amended By Adding			
KOTZEBUE, AK VOR/DME *2400—MCA SICOV, AK WP, SE BND	*SICOV, AK WP	3900	17500
SICOV, AK WP *2600—MCA HIBLA, AK WP, NW BND **2200—MOCA	*HIBLA, AK WP	**5000	17500
HIBLA, AK WP *5300—MCA UBASY, AK WP, N BND **5000—MOCA	*UBASY, AK WP	**5500	17500
UBASY, AK WP *4100—MCA PODKE, AK WP, S BND **5400—MOCA	*PODKE, AK WP	**6300	17500
PODKE, AK WP	JODGU, AK WP	4000	17500
JODGU, AK WP *1300—MOCA	ZISDU, AK WP	2300	17500
Is Amended To Read in Part			
NOME, AK VOR/DME *2300—MCA BALIN, AK FIX, SW BND **5900—MOCA	*BALIN, AK FIX	**8000	17500
§ 95.3364 RNAV Route T364 Is Added To Read			
COGNU, AK WP *1700—MOCA	HIPIV, AK WP	*3000	17500
HIPIV, AK WP	KOTZEBUE, AK VOR/DME	2600	17500
§ 95.3367 RNAV Route T367 Is Added To Read			
JOPES, AK WP *2800—MCA WOMEV, AK WP, NE BND **2100—MOCA	*WOMEV, AK WP	**2600	17500
WOMEV, AK WP *4200—MCA JERDN, AK WP, SW BND	*JERDN, AK WP	4600	17500
JERDN, AK WP *4400—MCA MKLUR, AK WP, SE BND **4000—MOCA	MKLUR, AK WP	**4400	17500
MKLUR, AK WP *5000—MCA HALUS, AK WP, NE BND	*HALUS, AK WP	3000	17500
HALUS, AK WP *3700—MCA FEMEP, AK WP, NW BND **3000—MOCA	*FEMEP, AK WP	**5000	17500
FEMEP, AK WP *2800—MCA JIGUM, AK WP, SE BND **5200—MOCA	*JIGUM, AK WP	**6500	17500
JIGUM, AK WP	KOTZEBUE, AK VOR/DME	2700	17500
KOTZEBUE, AK VOR/DME	CABGI, AK WP	4400	17500

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT—Continued

[Amendment 568 Effective Date, November 03, 2022]

From	To	MEA	MAA
§ 95.3368	**RNAV Route T368 Is Added To Read**		
KING SALMON, AK VORTAC	*CACCA, AK FIX	2300	17500
*3300—MCA CACCA, AK FIX, E BND			
CACCA, AK FIX	*ICADI, AK FIX	3300	17500
*3900—MCA ICADI, AK FIX, E BND			
ICADI, AK FIX	*ZAFPO, AK WP	4300	17500
*4900—MCA ZAFPO, AK WP, E BND			
ZAFPO, AK WP	*KOKOZ, AK FIX	4800	17500
*5900—MCA KOKOZ, AK FIX, NE BND			
KOKOZ, AK FIX	*WORRI, AK FIX	7000	17500
*7600—MCA WORRI, AK FIX, E BND			
WORRI, AK FIX	*CIXUL, AK WP	9200	17500
*8500—MCA CIXUL, AK WP, W BND			
CIXUL, AK WP	*OSBOE, AK FIX	4700	17500
*4700—MCA OSBOE, AK FIX, NW BND			
OSBOE, AK FIX	KODIAK, AK VOR/DME	4600	17500
§ 95.3369	**RNAV Route T369 Is Added To Read**		
BETHEL, AK VORTAC	JOPES, AK WP	*3000	17500
*1900—MOCA			
JOPES, AK WP	ZIPIX, AK WP	*3200	17500
*2400—MOCA			
ZIPIX, AK WP	NOME, AK VOR/DME	2800	17500
§ 95.3370	**RNAV Route T370 Is Added To Read**		
WIXER, AK WP	ITAWU, AK WP	3500	17500
ITAWU, AK WP	DILLINGHAM, AK VOR/DME	*2800	17500
*1500—MOCA			
DILLINGHAM, AK VOR/DME	*DUMZU, AK WP	3500	17500
*4600—MCA DUMZU, AK WP, NE BND			
DUMZU, AK WP	*AWOMY, AK FIX	6100	17500
*6300—MCA AWOMY, AK FIX, NE BND			
AWOMY, AK FIX	*MOFOF, AK FIX	8200	17500
*4900—MCA MOFOF, AK FIX, SW BND			
MOFOF, AK FIX	KENAI, AK VOR/DME	2800	17500
§ 95.3382	**RNAV Route T382 Is Added To Read**		
HOOPER BAY, AK VOR/DME	MEVIC, AK FIX	*3300	17500
*2400—MOCA			
MEVIC, AK FIX	JOPES, AK WP	*3300	17500
*2400—MOCA			
JOPES, AK WP	*FELSA, AK WP	3400	17500
*3700—MCA FELSA, AK WP, NE BND			
FELSA, AK WP	*YELLW, AK WP	3800	17500
*3500—MCA YELLW, AK WP, SW BND			
YELLW, AK WP	WEREL, AK WP	3000	17500
WEREL, AK WP	OTTAC, AK WP	*3600	17500
*3100—MOCA			
OTTAC, AK WP	*CHEFF, AK WP	3600	17500
*3900—MCA CHEFF, AK WP, E BND			
CHEFF, AK WP	MC GRATH, AK VORTAC	5400	17500
§ 95.3385	**RNAV Route T385 Is Added To Read**		
KODIAK, AK VOR/DME	WUMVI, AK WP	*7500	17500
*4700—MOCA			
WUMVI, AK WP	*GAMIC, AK WP	5400	17500
*4300—MCA GAMIC, AK WP, E BND			
GAMIC, AK WP	WUXON, AK WP	3000	17500
WUXON, AK WP	CUPTO, AK WP	3000	17500
CUPTO, AK WP	DUMZU, AK WP	4000	17500
§ 95.3416	**RNAV Route T416 Is Added To Read**		
SMYRNA, DE VORTAC	TEBEE, NJ FIX	1800	17500
TEBEE, NJ FIX	LULOO, NJ WP	1900	17500
LULOO, NJ WP	RIDNG, NJ WP	1900	17500

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From	To	MEA	MAA
RIDNG, NJ WP	*ALBEK, NJ FIX	1900	17500
*2000—MCA ALBEK, NJ FIX, E BND			
ALBEK, NJ FIX	COYLE, NJ VORTAC	2100	17500
COYLE, NJ VORTAC	PREPI, OA FIX	1900	17500
§ 95.3430 RNAV Route T430 Is Added To Read			
PHILIPSBURG, PA VORTAC	SELINSGROVE, PA VOR/DME	4900	17500
SELINSGROVE, PA VOR/DME	*PINNA, PA FIX	3500	17500
*3100—MCA PINNA, PA FIX, NW BND			
PINNA, PA FIX	EAST TEXAS, PA VOR/DME	2700	17500
EAST TEXAS, PA VOR/DME	TROXL, PA FIX	2600	17500
TROXL, PA FIX	BOPLY, PA FIX	2400	17500
BOPLY, PA FIX	LANNA, NJ FIX	2400	17500
LANNA, NJ FIX	SOLBERG, NJ VOR/DME	2400	17500
§ 95.3438 RNAV Route T438 Is Added To Read			
RASHE, PA FIX	*HERDA, PA FIX	4600	17500
*4300—MCA HERDA, PA FIX, W BND			
HERDA, PA FIX	MORTO, PA FIX	3800	17500
MORTO, PA FIX	RAVINE, PA VORTAC	3500	17500
RAVINE, PA VORTAC	VAYRE, PA FIX	3500	17500
VAYRE, PA FIX	DUMMR, PA FIX	3400	17500
DUMMR, PA FIX	FLOAT, PA FIX	3200	17500
FLOAT, PA FIX	HIKES, PA FIX	*2900	17500
*2400—MOCA			
HIKES, PA FIX	MAZIE, PA FIX	2800	17500
MAZIE, PA FIX	YARDLEY, PA VOR/DME	2000	17500
YARDLEY, PA VOR/DME	ROBBINSVILLE, NJ VORTAC	2100	17500
ROBBINSVILLE, NJ VORTAC	CASVI, NJ FIX	2000	17500
CASVI, NJ FIX	ZIGGI, NJ FIX	1900	17500
ZIGGI, NJ FIX	PREPI, OA FIX	1700	17500
§ 95.4000 High Altitude RNAV Routes			
§ 95.4081 RNAV Route Q81 Is Amended By Adding			
FIPES, OG WP	ZEILR, FL FIX	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
ZEILR, FL FIX	PIKKR, OG WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
PIKKR, OG WP	FARLU, FL WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
Is Amended To Delete			
FIPES, OG WP	THMPR, FL WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
THMPR, FL WP	LEEHI, FL WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
LEEHI, FL WP	FARLU, FL WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
§ 95.4122 RNAV ROUTE Q122 Is Amended By Adding			
O'NEILL, NE VORTAC	KATES, NE WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
KATES, NE WP	VIRGN, IA WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
VIRGN, IA WP	VIGGR, IA WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			

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[Amendment 568 Effective Date, November 03, 2022]

From	To	MEA	MAA
Is Amended To Delete			
O'NEILL, NE VORTAC *18000—GNSS MEA *DME/DME/IRU MEA	FORT DODGE, IA VORTAC	*18000	45000
§ 95.4136 RNAV Route Q136 Is Amended By Adding			
HIBAV, IA WP *18000—GNSS MEA *DME/DME/IRU MEA	DIYAP, IA WP	*19000	45000
Is Amended To Delete			
HIBAV, IA WP *18000—GNSS MEA *DME/DME/IRU MEA	BAACN, IA WP	*19000	45000
§ 95.4947 RNAV ROUTE Q947 Is Amended to Delete			
U.S. CANADIAN BORDER *18000—GNSS MEA *DME/DME/IRU MEA	TOPPS, ME FIX	*18000	45000
TOPPS, ME FIX *18000—GNSS MEA *DME/DME/IRU MEA	CUZWA, ME WP	*18000	45000
CUZWA, ME WP *18000—GNSS MEA *DME/DME/IRU MEA	U.S. CANADIAN BORDER	*18000	45000

From	To	MEA
§ 95.6001 Victor Routes–U.S.		
§ 95.6007 VOR Federal Airway V7 Is Amended To Delete		
VULCAN, AL VORTAC *2200—MOCA	MUSCLE SHOALS, AL VORTAC	*2800
§ 95.6008 VOR Federal Airway V8 Is Amended To Read in Part		
AHEIM, CA FIX *4300—MCA OLLIE, CA FIX, NE BND	OLLIE, CA FIX	3000
OLLIE, CA FIX	PARADISE, CA VORTAC	5300
PARADISE, CA VORTAC *8800—MCA RAVON, CA FIX, NE BND	*RAVON, CA FIX	4700
§ 95.6009 VOR Federal Airway V9 Is Amended To Delete		
MARVELL, AR VOR/DME	GILMORE, AR VOR/DME	1900
GILMORE, AR VOR/DME *2300—MOCA	MALDEN, MO VORTAC	*3000
MALDEN, MO VORTAC *2300—MOCA	FARMINGTON, MO VORTAC	*3000
§ 95.6014 VOR Federal Airway V14 Is Amended To Read in Part		
ONSOM, NM FIX *6400—MOCA	WINNS, TX FIX	*8000
WINNS, TX FIX *8000—MRA **5400—MOCA	*FLATT, TX FIX	**8000
FLATT, TX FIX *5000—MOCA	LUBBOCK, TX VORTAC	*5200
§ 95.6020 VOR Federal Airway V20 Is Amended To Read in Part		
COLUMBUS, GA VORTAC *2500—MOCA	SINCA, GA FIX	*4500

From	To	MEA
§ 95.6021 VOR Federal Airway V21 Is Amended To Read in Part		
AHEIM, CA FIX	*OLLIE, CA FIX	3000
*4300—MCA OLLIE, CA FIX, NE BND		
OLLIE, CA FIX	PARADISE, CA VORTAC	5300
PARADISE, CA VORTAC	*RAVON, CA FIX	4700
*8800—MCA RAVON, CA FIX, NE BND		
§ 95.6029 VOR Federal Airway V29 Is Amended To Read in Part		
SLATT, PA FIX	*WILKES–BARRE, PA VORTAC	4000
*4400—MCA WILKES–BARRE, PA VORTAC, N BND		
WILKES–BARRE, PA VORTAC	*SCOFF, PA FIX	4800
*4400—MCA SCOFF, PA FIX, S BND		
VESPE, NY FIX	SYRACUSE, NY VORTAC.	
N BND		4000
S BND		4500
§ 95.6031 VOR Federal Airway V31 Is Amended To Delete		
PATUXENT, MD VORTAC	*ARUYE, MD WP	2500
*6000—MRA		
ARUYE, MD FIX	NOTTINGHAM, MD VORTAC	#*6000
*3000—GNSS MEA		
#NOTTINGHAM R–138 UNUSABLE BELOW 6000′		
BALTIMORE, MD VORTAC	VINNY, PA FIX	3000
VINNY, PA FIX	GRAMO, PA FIX	*7000
*5000—GNSS MEA		
GRAMO, PA FIX	HARRISBURG, PA VORTAC	*7000
*5000—GNSS MEA		
HARRISBURG, PA VORTAC	MORTO, PA FIX	3000
MORTO, PA FIX	SELINSGROVE, PA VOR/DME	5000
SELINSGROVE, PA VOR/DME	WATSO, PA FIX	*3500
*3100—MOCA		
WATSO, PA FIX	WILLIAMSPORT, PA VOR/DME	3800
WILLIAMSPORT, PA VOR/DME	ELMIRA, NY VOR/DME	4000
ELMIRA, NY VOR/DME	GIBBE, NY FIX	3800
GIBBE, NY FIX	BEEPS, NY FIX	3500
BEEPS, NY FIX	ROCHESTER, NY VOR/DME	4000
ROCHESTER, NY VOR/DME	AIRCO, NY FIX	4000
§ 95.6035 VOR Federal Airway V35 Is Amended To Read in Part		
GREENVILLE, FL VORTAC	*SALER, GA FIX	UNUSABLE
*3000—MRA		
§ 95.6053 VOR Federal Airway V53 Is Amended To Read in Part		
COLUMBIA, SC VORTAC	WILLS, SC FIX	UNUSABLE
§ 95.6058 VOR Federal Airway V58 Is Amended To Delete		
PHILIPSBURG, PA VORTAC	WILLIAMSPORT, PA VOR/DME	4000
HELON, NY FIX	KINGSTON, NY VOR/DME	4000
KINGSTON, NY VOR/DME	HARTFORD, CT VOR/DME	3200
HARTFORD, CT VOR/DME	GROTON, CT VOR/DME	2500
GROTON, CT VOR/DME	SANDY POINT, RI VOR/DME	*2000
*1500—MOCA		
SANDY POINT, RI VOR/DME	NANTUCKET, MA VOR/DME	2000
§ 95.6071 VOR Federal Airway V71 Is Amended To Read in Part		
TOPEKA, KS VORTAC	PAWNEE CITY, NE VORTAC	*4000
*2900—MOCA		
§ 95.6100 VOR Federal Airway V100 Is Amended To Delete		
FORT DODGE, IA VORTAC	WATERLOO, IA VOR/DME	3000
§ 95.6106 VOR Federal Airway V106 Is Amended To Delete		
RASHE, PA FIX	SELINSGROVE, PA VOR/DME	14000
SELINSGROVE, PA VOR/DME	DIANO, PA FIX	3700
DIANO, PA FIX	WILKES–BARRE, PA VORTAC	4000
WILKES–BARRE, PA VORTAC	LAAYK, PA FIX.	

From	To	MEA
NE BND		*5000
SW BND		*4000
*4000—MOCA		
Is Amended To Read in Part		
JOHNSTOWN, PA VOR/DME	HUDON, PA FIX	5300
HUDON, PA FIX	RASHE, PA FIX	*7000
*4600—MOCA		
*4600—GNSS MEA		
§ 95.6107 VOR Federal Airway V107 Is Amended To Read in Part		
LOS ANGELES, CA VORTAC	STABO, CA FIX	2800
§ 95.6130 VOR Federal Airway V130 Is Amended To Delete		
NORWICH, CT VOR/DME	MINNK, RI FIX	2300
MINNK, RI FIX	MARTHAS VINEYARD, MA VOR/DME	*3000
*1600—MOCA		
§ 95.6138 VOR Federal Airway V138 Is Amended To Delete		
OMAHA, IA VORTAC	FORT DODGE, IA VORTAC	*4500
*3000—MOCA		
*3000—GNSS MEA		
FORT DODGE, IA VORTAC	MASON CITY, IA VOR/DME	3000
§ 95.6147 VOR Federal Airway V147 Is Amended To Read in Part		
SLATT, PA FIX	*WILKES–BARRE, PA VORTAC	4000
*4400—MCA WILKES–BARRE, PA VORTAC, NW BND		
§ 95.6149 VOR Federal Airway V149 Is Amended To Delete		
ALLENTOWN, PA VORTAC	BINGHAMTON, NY VOR/DME	*5000
*4000—MOCA		
§ 95.6155 VOR Federal Airway V155 Is Amended To Read in Part		
COLUMBUS, GA VORTAC	SINCA, GA FIX	*4500
*2500—MOCA		
§ 95.6159 VOR Federal Airway V159 Is Amended To Read in Part		
GREENVILLE, FL VORTAC	*SALER, GA FIX	UNUSABLE
*3000—MRA		
§ 95.6161 VOR Federal Airway V161 Is Amended To Read in Part		
LLANO, TX VORTAC	BUILT, TX FIX	*6000
*3400—MOCA		
BUILT, TX FIX	*DUFFA, TX FIX	**6000
*6000—MRA		
**2900—MOCA		
§ 95.6210 VOR Federal Airway V210 Is Amended To Read in Part		
UNPAS, NV FIX	PEACH SPRINGS, AZ VOR/DME	10500
§ 95.6214 VOR Federal Airway V214 Is Amended To Delete		
MARTINSBURG, WV VORTAC	WOOLY, MD FIX	3200
WOOLY, MD FIX	BALTIMORE, MD VORTAC	2600
BALTIMORE, MD VORTAC	SWANN, MD FIX	2000
SWANN, MD FIX	GATBY, MD FIX	#
#UNUSABLE		
GATBY, MD FIX	KERNO, MD FIX	#
#UNUSABLE		
KERNO, MD FIX	ODESA, MD FIX	#
#UNUSABLE		
ODESA, MD FIX	DUPONT, DE VORTAC	#*2000
*2000—GNSS MEA		
#DUPONT R–233 UNUSABLE BEYOND 22 NM		
DUPONT, DE VORTAC	YARDLEY, PA VOR/DME	*6000

From	To	MEA
*3000—GNSS MEA		
YARDLEY, PA VOR/DME	TETERBORO, NJ VOR/DME	*3000
*2000—MOCA MAA—10000		
§ 95.6264 VOR Federal Airway V264 Is Amended To Read in Part		
LOS ANGELES, CA VORTAC	*STABO, CA FIX	2800
*3300—MCA STABO, CA FIX, NE BND		
STABO, CA FIX	*AMTRA, CA FIX	3400
*3700—MCA AMTRA, CA FIX, E BND		
REANS, CA FIX	*YUCCA, CA FIX	13700
*12300—MCA YUCCA, CA FIX, W BND		
§ 95.6405 VOR Federal Airway V405 Is Amended To Read in Part		
PROVIDENCE, RI VOR/DME	FALMA, RI FIX	*3000
*1700—MOCA		
*2000—GNSS MEA		
§ 95.6445 VOR Federal Airway V445 Is Amended To Delete		
MITCH, MD FIX	SWANN, MD FIX	*7000
*3000—GNSS MEA		
SWANN, MD FIX	GATBY, MD FIX	#
#UNUSABLE		
GATBY, MD FIX	KERNO, MD FIX	#
#UNUSABLE		
KERNO, MD FIX	ODESA, MD FIX	#
#UNUSABLE		
ODESA, MD FIX	DUPONT, DE VORTAC	#*2000
*3000—GNSS MEA		
#DUPONT R–233 UNUSABLE BEYOND 22NM		
DUPONT, DE VORTAC	YARDLEY, PA VOR/DME	*6000
*3000—GNSS MEA		
YARDLEY, PA VOR/DME	EMPYR, NY FIX	2100
EMPYR, NY FIX	NANCI, NY FIX	2700
NANCI, NY FIX	LA GUARDIA, NY VOR/DME	2900
§ 95.6447 VOR Federal Airway V447 Is Amended To Delete		
CAMBRIDGE, NY VOR/DME	KERST, VT FIX	*5900
*5400—MOCA		
KERST, VT FIX	MUDDI, VT WP	*6000
*5500—MOCA		
MUDDI, VT WP	RUCKY, VT FIX	*6000
*5500—MOCA		
RUCKY, VT FIX	MONTPELIER, VT VOR/DME	*4500
*4000—MOCA		
MONTPELIER, VT VOR/DME	PLOTT, VT FIX	4800
PLOTT, VT FIX	HURDS, VT WP	5000
HURDS, VT WP	U.S. CANADIAN BORDER	5000
§ 95.6451 VOR Federal Airway V451 Is Amended To Delete		
LA GUARDIA, NY VOR/DME	*NESSI, CT FIX	**4000
*4000—MCA NESSI, CT FIX, W BND		
**1900—MOCA		
**2000—GNSS MEA		
NESSI, CT FIX	KEYED, NY FIX	#2500
#SEGMENT UNUSABLE EXCEPT FOR AIRCRAFT EQUIPPED WITH SUITABLE RNAV SYSTEM WITH GPS		
KEYED, NY FIX	CREAM, NY FIX	2000
CREAM, NY FIX	GROTON, CT VOR/DME	*6000
*4000—GNSS MEA		
§ 95.6456 VOR Federal Airway V456 Is Amended To Delete		
FORT DODGE, IA VORTAC	MANKATO, MN VOR/DME	3000
§ 95.6462 VOR Federal Airway V462 Is Amended To Delete		
FORT DODGE, IA VORTAC	SIOUX FALLS, SD VORTAC	4400

From	To	MEA
§ 95.6475 VOR Federal Airway V475 Is Amended To Delete		
LA GUARDIA, NY VOR/DME	DUNBO, NY FIX	2000
DUNBO, NY FIX	BRIDGEPORT, CT VOR/DME	*2000
*1500—MOCA		
BRIDGEPORT, CT VOR/DME	MADISON, CT VOR/DME	*2000
*1500—MOCA		
MADISON, CT VOR/DME	NORWICH, CT VOR/DME	#2600
#MADISON R–078 UNUSABLE BYD 16 NM USE NORWICH R–259		
NORWICH, CT VOR/DME	PROVIDENCE, RI VOR/DME	*2400
*1900—MOCA		
§ 95.6505 VOR Federal Airway V505 Is Amended To Delete		
DES MOINES, IA VORTAC	GUMBO, IA FIX	2700
GUMBO, IA FIX	FORT DODGE, IA VORTAC	3000
FORT DODGE, IA VORTAC	MASON CITY, IA VOR/DME	3000
§ 95.6357 Alaska VOR Federal Airway V357 Is Amended To Read in Part		
SANER, AK FIX	HOMER, AK VOR/DME.	
N BND		6000
S BND		9000
§ 95.6406 Hawaii VOR Federal Airway V6 Is Amended To Read in Part		
PLUMB, HI FIX	MAUI, HI VORTAC	4400
§ 95.6422 Hawaii VOR Federal Airway V22 Is Amended To Read in Part		
PLUMB, HI FIX	*MAUI, HI VORTAC	4400
*6300—MCA MAUI, HI VORTAC, E BND		

From	To	MEA	MAA
§ 95.7001 Jet Routes			
§ 95.7014 Jet Route J14 Is Amended To Delete			
GREENSBORO, NC VORTAC	RICHMOND, VA VORTAC	18000	45000
RICHMOND, VA VORTAC	PATUXENT, MD VORTAC	18000	45000
§ 95.7024 Jet Route J24 Is Amended To Delete			
MONTEBELLO, VA VOR/DME	FLAT ROCK, VA VORTAC	18000	41000
FLAT ROCK, VA VORTAC	HARCUM, VA VORTAC	18000	29000
§ 95.7052 Jet Route J52			
SIDON, MS VORTAC	BIGBEE, MS VORTAC	18000	45000
BIGBEE, MS VORTAC	VULCAN, AL VORTAC	18000	45000
TUBAS, NC FIX	RALEIGH/DURHAM, NC VORTAC	18000	45000
RALEIGH/DURHAM, NC VORTAC	RICHMOND, VA VORTAC	18000	45000
§ 95.7068 Jet Route J68 Is Amended To Delete			
HANCOCK, NY VOR/DME	PUTNAM, CT VOR/DME	18000	45000
PUTNAM, CT VOR/DME	PROVIDENCE, RI VOR/DME	18000	45000
PROVIDENCE, RI VOR/DME	NANTUCKET, MA VOR/DME	18000	45000
§ 95.7082 Jet Route J82 Is Amended to Delete			
SIOUX FALLS, SD VORTAC	FORT DODGE, IA VORTAC	18000	45000
FORT DODGE, IA VORTAC	DUBUQUE, IA VORTAC	18000	45000
§ 95.7094 Jet Route J94 Is Amended To Delete			
O'NEILL, NE VORTAC	FORT DODGE, IA VORTAC	18000	45000
FORT DODGE, IA VORTAC	DUBUQUE, IA VORTAC	18000	45000
§ 95.7165 Jet Route J165 Is Amended To Delete			
DWYTE, SC FIX	RICHMOND, VA VORTAC	18000	45000

From	To	MEA	MAA
§ 95.7207 Jet Route J207 Is Amended To Delete			
FLORENCE, SC VORTAC	RALEIGH/DURHAM, NC VORTAC	31000	45000
RALEIGH/DURHAM, NC VORTAC	FRANKLIN, VA VORTAC	18000	45000
§ 95.7506 Jet Route J506 Is Amended To Delete			
MILLINOCKET, ME VOR/DME	U.S. CANADIAN BORDER	18000	45000
§ 95.7561 Jet Route J561 Is Amended To Delete			
PRESQUE ISLE, ME VOR/DME	U.S. CANADIAN BORDER	18000	45000
§ 95.7563 Jet Route J563 Is Amended To Delete			
ALBANY, NY VORTAC U.S	CANADIAN BORDER	18000	45000
§ 95.7573 Jet Route J573 Is Amended To Delete			
KENNEBUNK, ME VOR/DME	U.S. CANADIAN BORDER	18000	45000
§ 95.7582 Jet Route J582 Is Amended To Delete			
PRESQUE ISLE, ME VOR/DME	U.S. CANADIAN BORDER	18000	45000
§ 95.7585 Jet Route J585 Is Amended To Delete			
NANTUCKET, MA VOR/DME	U.S. CANADIAN BORDER	18000	45000

From	To	Changeover points	
		Distance	From
§ 95.8003 VOR Federal Airway Changeover Point V3 Is Amended To Add Changeover Point			
FORT LAUDERDALE, FL VOR/DME	PALM BEACH, FL VORTAC	24	FORT LAUDERDALE.
V31 Is Amended To Delete Changeover Point			
HARRISBURG, PA VORTAC	SELINGSGROVE, PA VOR/DME	19	HARRISBURG.
V475 Is Amended To Delete Changeover Point			
LA GUARDIA, NY VOR/DME	BRIDGEPORT, CT VOR/DME	9	LA GUARDIA.
MADISON, CT VOR/DME	NORWICH, CT VOR/DME	16	MADISON.
§ 95.8005 Jet Routes Changeover Points J52 Is Amended To Delete Changeover Point			
BIGBEE, MS VORTAC	VULCAN, AL VORTAC	25	BIGBEE.

[FR Doc. 2022–21718 Filed 10–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 766

[Docket No. 220930–9998]

RIN 0694–AI91

Export Administration Regulations: Guidance on Penalty Determinations in the Settlement of Administrative Enforcement Cases Involving Antiboycott Matters

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: In this final rule, the Bureau of Industry and Security (BIS) amends a supplement to the Export Administration Regulations (EAR) that sets forth guidance regarding BIS's penalty determinations in the settlement of administrative enforcement cases involving violations of the antiboycott provisions of the EAR. This amendment clarifies and realigns such guidance with current boycott-related activity and BIS's priorities and charging practices. BIS also updates the reference to the statutory authority for the EAR's antiboycott provisions.

DATES: This rule is effective October 7, 2022.

FOR FURTHER INFORMATION CONTACT: Cathleen Ryan, Director, Office of Antiboycott Compliance, Bureau of Industry and Security, U.S. Department of Commerce, by email at *OAC.WebQueries@bis.doc.gov* or *OACINQUIRIES@bis.doc.gov,* or by phone at 202–482–2381.

SUPPLEMENTARY INFORMATION:

Background

Supplement No 2 to Part 766—(Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases Involving Antiboycott Matters) (''Antiboycott Penalty Guidance''), a supplement added to the EAR in July 2007, describes how BIS's Office of Antiboycott Compliance (OAC) responds to violations of part 760 of the EAR (''Restrictive Trade Practices or Boycotts'') and to violations of related recordkeeping requirements set forth in part 762 of the EAR (''Recordkeeping'') (together, ''the antiboycott provisions of the EAR''). Paragraph (d) of the Antiboycott Penalty Guidance specifies how BIS determines the appropriate sanctions in the settlement of administrative enforcement cases involving violations of the antiboycott provisions of the EAR.

In this final rule, BIS revises paragraph (d)(1)(ii)—Category of Violations, which categorizes violations by the seriousness of the alleged violations. Based on administrative antiboycott enforcement cases pursued in recent years under new statutory authority, the Export Control Reform Act of 2018 (50 U.S.C. 4801–4852), specifically, Part II (the Anti-Boycott Act of 2018), and current boycott-related trends and conditions, it is BIS's view that certain of the violations specified under Categories A and B in paragraph (d) do not accurately reflect BIS's current antiboycott enforcement priorities and practices or the agency's assessment of the seriousness of the alleged violations.

Accordingly, as detailed below, this rule makes certain revisions and clarifications to Categories A and B. By making these revisions, this amendment updates the two categories to better comport with current boycott-related activity and to better align BIS's penalty determinations with the agency's view of the seriousness of the alleged violations. BIS has revised Category A to include only those violations deemed the most serious; these violations will ordinarily warrant the maximum penalty available under the Anti-Boycott Act of 2018. BIS has also revised Category B, reflecting shifting trends in boycott activity, to include violations that most commonly and currently arise in commercial transactions in a boycott context; these violations will be the focus of OAC's antiboycott enforcement and subject to enhanced penalties to discourage cooperation with boycott-related requirements and to promote awareness, accountability and deterrence.

Specifically, consistent with these policy considerations, this rule moves certain violations from Category B to Category A and moves other violations from Category A to Category B. It also clarifies the references to certain violations. This rule does not make any revisions to Category C.

Section 760.2(a) (Refusals To Do Business)

Section 760.2(a) (Refusals to do business) of the EAR is a prohibition that may take one of four forms identified in paragraph (a)(1). BIS will continue to classify the first of these forms, refusing to do business, as a Category A violation. However, this rule moves the second form of this prohibition, knowingly agreeing to refuse to do business, from Category A to B, and also corrects the inadvertent omission of the word ''knowingly'' in the former reference at paragraph (d)(1)(ii)(A)(2) of Supp. No. 2 to part 766. Additionally, this rule makes clarifying additions to Category B by adding in specific references to the two other forms that Section 760.2(a)(1) may take, namely, requiring, or knowingly agreeing to require, any other person to refuse to do business. These clarifying additions reflect BIS's longstanding assessment of these two forms of the prohibition as Category B violations.

Furnishing Information About Associations With Charitable or Fraternal Organizations Which Support a Boycotted Country—§ 760.2(e)

This rule moves this violation from Category B to A.

Implementing Letters of Credit—§ 760.2(f)

This rule moves this violation from Category A to B.

Furnishing Information About Business Relationships With Boycotted Countries or Blacklisted Persons—§ 760.2(d)

This rule moves this violation from Category A to B.

These revisions and clarifications are intended to increase transparency and add clarity to the administrative enforcement process with respect to violations of the antiboycott provisions of the EAR and, in turn, to incentivize compliance and strengthen deterrence.

Corrections

Additionally, this rule makes a technical amendment to the introductory paragraph of (b) of Supplement No. 2 to Part 766. Specifically, it replaces the outdated reference to Section 8 of the Export Administration Act of 1979, as amended, with a reference to the Export Control Reform Act of 2018, the current statutory authority for the antiboycott provisions of the EAR.

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). Part II of ECRA contains the Anti-Boycott Act of 2018. ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as not significant for purposes of Executive Order 12866.

2. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

3. Pursuant to section 1762 of the Export Control Reform Act of 2018 (50 U.S.C. 4821), 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.

4. 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.

5. Notwithstanding any other provision of law, no person may be 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.*), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves a collection currently approved by OMB under control number 0694–0012, Report of Requests for Restrictive Trade Practice or Boycott—Single or Multiple Transactions. The collection carries a burden estimate of 60 to 90 minutes for a manual or electronic submission for a total burden estimate of 482 hours. BIS expects the burden hours associated with this collection to not to be impacted with the publication of this rule.

List of Subjects in 15 CFR Part 766

Administrative practice and procedure, Confidential business information, Exports, Law enforcement, Penalties.

Accordingly, part 766 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 766—ADMINISTRATIVE ENFORCEMENT PROCEEDINGS

■ 1. The authority citation for part 766 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.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 2. Supplement no. 2 to part 766 is amended by revising paragraph (b) introductory text and paragraph (d)(1)(ii) to read as follows:

Supplement No. 2 to Part 766—Guidance on Charging and Penalty Determinations in Settlement of Administrative Enforcement Cases Involving Antiboycott Matters

* * * * *

(b) *Responding to Violations.*

OAC within BIS investigates possible violations of the Anti-Boycott Act of 2018, the antiboycott provisions of the EAR, or any order or authorization related thereto. When BIS has reason to believe that such a violation has occurred, BIS may issue a warning letter or initiate an administrative enforcement proceeding. A violation may also be referred to the Department of Justice for criminal prosecution.

* * * * *

(d) *How BIS determines what sanctions are appropriate in a settlement.*

(1) General Factors. BIS looks to the following general factors in determining what administrative sanctions are appropriate in each settlement.

(i) Degree of seriousness. In order to violate the antiboycott provisions of the EAR, a U.S. person does not need to have actual ''knowledge'' or a reason to know, as that term is defined in § 772.1 of the EAR, of relevant U.S. laws and regulations. Typically, in cases that do not involve knowing violations, BIS will seek a settlement for payment of a civil penalty (unless the matter is resolved with a warning letter). However, in cases involving knowing violations, conscious disregard of the antiboycott provisions, or other such serious violations (*e.g.,* furnishing prohibited information in response to a boycott questionnaire with knowledge that such furnishing is in violation of the EAR), BIS is more likely to seek a denial of export privileges or an exclusion from practice, and/or a greater monetary penalty as BIS considers such violations particularly egregious.

(ii) Category of violations. In connection with its activities described in paragraph (a)(1) of this supplement, BIS recognizes three categories of violations under the antiboycott provisions of the EAR. (See § 760.2, § 760.4 and § 760.5 of the EAR for examples of each type of violation other than recordkeeping). These categories reflect the relative seriousness of a violation, with Category A violations typically warranting the most stringent penalties, including up to the maximum monetary penalty, a denial order and/or an exclusion order. Through providing these categories in this penalty guidelines notice, BIS hopes to give parties a general sense of how it views the seriousness of various violations. This guidance, however, does not confer any right or impose any obligation as to what penalties BIS may impose based on its review of the specific facts of a case.

(A) The Category A violations and the sections of the EAR that set forth their elements are:

(1) Discriminating against U.S. persons on the basis of race, religion, sex, or national origin—§ 760.2(b);

(2) Refusing to do business—§ 760.2(a);

(3) Furnishing information about race, religion, sex or national origin of U.S. persons including, but not limited to, providing information in connection with a boycott questionnaire about the religion of employees—760.2(c).

(4) Evading the provisions of part 760—§ 760.4; and

(5) Furnishing information about associations with charitable or fraternal organizations which support a boycotted country—§ 760.2(e).

(B) The Category B violations and the sections of the EAR that set forth their elements are:

(1) Knowingly agreeing to refuse to do business—§ 760.2(a);

(2) Requiring, or knowingly agreeing to require, any other person to refuse to do business—§ 760.2(a);

(3) Implementing letters of credit—§ 760.2(f);

(4) Furnishing information about business relationships with boycotted countries or blacklisted persons—§ 760.2(d); and

(5) Making recordkeeping violations—part 762.

(C) The Category C violation and the section of the EAR that sets forth its elements is: Failing to report timely receipt of boycott requests—§ 760.5.

* * * * *

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2022–21713 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0835]

Safety Zone; Battle of the Basin Boat Races Morgan City, LA

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

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the regulations for the Battle of the Basin Boat Races set forth in our regulations regarding Annual Marine Events in the Eighth Coast Guard District between mile marker (MM) 4 and MM 5 on the Morgan City, Port Allen Route, Louisiana (LA). This action is necessary to provide for the safety of life on these navigable waters near Morgan City, LA during high speed boat races on October 29, 2022 and October 30, 2022. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the local Patrol Commander.

DATES: The regulations in 33 CFR 100.801 will be enforced from 10 a.m. to 6 p.m. on October 29, 2022, and October 30, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Jenelle Piché, Marine Safety Unit (MSU) Morgan City, U.S. Coast Guard; telephone 985–855–0724, email *Jenelle.L.Piche@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the regulations set forth in 33 CFR 100.801 for the Battle of the Basin Boat Races. The regulations will be enforced from 10 a.m. to 6 p.m. on October 29, 2022, and October 30, 2022. This action is being taken to provide for the safety of life on navigable waterways during this event, which will be located between MM 4 and MM 5 on the Morgan City, Port Allen Route, LA. During the enforcement periods, if you are the

operator of a vessel in the regulated area you must comply with the regulations set forth in 33 CFR 100.801.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via a Safety Marine Information Broadcast and Broadcast Notice to Mariners.

Dated: September 29, 2022.

L.T. O'Brien,

Captain, U.S. Coast Guard, Captain of the Port Houma.

[FR Doc. 2022–21871 Filed 10–6–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0833]

RIN 1625–AA87

Security Zone; Puget Sound, Tacoma, WA

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

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is extending the effective period of a temporary, 500-yard radius, moving security zone for a vessel carrying Certain Dangerous Cargo (CDC) within Puget Sound. This temporary security zone is needed to protect the vessel, the CDC, and the surrounding waterway from terrorist acts, sabotage, or other subversive acts, accidents, or other events of a similar nature. Entry of vessels or persons into this zone is prohibited while the Motor Vessel (M/V) GREEN RIDGE is in transit unless specifically authorized by the Captain of the Port Puget Sound (COTP) or a designated representative.

DATES: This rule is effective without actual notice from October 5, 2022, through October 8, 2022. For the purposes of enforcement, actual notice will be used from October 4, 2022, until 8:45 a.m. on October 5, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Rob Nakama, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone 206–217–6089, email *SectorPugetSoundWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Puget Sound
DHS Department of Homeland Security
FR Federal Register
M/V Motor Vessel
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On September 30, 2022, the Coast Guard issued a rulemaking that created a temporary security zone effective October 4, 2022. Due to the vessel's new departure date, additional time is needed; as a result, the Coast Guard is establishing through temporary regulations a security zone that will be in effect through October, 8, 2022. The temporary rule was issued 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. The Coast Guard established this security zone to ensure security of the vessel, the CDC, and the surrounding waterway from terrorist acts, sabotage, or other subversive acts, accidents, or other events of a similar nature and the effective date of the zone must be extended due to the vessel's new departure date. It would be contrary to public interest to postpone extending the temporary security zone.

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 because the security zone is needed for immediate action to respond to potential security concerns associated with the vessel.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that potential hazards associated with the transit of the M/V GREEN RIDGE when loaded will be a security concern within a 500-yard radius of the vessel. This rule is needed to provide for the safety and security the vessel, its cargo, and surrounding waterway from terrorist acts, sabotage or other subversive acts, accidents, or other events of a similar nature while the vessel is transiting within Puget Sound.

IV. Discussion of the Rule

The Coast Guard is establishing a 500-yard radius temporary moving security zone around the M/V GREEN RIDGE. The zone for the vessel is effective from October 4, 2022, through October 8, 2022. It will be subject to enforcement this entire period unless the COTP determines it is no longer needed, in which case the Coast Guard will inform mariners via Notice to Mariners. The duration of the zone is intended to protect the vessel, the cargo, and the surrounding waterway from terrorist acts, sabotage or other subversive acts, accidents, or other events of a similar nature. No vessel or person will be permitted to enter the security zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, duration, and location of the security zone. This rule will impact a small designated area of 500-yards around the moving vessel while transiting from Terminal 7 in Tacoma, WA, to Admiralty Inlet, WA. Moreover, the rule allows vessels to seek permission to enter 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 security zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please 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 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a moving security zone lasting for the duration of time that the M/V GREEN RIDGE is transiting while loaded with cargo. It will prohibit entry within a 500 yard radius of the M/V GREEN RIDGE while the vessel is transiting loaded within Puget Sound. It is categorically excluded from further review under L60(d) in Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to 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.T13–0833 to read as follows:

§ 165.T13–0833 Security Zone; Puget Sound, Tacoma, WA.

(a) *Location.* The following area is a security zone: All navigable waters encompassing a 500-yard radius around the Motor Vessel (M/V) GREEN RIDGE while the vessel is underway from Terminal 7 in Tacoma, WA, until the vessel reaches a pier in Admiralty Bay, WA.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Puget Sound (COTP) in the enforcement of the security zone.

(c) *Enforcement period.* This section will be enforced from October 4, 2022, through October 8, 2022.

(d) *Regulations.* (1) The general regulations in § 165.33 apply. Entry into the zone is prohibited unless authorized by the COTP or a designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16 or at 206–217–6051. Those in the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

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

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

Dated: October 4, 2022.

P.M. Hilbert,

Captain, U.S. Coast Guard, Captain of the Port Puget Sound.

[FR Doc. 2022–21950 Filed 10–5–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0036; FRL–10151–02–R4]

Air Plan Approval; North Carolina; Source Testing and Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is finalizing the approval of changes to the North Carolina State Implementation Plan (SIP), submitted by the State of North Carolina through the North Carolina Division of Air Quality (NCDAQ), through a letter dated October 9, 2020. The SIP revisions include changes to NCDAQ's regulations regarding monitoring and performance testing for stationary sources of air pollution. EPA is approving these changes pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective November 7, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0036. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Sarah LaRocca, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Ms. LaRocca can be reached via electronic mail at *larocca.sarah@epa.gov* or via telephone at (404) 562–8944.

SUPPLEMENTARY INFORMATION:

I. Background

On October 9, 2020, NCDAQ submitted a SIP revision addressing changes to North Carolina's regulations on monitoring and performance testing for stationary sources of air pollution. Specifically, the revisions address several regulations under 15A North Carolina Administrative Code (NCAC) Subchapter 02D, Section .0600, *Air Contaminants; Monitoring; Reporting,* and Section .2600, *Source Testing.*[1]

The October 9, 2020, revisions to the North Carolina SIP mostly include changes that do not alter the meaning of the regulations, such as clarifying changes, updating cross-references, and making several ministerial language changes. However, as described in an August 24, 2022, Notice of Proposed Rulemaking (NPRM), other changes transmitted include requiring additional information in the source testing protocols and revising the required test methods in certain cases.

On August 24, 2022, EPA published a NPRM proposing to approve these revisions. Additional details on the revisions, as well as EPA's rationale for approving these changes, can be found in the August 24, 2022, NPRM. *See* 87 FR 51941. Comments on the August 24, 2022, NPRM were due on or before September 23, 2022. EPA received no comments on the NPRM.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, and as specified in Section I of this preamble, EPA is finalizing the incorporation by reference of the following North Carolina rules, with a state effective date of November 1, 2019: Rule 02D .0607, *Large Wood and Wood-Fossil Fuel Combination Units,* Rule 02D .0608, *Other Large Coal or Residual Oil Burners,* Rule 02D .0610, *Federal Monitoring Requirements,* Rule 02D .0612, *Alternative Monitoring and Reporting Procedures,* Rule 02D .0613, *Quality Assurance Program,* Rule 02D .2603, *Testing Protocol,* Rule 02D .2604, *Number of Test Points,* Rule 02D .2605, *Velocity and Volume Flow Rate,* Rule 02D .2606, *Molecular Weight,* Rule 02D .2607, *Determination of Moisture Content,* Rule 02D .2608, *Number of Runs and Compliance Determination,* Rule 02D .2610, *Opacity,* Rule 02D .2612, *Nitrogen Oxide Testing Methods,* Rule 02D .2613, *Volatile Organic Compound Testing Methods,* and Rule 02D .2614, *Determination of VOC Emission Control System Efficiency.* EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 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.[2]

III. Final Action

EPA is approving the October 9, 2020, SIP revisions to incorporate multiple changes to North Carolina's source monitoring and testing provisions into the SIP. Specifically, EPA is approving various ministerial and minor changes to language and other clarifying changes throughout North Carolina's rules in 02D Section .0600, *Monitoring: Recordkeeping: Reporting,* and .2600, *Source Testing.* EPA is approving these changes for the reasons discussed above and in the NPRM.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 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 they meet the criteria of the CAA. 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

[1] EPA notes that the Agency received several submittals revising the North Carolina SIP transmitted with the same October 9, 2020, cover letter. EPA will be considering action for these other SIP revisions, including certain 02D Section .0600 and Section .2600 rules not considered in this action, in separate rulemakings.

[2] *See* 62 FR 27968 (May 22, 1997).

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).

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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 30, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, the 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.*

Subpart II—North Carolina

■ 2. In § 52.1770(c), amend table (1) under ''Subchapter 2D Air Pollution Control Requirements'' by removing the entries for ''Section .0607,'' ''Section .0608,'' ''Section .0610,'' ''Section .0612,'' ''Section .0613,'' ''Section .2603,'' ''Section .2604,'' ''Section .2605,'' ''Section .2606,'' ''Section .2607,'' ''Section .2608,'' ''Section .2610,'' ''Section .2612,'' ''Section .2613,'' and ''Section .2614;'' and adding in their place entries for ''Rule .0607,'' ''Rule .0608,'' ''Rule .0610,'' ''Rule .0612,'' ''Rule .0613,'' ''Rule .2603,'' ''Rule .2604,'' ''Rule .2605,'' ''Rule .2606,'' ''Rule .2607,'' ''Rule .2608,'' ''Rule .2610,'' ''Rule .2612,'' ''Rule .2613,'' and ''Rule .2614.'' The additions read as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

(1) EPA Approved North Carolina Regulations

State citation	Title/subject	State effective date	EPA approval date	Explanation
* *	*	*	* *	*
Rule .0607	Large Wood and Wood-Fossil Fuel Combination Units.	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .0608	Other Large Coal or Residual Oil Burners.	11/1/2019	10/7/2022, [Insert citation of publication].	
* *	*	*	* *	*
Rule .0610	Federal Monitoring Requirements.	11/1/2019	10/7/2022, [Insert citation of publication].	
* *	*	*	* *	*
Rule .0612	Alternative Monitoring and Reporting Procedures.	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .0613	Quality Assurance Program ...	11/1/2019	10/7/2022, [Insert citation of publication].	

(1) EPA APPROVED NORTH CAROLINA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
* *	*	*	*	* *
Rule .2603	Testing Protocol	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .2604	Number of Test Points	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .2605	Velocity and Volume Flow Rate.	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .2606	Molecular Weight	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .2607	Determination of Moisture Content.	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .2608	Number of Runs and Compliance Determination.	11/1/2019	10/7/2022, [Insert citation of publication].	
* *	*	*	*	* *
Rule .2610	Opacity	11/1/2019	10/7/2022, [Insert citation of publication].	
* *	*	*	*	* *
Rule .2612	Nitrogen Oxide Testing Methods.	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .2613	Volatile Organic Compound Testing Methods.	11/1/2019	10/7/2022, [Insert citation of publication].	
Rule .2614	Determination of VOC Emission Control System Efficiency.	11/1/2019	10/7/2022, [Insert citation of publication].	
* *	*	*	*	* *

* * * * *

[FR Doc. 2022–21647 Filed 10–6–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–HQ–OAR–2021–0742; FRL–8425–02–OAR]

Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Areas Classified as Marginal for the 2015 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is finalizing three types of actions the Clean Air Act (CAA or Act) related to 28 areas classified as ''Marginal'' for the 2015 ozone National Ambient Air Quality Standards (NAAQS). First, the Agency is determining that five Marginal areas attained the standards by the August 3, 2021, applicable attainment date. Second, the Agency is granting a 1-year attainment date extension for the Uinta Basin, Utah (UT), nonattainment area. Third, the Agency is determining that 22 Marginal areas or portions of areas failed to attain the standards by the applicable attainment date. The effect of failing to attain by the applicable attainment date is that these areas or portions of areas will be reclassified by operation of law to ''Moderate'' nonattainment for the 2015 ozone NAAQS on November 7, 2022, the effective date of this final rule. Accordingly, the responsible state air agencies must submit State Implementation Plan (SIP) revisions and implement controls to satisfy the statutory and regulatory requirements for Moderate areas for the 2015 ozone NAAQS according to the deadlines established in this final rule.

DATES: The effective date of this rule is November 7, 2022.

ADDRESSES: The EPA has established a public docket for these ozone designations at *https://www.regulations.gov* under Docket ID No. EPA–HQ–OAR–2021–0742. Although listed in the docket index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: For general questions concerning this action, contact Emily Millar, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, C539–01 Research Triangle Park, NC 27709; telephone number: 919–541–2619; email address: *millar.emily@epa.gov;* or Robert Lingard, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, C539–01 Research Triangle Park, NC 27709; by telephone number: 919–541–5272; email address: *lingard.robert@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

The following is an outline of the Preamble.

I. Proposed Actions

A. Proposed Determinations of Attainment by the Attainment Date, Determinations of Failure To Attain by the Attainment Date and Extensions of the Attainment Date

On April 13, 2022, the EPA proposed actions to fulfill its statutory obligation under CAA section 181 to determine whether 31 Marginal ozone nonattainment areas attained the 2015 ozone NAAQS by August 3, 2021, the applicable attainment date for such areas.[1]

First, the EPA proposed to find that six areas—Atlanta, Georgia (GA); Manitowoc County, Wisconsin (WI); Southern Wasatch Front, Utah; Amador County, California (CA); San Francisco Bay, California; and Yuma, Arizona (AZ)—attained the 2015 ozone NAAQS by the applicable attainment date based on complete, quality-assured and certified ozone air quality monitoring data for the 2018–2020 calendar years.

Second, the EPA proposed to grant the state of Utah's request for a 1-year extension of the attainment date from August 3, 2021, to August 3, 2022, for the Uinta Basin, UT nonattainment area. The proposed extension was based on a finding that the state met the statutory and regulatory requirements for a 1-year extension of the attainment date. Other information the EPA analyzed, such as air quality data indicating that the Uinta Basin area would likely qualify for a second extension and could possibly attain the NAAQS by a second extended attainment date, and screening analyses indicating that existing pollution burdens within the Uinta Basin area were not disproportionately high relative to the rest of the United States, were consistent with the EPA's proposal that an extension was appropriate under these circumstances. The EPA therefore proposed that upon the effective date of a final reclassification action, the attainment date for this area would be extended to August 3, 2022.

Third, the EPA proposed to find that 24 areas failed to attain the 2015 ozone NAAQS by the applicable attainment date and did not qualify for a 1-year attainment date extension. The 24 areas were: Allegan County, Michigan (MI); Baltimore, Maryland (MD); Berrien County, Michigan; Chicago, Illinois-Indiana-Wisconsin (IL-N-WI); Cincinnati, Ohio-Kentucky (OH-KY); Cleveland, Ohio; Dallas-Fort Worth, Texas (TX); Denver Metro/North Front Range, Colorado (CO) (Denver area); Detroit, Michigan; Door County-Revised, Wisconsin; Greater Connecticut, Connecticut (CT); Houston-Galveston-Brazoria, Texas; Louisville, Kentucky-Indiana; Mariposa, California; Milwaukee, Wisconsin; Muskegon County, Michigan; North Wasatch Front, Utah; Pechanga Band of Luiseño Mission Indians; Philadelphia-Wilmington-Atlantic City, Pennsylvania-New Jersey-Maryland-Delaware (PA-NJ-MD-DE); Phoenix-Mesa, Arizona; San Antonio, Texas; Sheboygan County, Wisconsin; St. Louis, Missouri-Illinois (MO-L); and Washington, District of Columbia-Maryland-Virginia (DC-MD-VA). The proposed determination for each of these areas was based upon complete, quality-assured and certified ozone air quality monitoring data that showed that the 8-hour ozone design value (DV) for the area exceeded 0.070 parts per million (ppm) for the period 2018–2020, *i.e.,* the area's DV as of the attainment date. The EPA proposed that these 24 areas would be reclassified as Moderate nonattainment areas by operation of law on the effective date of a final action finding that these areas failed to attain the 2015 ozone NAAQS by the applicable attainment date for Marginal areas.[2]

Since the EPA issued its proposal in April, the Agency redesignated the Manitowoc County, WI area to attainment for the 2015 ozone NAAQS, therefore we are not finalizing our proposed determination of attainment for the area as part of this notice.[3] Similarly, since April, the EPA has redesignated the Door County-Revised, WI area; the Ohio portion of the Cincinnati area; and, the Indiana portion of Louisville area to attainment for the 2015 ozone NAAQS based on attaining air quality for the period 2019–2021 and, therefore, we are not finalizing our proposed determinations of failure to attain and reclassifications for these areas or portions of redesignated areas.[4]

Separately, ten additional Marginal areas are not included in this action because they are being addressed in separate actions:

1. On July 14, 2022, the EPA proposed to find that the Butte County, Calaveras County, San Luis Obispo (Eastern part), Sutter Buttes, Tuolumne County, and Tuscan Buttes areas in California attained by the attainment date (87 FR 42126).

2. On July 22, 2022, the EPA proposed to find that the Las Vegas, Nevada (NV) nonattainment area failed to attain by the attainment date. If this action is finalized as proposed, the Las Vegas, NV area will be reclassified as Moderate (87 FR 43764).

3. On August 15, 2022, the EPA proposed to find that the Imperial County, CA nonattainment area attained by the attainment date but for emissions emanating from outside the United States (87 FR 50030).

4. The EPA will be acting on the El Paso-Las Cruces, Texas-New Mexico nonattainment area in a separate action.

5. The EPA will be acting on the Detroit, MI nonattainment area in a separate action.

A summary of the actions proposed for the 28 areas covered by this final action is provided in Table 1 of this action.

[1] *See* 87 FR 21842 (April 13, 2022).

[2] *See* CAA section 181(b)(2)(A).

[3] The Manitowoc County area was redesignated to attainment for the 2015 ozone NAAQS effective March 31, 2022 (87 FR 18702, March 31, 2022).

[4] Final redesignation actions for these areas were effective upon publication in the **Federal Register:** Door County-Revised, WI area (87 FR 25410, April 29, 2022); the Ohio portion of the Cincinnati, OH-KY area (87 FR 35104, June 9, 2022); and the Indiana portion of Louisville, KY-IN area (87 FR 37950, July 5, 2022).

TABLE 1—2015 OZONE NAAQS MARGINAL NONATTAINMENT AREA PROPOSED ACTION SUMMARY

2015 NAAQS nonattainment area	2018–2020 design value (DV) (ppm)	2015 NAAQS attained by the Marginal attainment date	2020 4th highest daily maximum 8-hr average (ppm)	Area failed to attain 2015 NAAQS but state requested 1-year attainment date extension based on 2020 4th highest daily maximum 8-hr average ≤0.070 ppm
Allegan County, MI	0.073	Failed to Attain	0.076	No.
Amador County, CA	0.069	Attained	Not applicable	Not applicable.
Atlanta, GA *	0.070	Attained	Not applicable	Not applicable.
Baltimore, MD	0.072	Failed to Attain	0.069	No.
Berrien County, MI	0.072	Failed to Attain	0.078	No.
Chicago, IL-IN-WI	0.077	Failed to Attain	0.079	No.
Cincinnati, OH-KY **	0.074	Failed to Attain	0.071	No.
Cleveland, OH	0.074	Failed to Attain	0.075	No.
Dallas-Fort Worth, TX	0.076	Failed to Attain	0.077	No.
Denver Metro/North Front Range, CO	0.081	Failed to Attain	0.087	No.
Greater Connecticut, CT	0.073	Failed to Attain	0.071	No.
Houston-Galveston-Brazoria, TX	0.079	Failed to Attain	0.075	No.
Louisville, KY-IN ***	0.072	Failed to Attain	0.071	No.
Mariposa County, CA	0.079	Failed to Attain	0.091	No.
Milwaukee, WI	0.071	Failed to Attain	0.077	No.
Muskegon County, MI	0.076	Failed to Attain	0.080	No.
Northern Wasatch Front, UT ****	0.077	Failed to Attain	0.080	No.
Pechanga Band of Luiseño Mission Indians *****	0.078	Failed to Attain	0.084	No.
Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE	0.074	Failed to Attain	0.071	No.
Phoenix-Mesa, AZ	0.079	Failed to Attain	0.087	No.
San Antonio, TX ******	0.072	Failed to Attain	0.074	No.
San Francisco Bay, CA	0.069	Attained	Not applicable	Not applicable.
Sheboygan County, WI	0.075	Failed to Attain	0.076	No.
Southern Wasatch Front, UT	0.069	Attained	Not applicable	Not applicable.
St. Louis, MO-IL	0.071	Failed to Attain	0.074	No.
Uinta Basin, UT	0.076	Failed to Attain	0.066	Yes.
Washington, DC-MD-VA	0.071	Failed to Attain	0.065	No.
Yuma, AZ	0.068	Attained	Not applicable	Not applicable.

* On August 26, 2022, the EPA proposed to redesignate the Atlanta, GA area to attainment for the 2015 ozone NAAQS (87 FR 52487).
** Ohio portion of area redesignated to attainment (87 FR 35104, June 9, 2022).
*** Indiana portion of area redesignated to attainment (87 FR 39750, July 5, 2022).
**** On May 28, 2021, the state of Utah submitted a CAA section 179B demonstration for the Northern Wasatch Front nonattainment area, which EPA found does not meet the criteria for such a demonstration.
***** Concentrations listed are for the Temecula monitor (AQS ID 06–065–0016); quality assurance issues with the data from the Pechanga monitor resulted in the 2018 data year not being appropriate for comparison to the NAAQS, and an invalid 2020 DV per DV calculation requirements contained in 40 CFR part 50, Appendix U, section 4(b). Ozone data collected at the Temecula monitoring site was used in previous regulatory actions and deemed representative of ozone conditions on the Pechanga Reservation. *E.g.,* 80 FR 18120, April 3, 2015, at 18121–18122 (final rule redesignating the Pechanga air quality planning area from nonattainment to attainment for the 1997 ozone NAAQS).
****** On July 13, 2020, the state of Texas submitted a CAA section 179B demonstration for the San Antonio nonattainment area that the EPA found does not meet the criteria for such a demonstration.

B. Proposed International Transport and Requirements for CAA Section 179B

In the April 2022 proposal, the EPA proposed to disapprove the CAA section 179B demonstrations submitted by the states of Texas and Utah for the San Antonio, Texas, and Northern Wasatch Front, Utah, nonattainment areas, respectively. The EPA sought comment on its application of the statutory provisions in CAA section 179B to these submissions, consistent with the Agency recommendations in the CAA section 179B Guidance.[5]

[5] *See* ''Final Guidance on the Preparation of Clean Air Act Section 179B Demonstrations for Nonattainment Areas Affected by International Transport of Emissions'' available in the docket for this action.

C. Proposed Moderate Area SIP Submission and Controls Implementation Deadlines

In the April 2022 proposal, the EPA solicited comment on adjusting the due dates, in accordance with CAA section 182(i), for submission and implementation deadlines for all SIP requirements that apply to Moderate areas (*see* CAA sections 172(c)(1) and 182(a) and (b), and 40 CFR 51.1300 *et seq.*). Under CAA section 181(b)(2), Marginal nonattainment areas that fail to attain the 2015 ozone NAAQS by the applicable attainment date will be reclassified as Moderate by operation of law upon the effective date of the final determination. Each responsible state air agency must subsequently submit a SIP revision that satisfies the air quality planning requirements for a Moderate area under CAA section 182(b).

On August 3, 2018 (September 24, 2018, for the San Antonio area), when final nonattainment designations became effective for the 2015 ozone NAAQS, states responsible for areas initially classified as Moderate were required to prepare and submit SIP revisions by deadlines relative to that effective date. For those areas, the submission deadlines ranged from 2 to 3 years after the effective date of designation, depending on the SIP element required (*e.g.,* 2 years for the reasonably available control technology (RACT) SIP, 3 years for the attainment plan with reasonably available control measures (RACM) and attainment

demonstration, and 3 years for a Basic vehicle inspection and maintenance (I/M) program SIP if required). Areas initially classified as Moderate are also required to implement RACM and RACT as expeditiously as practicable but no later than January 1 of the 5th year after the effective date of designations, *i.e.,* January 1, 2023, with 2023 being the Moderate area attainment year (defined as the last calendar year prior to the applicable attainment date of August 3, 2024). Since those SIP submission dates have passed, the EPA proposed in its April 2022 proposal to apply the Administrator's discretion provided in CAA section 182(i) to adjust the Moderate area SIP due dates as well as certain implementation deadlines for newly reclassified areas. CAA section 182(i) requires that reclassified areas meet the applicable plan submission requirements ''according to the schedules prescribed in connection with such requirements, except that the Administrator may adjust any applicable deadlines (other than attainment dates) to the extent such adjustment is necessary or appropriate to assure consistency among the required submissions.''

1. Submission Deadlines for SIP Revisions

The EPA proposed to align the SIP submission deadlines for RACT and I/M with the proposed January 1, 2023, submission deadline for other Moderate area requirements, given the compressed timeline and the need to achieve consistency among those submissions as discussed previously. The EPA adopted this approach previously for Marginal areas reclassified as Moderate for failure to timely attain the 2008 ozone NAAQS, to achieve consistency among required SIP submissions for areas facing a similarly compressed timeframe between the effective date of reclassification and the Moderate area attainment date.[6] Similarly, with respect to the SIP submission deadline for I/M for the 2015 ozone NAAQS, we proposed a January 1, 2023, deadline consistent with the I/M regulations which provide that an I/M SIP shall be submitted no later than the deadline for submitting the area's attainment SIP.[7]

2. RACM and RACT Implementation Deadline

The EPA's implementing regulations for the 2015 ozone NAAQS require that, for areas initially classified as Moderate or higher, a state shall provide for implementation of RACT as expeditiously as practicable but no later than January 1 of the 5th year after the effective date of designation (*see* 40 CFR 51.1312(a)(3)(i)), which corresponds with the beginning of the attainment year for initially classified Moderate areas (*i.e.,* January 1, 2023). The modeling and attainment demonstration requirements for 2015 ozone NAAQS areas classified Moderate or higher require that a state must provide for implementation of all control measures needed for attainment no later than the beginning of the attainment year ozone season, notwithstanding any alternative deadline established per 40 CFR 51.1312 (*see* 40 CFR 51.1308(d)). For reclassified areas, the EPA's implementing regulations for the 2015 ozone NAAQS require that the state shall provide for implementation of RACT as expeditiously as practicable, but no later than the start of the attainment year ozone season associated with the area's new attainment deadline, or January 1 of the third year after the associated SIP submission deadline, whichever is earlier; or the deadline established by the Administrator in the final action issuing the area reclassification (*see* 40 CFR 51.1312(a)(3)(ii)).

The EPA requested comment on the proposed January 1, 2023, RACM/RACT implemented deadline. This proposed deadline is the same as the single RACT implementation deadline for all areas initially classified Moderate per 40 CFR 51.1312(a)(3) and would require implementation of any identified RACM/RACT as early as possible in the attainment year to influence an area's air quality and 2021–2023 attainment DV. The proposed RACT implementation deadline would also align with the proposed SIP submission deadline of January 1, 2023, and ensure that SIPs requiring control measures needed for attainment, including RACM, would be submitted no later than when those controls are required to be implemented. A single deadline for the Moderate area SIP submissions and RACT implementation would also treat states consistently, in keeping with CAA section 182(i).

3. I/M Implementation Deadline

For states that intend to use emission reductions from Basic I/M programs for the 2015 ozone NAAQS, the EPA proposed an implementation deadline of no later than the beginning of the applicable attainment year, *i.e.,* January 1, 2023. In the case, however, that a state does not intend to rely upon emission reductions from their I/M program in attainment or reasonable further progress (RFP) SIPs, the EPA proposed to allow these I/M programs to be fully implemented no later than 4 years after the effective date of reclassification. The EPA also requested comment on allowing any newly reclassified areas required to implement a Basic I/M program (but not needing I/M for attainment or RFP SIP purposes) to fully implement such a program by no later than the Moderate area attainment date of August 3, 2024 (September 24, 2024, for the San Antonio area) in order to align the I/M implementation deadline with that of the other required Moderate area elements.[8]

II. Responses to Comments and Final Actions

The public comment period for the EPA's April 2022 proposal closed on June 13, 2022, and included a public hearing held on May 9, 2022. The comments received during this period and the public hearing transcript can be found in the docket for this action. A majority of commenters supported the EPA's proposal to determine that certain areas failed to attain the 2015 ozone NAAQS by the applicable attainment date and to reclassify to Moderate the nonattaining areas that do not qualify for an attainment date extension. Our final actions are summarized in Table 2 of this action.

[6] ''Final Rule—Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Several Areas for the 2008 Ozone National Ambient Air Quality Standards'' (81 FR 26697, 26705, May 4, 2016).

[7] 40 CFR 51.372(b)(2). See the April 2022 proposal for more background information on I/M SIP requirements (87 FR 21852–21855).

[8] *See* 87 FR 21842, 21856 (April 13, 2022).

TABLE 2—2015 OZONE MARGINAL NONATTAINMENT AREA FINAL ACTION SUMMARY

2015 NAAQS nonattainment area	Attained by the attainment date	Failed to attain by the attainment date	Extension of the marginal area attainment date to August 3, 2022
Allegan County, MI		X	
Amador County, CA	X		
Atlanta, GA	X		
Baltimore, MD		X	
Berrien County, MI		X	
Chicago, IL-IN-WI		X	
Cincinnati, OH-KY (KY portion)		X	
Cleveland, OH		X	
Dallas-Fort Worth, TX		X	
Denver Metro/North Front Range, CO		X	
Greater Connecticut, CT		X	
Houston-Galveston-Brazoria, TX		X	
Louisville, KY-IN (KY portion)		X	
Mariposa County, CA		X	
Milwaukee, WI		X	
Muskegon County, MI		X	
Northern Wasatch Front, UT		X	
Pechanga Band of Luiseño Mission Indians		X	
Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE		X	
Phoenix-Mesa, AZ		X	
San Antonio, TX		X	
San Francisco Bay, CA	X		
Sheboygan County, WI		X	
Southern Wasatch Front, UT	X		
St. Louis, MO-IL		X	
Uinta Basin, UT			X
Washington, DC-MD-VA		X	
Yuma, AZ	X		

The EPA is responding to certain key comments in this section of the preamble. The remaining comments and EPA's responses can be found in the Response to Comments document, which is found in the docket for this rulemaking. To access the Response to Comments document, please go to *http://www.regulations.gov,* and search for Docket No. EPA–HQ–OAR–2021–0742, or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

A. Determinations of Attainment by the Attainment Date

Pursuant to section 181(b)(2)(A) of the CAA and 40 CFR 51.1303 and after considering comments received, the EPA is making final determinations that the Atlanta, GA; Southern Wasatch Front, UT; Amador County, CA; San Francisco Bay, CA; and Yuma, AZ Marginal nonattainment areas listed in Table 2 attained the 2015 ozone NAAQS by the applicable attainment date of August 3, 2021. Once effective, this final action satisfies the EPA's obligation pursuant to CAA section 181(b)(2)(A) to determine, based on an area's air quality as of the attainment date, whether the area attained the standard by the applicable attainment date. The effect of a final determination of attainment by an area's attainment date is to discharge the EPA's obligation under CAA section 181(b)(2)(A) with respect to that attainment date, and to establish that, in accordance with CAA section 181(b)(2)(A), the area will not be reclassified for failure to attain by the applicable attainment date.

These determinations of attainment do not constitute a redesignation to attainment as provided for under CAA section 107(d)(3). The EPA may redesignate an area if the state meets additional statutory criteria, including the EPA approval of a state plan demonstrating maintenance of the air quality standard for 10 years after redesignation, as required under CAA section 175A. As for all NAAQS, the EPA is committed to working with states that choose to submit redesignation requests for areas that are attaining the 2015 ozone NAAQS.

The EPA received adverse comments on our proposed determination of attainment for the Atlanta area, which are addressed as follows. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to Comments document in the docket for this action.

Comment: One commenter stated that the EPA is proposing to determine the Atlanta area as having attained the standard based on its 2019–2021 DV, which the commenter states are exactly at 70 parts per billion (ppb). The commenter claimed that the years of 2020 and 2021 were characterized by the unusual and unique events related to the COVID–19 epidemic (including significant reductions in traffic) which the commenter states could have significantly influenced the ozone levels in the region. The commenter also stated that another factor ''potentially skewing the averaging is the likely removal of high ozone days via claims of exceptional events due to the large number of fires in the western states in 2020, which was among the top five years with largest wildfire acreage burned since 1960.'' The commenter concluded by asking the EPA to ''redesignate the Atlanta metro area as a Moderate NAA [nonattainment area] for the 2015 standard.''

Response: CAA section 181(b)(2)(A) requires that the EPA determine whether an area attained by the attainment date ''based on the area's design value [DV] (as of the attainment date).'' The DV, as defined and explained in 40 CFR part 50, Appendix U, refers to the metric that is used to compare ambient ozone concentration data measured at a site in order to

determine compliance with the NAAQS. Per 40 CFR 50.19, the 2015 ozone NAAQS is met when the 3-year DV is less than or equal to 70 ppb (*i.e.,* 0.070 ppm). Per the CAA and EPA's regulations, the Atlanta area's DV for the relevant time period (*i.e.,* the 2018–2020 DV, for an attainment date in 2021) meets the level of the NAAQS, and the area therefore attained by its applicable attainment date.

We also note that even though the recorded DV for the 2018–2020 period is at 0.070 ppm, an area's DV is determined by the monitor with the highest monitored reading. While one monitor in the Atlanta area recorded a 2018–2020 DV of 0.070 ppm, the remaining monitors in the area showed 2018–2020 DVs below 0.070 ppm. More recent data indicate that for the period 2019–2021, the DVs at all of the Atlanta area monitors are below 0.070 ppm; the highest 2019–2021 DV value for the Atlanta Area is 0.068 ppm.[9] To the extent that events related to the COVID–19 pandemic may have ''significantly influenced the ozone levels in the region,'' the EPA did not consider such events in this determination of attainment action, which is based solely on an area's monitored air quality as of the applicable attainment date.

Regarding the commenter's statement that another factor ''potentially skewing the averaging is the likely removal of high ozone days via claims of exceptional events due to the large number of fires in the western states in 2020,'' the EPA has not received an exceptional events request related to ozone data for the Atlanta area. In order for the EPA to exclude particular periods of ozone monitoring data from consideration in calculating DVs, the EPA would have to concur on an exceptional events demonstration from Georgia. The EPA has not excluded any ozone data from monitors in the Atlanta area via claims of exceptional events during the 2018–2020 period.

Finally, the EPA assumes the commenter is asking the EPA to reclassify (not redesignate) the Atlanta area to Moderate. However, based on certified 2018–2020 monitored air quality data, because EPA is determining that the Atlanta area attained the 2015 ozone NAAQS by the required August 3, 2021, attainment date, the EPA does not have the authority under the CAA to reclassify the Atlanta area to Moderate for the 2015 ozone NAAQS, unless the area were to voluntarily request that reclassification under CAA section 181(b)(3).

[9] *See https://www.epa.gov/aqs.*

B. Extension of the Marginal Area Attainment Date

Pursuant to CAA section 181(a)(5) and 40 CFR 51.1307 and after considering comments received, the EPA is finalizing its proposal to grant the Utah Division of Air Quality's (UDAQ) request to extend the attainment date for the Uinta Basin Marginal area by one year from August 3, 2021, to August 3, 2022.[10] In a letter dated May 25, 2021, the Ute Indian Tribe also requested an attainment date extension for the area.[11] Section 181(a)(5) of the CAA provides the EPA the discretion (*i.e.,* ''the Administrator may'') to extend an area's applicable attainment date by one additional year upon application by any state if the state meets the two criteria under CAA section 181(a)(5) as interpreted by the EPA in 40 CFR 51.1307; specifically, that a state can certify compliance with the applicable SIP and can demonstrate that, for the first attainment date extension, an area's fourth highest daily maximum 8-hour value for the attainment year does not exceed the level of the standard (0.070 ppm). In proposing to grant a first attainment date extension for the Uinta Basin area, we considered additional facts and circumstances, such as air quality trends and the existing pollution burden in the area, and found that the additional information did not weigh against our proposal to grant UDAQ's request.[12]

The EPA received favorable and adverse comments on its proposal to grant the 1-year attainment date extension for the Uinta Basin area, which are addressed as follows. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to Comments document in the docket for this action.

Comment: One commenter supported the EPA's proposal to grant the 1-year attainment date extension for the Uinta Basin area, stating that the area fully met the statutory criteria for the first one-year extension. The commenter also noted that the area fully meets the statutory criteria for a second one-year extension requested by UDAQ and supported by the Ute Indian Tribe, and may attain the 2015 ozone NAAQS with its 2020–2022 DV. Further, while they appreciated there may be circumstances where a regulatory decision may include EJ considerations, the commenter emphasized their hope that future decisions on the second attainment date extension and potential redesignation for the Uinta Basin area follow only the ''clear'' requirements set out in the CAA.

Response: The EPA agrees that UDAQ's request for a first attainment date extension for the Uinta Basin area met the two qualifying criteria under CAA section 181(a)(5) as interpreted by the EPA in 40 CFR 51.1307. The status of, and the EPA's future action on, a UDAQ request for a second extension are outside the scope of this final action; however, we acknowledge that that the fourth highest daily maximum 8-hour value for 2021 would allow it to meet one of the necessary criteria to qualify for a second attainment date extension.[13] We also agree that the Uinta Basin area could potentially attain the 2015 ozone standard by a second extended attainment date (August 3, 2023) if the fourth highest daily maximum 8-hour average concentration for 2022 remains consistent with the final values for 2020 (0.066 ppm), 0.072 ppm (2021) and, *e.g.,* 0.066 ppm (2022 preliminary) that, when averaged with the 2020 and 2021 values, would result in an attaining 2020–2022 DV of 0.068 ppm.

The EPA disagrees that the Agency's decision to consider relevant information in exercising its discretion under a statutory provision is in any way in contravention of the ''clear'' requirements set out in the CAA. The requirement at issue in the CAA directs the Administrator to exercise discretion, establishing two minimum criteria that must be met before a request for an attainment date extension *may* be granted. Therefore, the ''clear'' requirement in the Act is for the Administrator to exercise judgment, and that exercising of judgment must, as always, be reasonable and based on relevant facts and factors. The ultimate goal of Part D of the CAA, which governs planning requirements for nonattainment areas, and the responsibility of states and the EPA

[10] Bird, Bryce, Director, UDAQ. ''Request for One-year Extension of the 2015 Ozone National Ambient Air Quality Standard Attainment Date for the Uinta Basin Marginal Nonattainment Area.'' March 29, 2021.

[11] Chapoose, Shaun, Chairman, Ute Indian Tribe Business Committee. ''Request for One Year Extension of the 2015 Ozone National Ambient Air Quality Standard Attainment Date for the Uinta Basin Marginal Nonattainment Area.'' May 25, 2021.

[12] *See* 87 FR 21842, 21848, April 13, 2022.

[13] The Uinta Basin area's 2021 fourth highest daily maximum 8-hour value was 0.072 ppm, available at *https://www.epa.gov/outdoor-air-quality-data/download-daily-data.* To qualify for a second 1-year extension, an area's fourth highest daily maximum 8-hour value, averaged over both the original attainment year and the first extension year, must be 0.070 ppm or less (40 CFR 51.1307(a)(2)). The fourth highest daily maximum 8-hour value, averaged over 2020 (0.066 ppm) and 2021 (0.072 ppm), is 0.069 ppm.

under that section of the Act, is to drive progress in nonattainment areas towards attainment of the NAAQS in order to protect public health, and to attain the NAAQS as expeditiously as practicable but by no later than the attainment dates prescribed by the Act.[14] CAA section 181(a)(5) in particular is intended to provide flexibility where an area is close to achieving attainment and can likely do so with a bit more time.

It is therefore reasonable, in exercising discretion under CAA section 181(a)(5), for the EPA to consider facts and circumstances that are directly relevant to this inquiry, including what current air quality data indicate about the likelihood of timely attainment in the area, or likelihood of eligibility for a second extension, and what the existing public health burden is in the area that would be impacted by the EPA's decision. The EPA also took note of the source categories and unique conditions leading to elevated ozone concentrations in the Uinta Basin area, and the anticipated emission reductions that had the potential to have a significant impact on ozone concentrations in the area in the near future. To the extent that the commenter is asserting that the EPA should interpret CAA section 181(a)(5) to mean that the EPA *must* grant a state's request for an extension if the two criteria are met, we do not agree. The Act says ''may,'' and that word has meaning.

Comment: Three commenters opposed the proposed attainment date extension for the Uinta Basin area. Two of the commenters contended that the extension should not be granted because the area would not be able to attain by the extended August 3, 2022, attainment date based on the 2019–2021 DV of 0.078 ppm and a fourth highest daily maximum value of 0.072 ppm in 2021, and that granting the request would delay implementation of needed Moderate area controls. One of the commenters added that the EPA should not grant the extension request because doing so would not be based on an identifiable trend toward cleaner air, documented reductions in the emissions of ozone precursors, or enforceable controls shown to achieve attainment. Further, they claimed that the Uinta Basin area attaining the 2015 ozone NAAQS by a second extended attainment date (*i.e.,* August 3, 2023) would not demonstrate that ozone concentrations in the area will remain low based on concrete emission reductions or air quality trends that showed consistent progress toward attainment, but rather because the 2020–2022 DV would no longer include the 2019 fourth highest daily maximum value of 0.098 ppm. Finally, a third commenter stated that all 1-year extensions should be denied due to the adverse health impacts of ozone.

Response: The EPA disagrees with the commenters. CAA section 181(a)(5) is intended to provide flexibility where an area is close to achieving attainment and can likely do so with a bit more time. Rather than require an area to attain the NAAQS by a first extended attainment date, the provision expressly allows for a maximum of two 1-year extensions for a single area. Not being able to possibly attain by a second extended attainment date would weigh against the EPA granting a first extension request. That is not the case for the Uinta Basin area, where air quality data indicate that the area can meet the necessary air quality criterion for a second 1-year extension and could potentially attain the 2015 ozone NAAQS by the second extended attainment date of August 3, 2023. Attainment in 2023 would be based on the area's 2020–2022 DV, which would necessarily exclude 2019 air quality data and represent a 3-year air quality trend preceding the extended attainment date. In our proposal to grant UDAQ's extension request, we also considered the proposed Federal Implementation Plan (FIP) for Managing Emissions from Oil and Natural Gas Sources on Indian Country Lands within the Uintah and Ouray (U&O) Indian Reservation in Utah (U&O FIP), which the EPA is working to finalize.[15] We anticipate that the new control requirements in the final U&O FIP could make a meaningful improvement in air quality and address periodic winter ozone exceedances on the reservation, and in the nonattainment area and larger Uinta Basin region.

The types of considerations raised by the commenters—documented reductions in emissions of ozone precursors and demonstrations that enforceable controls achieved attainment—are relevant inquiries for states that are seeking redesignations to attainment. *See* CAA section 107(d)(3)(E)(iii). By contrast, the CAA mandates that the EPA determine whether an area attained the NAAQS solely on the basis of the area's DV as of the attainment date, CAA section 181(b)(2)(A), and does not permit the EPA to consider in making that determination how the area attained or whether the area will continue to attain in making that determination. Therefore, we decline to consider these factors in determining whether to grant Utah's request for an attainment date extension for the Uinta Basin area.

C. Determinations of Failure To Attain and Reclassification

Pursuant to CAA section 181(b)(2) and after considering comments received, the EPA is finalizing the proposed determinations for 22 Marginal nonattainment areas or portions of areas listed in Table 2 that failed to attain the 2015 ozone NAAQS by the applicable attainment date of August 3, 2021. Therefore, upon the effective date of this final action, these 22 areas or portions of areas will be reclassified, by operation of law, to Moderate for the 2015 ozone NAAQS. Once reclassified as Moderate, these areas will be required to attain the standard ''as expeditiously as practicable'' but no later than 6 years after the initial designation as nonattainment, which in this case would be no later than August 3, 2024. If any of these areas attains the 2015 ozone NAAQS prior to the Moderate area attainment date, the relevant state may request redesignation to attainment, provided the state can demonstrate at a minimum that the other criteria under CAA section 107(d)(3)(E) are met.[16]

The EPA received adverse comments on its proposal to determine that certain areas failed to attain by the applicable attainment date and to reclassify those areas as Moderate, which are addressed as follows. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to

[14] *See, e.g.* CAA section 171(1) (defining reasonable further progress as annual incremental reductions in emissions of the relevant air pollutant . . . for the purpose of ensuring attainment of the applicable [NAAQS] by the applicable date''); CAA section 172(a)(2)(A) (establishing attainment dates for the primary NAAQS as ''the date by which attainment can be achieved as expeditiously as practicable, but no later than 5 years from the date such area was designated nonattainment under [107(d)] of this title . . .''); CAA section 172(c)(1) (requiring implementation of all reasonably available control measures as expeditiously as practicable and that plans provide for attainment of the NAAQS); CAA section 172(c)(6) (requiring state plans to include enforceable emission limitations, and such other control measures, means or techniques, as well as schedules and timetables for compliance, as may be necessary or appropriate to provide for attainment of the NAAQS by the applicable attainment date).

[15] ''Proposed Rule: Federal Implementation Plan for Managing Emissions From Oil and Natural Gas Sources on Indian Country Lands Within the Uintah and Ouray Indian Reservation in Utah'' (85 FR 3492, January 21, 2020), as discussed at 87 FR 21842, 21848 (April 13, 2022).

[16] More information about redesignation is available at *https://www.epa.gov/ground-level-ozone-pollution/redesignation-and-clean-data-policy-cdp.*

Comments document in the docket for this action.

Comment: One commenter opposed the proposed reclassification of the Denver Metro/North Front Range, CO area to Moderate, citing extensive existing state regulations, prior emissions reductions, adverse effects of the reclassification (permitting burdens, economic impacts, costs that outweigh benefits), and the role of wildfires/exceptional events and international transport.

Response: The EPA disagrees with the assertion that the Denver area should not be reclassified as Moderate. The EPA has a mandatory duty under CAA section 181(b)(2)(A) to determine whether the Denver area attained by its August 3, 2021, attainment date, based on the area's design value as of the attainment date. The CAA does not allow the EPA to consider permitting, economic, or cost impacts in assessing whether an area has attained the NAAQS by the applicable date. Instead, CAA section 181(b)(2) requires the EPA to make the determination of attainment based solely on the area's DV, which is derived entirely from monitored air quality data.

Comment: One commenter opposed the EPA's proposal to reclassify the Wisconsin nonattainment areas from Marginal to Moderate. The commenter noted that Wisconsin's lakeshore air quality is heavily impacted by ozone precursors originating from upwind states and asserted that further actions taken by Wisconsin to address Moderate area planning requirements are unlikely to significantly improve air quality in Kenosha County (part of the Chicago area), Sheboygan County, or Milwaukee areas.

Response: CAA section 181(b)(2) requires the EPA to determine, based on an area's ozone design value as of the area's attainment deadline, whether the area has attained the ozone standard by that date. The CAA also requires that any area that the EPA finds has not attained the standard by the attainment deadline shall be reclassified by operation of law to the higher of the next ''highest'' classification (*e.g.,* Marginal to Moderate, Moderate to Serious, etc.) or the classification applicable to the area's DV. Further, the Agency's mandatory duty to make determinations of attainment or failure to attain the NAAQS exists regardless of the nature or effect of transported ozone on monitored air quality in a given nonattainment area. *Cf. Sierra Club* v. *EPA,* 294 F.3d 155 (D.C. Cir. 2002) (rejecting the EPA's decision not to reclassify a downwind nonattainment area that failed to timely attain due to transported pollution from upwind states).

Under EPA regulations at 40 CFR part 50, appendix U, the 2015 ozone NAAQS is attained at a monitoring site when the three-year average of the annual fourth-highest daily maximum eight-hour average ozone concentration (*i.e.,* the DV) is less than or equal to 0.070 ppm. When the DV is less than or equal to 0.070 ppm at each ambient air quality monitoring site within the area, the area is deemed to be meeting the NAAQS. If the DV is greater than 0.070 ppm at any site in the area, the area is deemed to be violating the NAAQS. Because monitoring sites in the Chicago, Sheboygan County and Milwaukee areas have DVs of 0.079 ppm, 0.077 ppm, and 0.076 ppm, respectively, for the 2018–2020 period, the EPA must determine that the areas failed to attain the standard by the August 3, 2021, Marginal attainment deadline and reclassify the areas as Moderate as required by section 181(b)(2) of the CAA.

D. International Transport and Requirements for CAA Section 179B

The EPA is finalizing the proposed disapprovals of the CAA section 179B demonstrations submitted by the states of Texas and Utah for the San Antonio, Texas, and Northern Wasatch Front, Utah, nonattainment areas, respectively. The EPA interprets CAA section 179B to provide the EPA with authority to consider impacts from international emissions in two contexts: (1) A ''prospective'' state demonstration submitted as part of an attainment plan, which the EPA considers when determining whether the SIP submission adequately demonstrates that a nonattainment area will attain the NAAQS by its future attainment date (*see* CAA section 179B(a)), but for emissions emanating from outside of the United States (*i.e.,* international transport); or (2) a ''retrospective'' state demonstration, which the EPA considers when determining after the attainment date whether a nonattainment area attained the NAAQS by the attainment date or would have attained but for international transport (*see* CAA section 179B(b)–(d)). Any State that establishes to the satisfaction of the Administrator that an area *would have attained* the national ambient air quality standard by the applicable attainment date but for emissions emanating from outside of the United States shall not be subject to reclassification to a higher classification category. The EPA interprets the statute to require states to meet all nonattainment area requirements applicable for the relevant NAAQS and area classification, regardless of any CAA section 179B submission. The EPA provides examples and describes the kinds of information and analyses that are relevant to this issue to assist air agencies better understand how to satisfy the requirements of CAA section 179B in the ''Guidance on the Preparation of Clean Air Act Section 179B Demonstrations for Nonattainment Areas Affected by International Transport of Emissions'' (CAA Section 179B Guidance).[17] The guidance also describes the weight of evidence approach that the EPA uses when evaluating CAA section 179B demonstrations.

The EPA received adverse comments on our proposed disapprovals of the CAA section 179B demonstrations from Texas and Utah, which are addressed as follows. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to Comments document in the docket for this action.

Comment: One commenter disagreed with EPA's authority to consider impacts from international emissions in two contexts, prospective or retrospective. The commenter disagreed that the state should have considered a ''retrospective'' demonstration under CAA section 179B(b) to address reclassification. The commenter asserted that CAA section 179B(a) was written to cover any NAAQS, and that CAA sections 179B(b-d) were written to clarify that any CAA section 179B demonstration would also provide relief to reclassifications that only apply to ozone, carbon monoxide and particulate matter (PM_{10}). In essence, the commenter argued that a state can seek to avoid reclassification for failure to attain the NAAQS by the attainment date under CAA section 179B(b) at any time, and EPA need not wait for the facts and analysis to evaluate the impacts of international transport until the attainment date actually occurs.

Response: The EPA disagrees with the commenter's interpretation that a single demonstration would be adequate to obtain the specific and differing regulatory relief described in CAA section 179B(a) (relief from the attainment demonstration requirement) and CAA sections 179B(b-d) (relief from

[17] ''Guidance on the Preparation of Clean Air Act Section 179B Demonstrations for Nonattainment Areas Affected by International Transport of Emissions'' issued on December 18, 2020; available at *https://www.epa.gov/sites/default/files/2020-12/documents/final_caa_179b_guidance_december_2020_with_disclaimer_ogc.pdf.* The EPA also issued a related notice of availability in the **Federal Register** on January 7, 2021 (86 FR 1107).

the reclassification requirement). The EPA submitted comments to the Texas Commission on Environmental Quality on the Bexar County (San Antonio), Texas CAA section 179B proposal, echoing the CAA section 179B language and the interpretations expressed in EPA's December 2019 draft guidance, describing how the State's proposed ''prospective'' demonstration (addressing the standard laid out in CAA section 179B(a) and focusing on data available to the State in 2019) would not provide the San Antonio area relief from failing to meet its attainment deadline. The EPA indicated that the State should develop a ''retrospective'' demonstration under CAA section 179B(b) if seeking relief from the reclassification requirement.

As stated in the April 2022 proposal and EPA's final CAA Section 179B Guidance, both the distinct language in CAA sections 179B(a) and 179B(b) and the different regulatory relief those two sections grant support EPA's interpretation that different types of demonstrations are needed for areas seeking the different forms of relief. For a state that is required to submit an attainment plan demonstrating that a nonattainment area will attain by the applicable attainment date, CAA section 179B(a) allows the state to submit, and the Administrator to assess, a demonstration that such a plan ''would be adequate to attain'' the NAAQS by the attainment date, but for international transport. For a nonattainment area that has not attained the NAAQS by the attainment date, and thus is facing reclassification to a higher classification level, CAA section 179B(b) allows the state to submit, and the Administrator to assess, a demonstration that the area ''would have attained'' the NAAQS by the attainment date, but for international transport. For a state to gain this latter type of relief, the EPA believes it is reasonable to require that the state include in its demonstration emissions and air quality data from the 3 years preceding the attainment date, along with analyses of the amount and nature of impacts attributed to international transport that actually occurred during that same relevant period of time.

Comment: A few commenters asserted that the term ''but for'' under CAA section 179B is not defined and disagreed with the EPA's interpretation of that term and requirements for CAA section 179B. A commenter asserted that its CAA section 179B demonstration should not have to show that international anthropogenic emissions solely or primarily cause exceedances. A few commenters indicated that any impact of international emissions should be enough for an approvable demonstration. One commenter claimed that the EPA has imposed arbitrary hurdles on the Northern Wasatch Front nonattainment area to achieve a successful CAA section 179B demonstration. The commenter alleged that the EPA's requirements are not supported by the statute and are outside of Congress's intent. Furthermore, the commenter stated that the EPA's argument for disapproving Utah's demonstration is inappropriate in finding that ozone exceedance days ''are predominantly due to local contributions.'' In addition, they stated that the EPA should find that a 10–15 percent contribution from international sources to local ozone in the Northern Wasatch Front meets the CAA ''but for'' criteria. The commenter disagreed that only sources causing peak ozone concentrations should matter in the CAA section 179B evaluation. The commenter also stated that although the CAA establishes the ''but for'' test, the statute makes no differentiation between base contributions or peak contributions. The commenter claimed that by the EPA considering whether international contributions are greater on exceedance days than on non-exceedance days, the EPA suggests that the influence of international emissions on Northern Wasatch Front ozone must be event-based rather than continuous and the commenter states that this line of reasoning is inconsistent with the scientific literature cited by the EPA. The commenter also asserted that the EPA is inappropriately requiring a large international contribution relative to the domestic contribution for a valid CAA section 179B demonstration and referenced the EPA's response to comment for the CAA Section 179B Guidance to support the argument that the EPA did not intend this to be a requirement at the time of the issuance of the Guidance.[18]

Response: The EPA disagrees with the commenters concerning the appropriate application of CAA section 179B, and in particular the appropriate interpretation of the term ''but for'' in this specific context. As acknowledged by the commenters, CAA section 179B is notably silent on the definition of ''but for.'' Specifically, the statute does not define ''but for,'' nor does it define what criteria the EPA should use to evaluate whether a state has demonstrated the relevant statutory criteria to the ''satisfaction of the Administrator.'' Given the ambiguous statutory text, the EPA has authority to interpret the term ''but for'' in the way most consistent with the purpose of CAA section 179B. Given the statute's explicit inclusion of the phrase ''to the satisfaction of the Administrator,'' the EPA concludes that this can entail what the Agency considers relevant for this type of demonstration. For example, the EPA reasonably interprets the language in CAA section 179B to authorize it to differentiate between base and peak contributions in exercising its technical judgment in assessing CAA section 179B demonstrations made by states. This distinction is very relevant when determining the degree to which international transport affects ambient pollutant levels during periods that are relevant to determining attainment. The commenter intimated that when ambient concentrations minus modeled international contributions are less than the level of the NAAQS, the state should automatically receive CAA section 179B relief. The EPA does not agree with this ''simple subtraction'' interpretation of ''but for,'' which would ignore the complex nature of ozone sources and transport, as well as the multitude of analysis methods and tools which states and the EPA may use to evaluate and characterize sources impacting ozone concentrations at violating monitors. In addition, this simplistic interpretation of ''but for'' would in effect functionally raise the level of the NAAQS in all areas of the country for which states claim that there is international transport, regardless of what any other facts or analyses would indicate about the nature and impacts of such transport.[19] Given the statutory directive to the EPA to promulgate NAAQS that are adequately protective of public health with an ample margin of safety, the EPA does not consider a ''simple subtraction'' approach to be appropriate.[20] Rather, the EPA has

[18] ''Review Of Draft CAA Section 179B Guidance On International Emissions,'' CAA Section 179B Guidance Briefing for OMB; September 16, 2020; p. 2; attachment to email dated November 18, 2020, from Gobeail McKinley to Elke L. Hodson Marten transmitting responses to interagency comments on the CAA Section 179B Guidance Document; located in Docket Number EPA–HQ–OAR–2019–0668 at *regulations.gov* (accessed on June 9, 2022) (''Response to Comment'').

[19] Given that international emissions contribute some amount to background ozone across all locations in the US and that this fact was understood when the 179B provision of the CAA was written, a ''simple subtraction'' interpretation would be akin to adding the ozone increment associated with the typical international contribution to the level of the NAAQS.

[20] The EPA considers background ozone when setting the NAAQS. (80 FR 65291, October 26, 2015) The EPA is aware that international emissions contribute partially to background ozone

Continued

provided the CAA section 179B Guidance to give recommendations for a more comprehensive weight of evidence approach, which states and EPA should use to evaluate international emissions contributions at violating ozone monitors.

As we stated in the proposal, ''[g]iven the extensive number of technical factors and meteorological conditions that can affect international transport of air pollution, EPA relies on the weight of evidence of all information and analyses provided by the air agency. The appropriate level of supporting documentation will vary on a case-by-case basis, depending on the nature and severity of international influence. EPA considers and qualitatively weighs all evidence based on its relevance to CAA section 179B and the nature of international contributions as described in the demonstration's conceptual model. Every demonstration should include fact-specific analyses tailored to the nonattainment area in question. When a CAA section 179B demonstration shows that international contributions are larger than domestic contributions, the weight of evidence will be more compelling than if the demonstration shows domestic contributions exceeding international contributions.'' [21]

Furthermore, as explained in the proposal, there are four characteristics that the EPA thinks indicate that an area needs a more involved weight of evidence showing: (1) Affected monitors not located near an international border; (2) Specific international sources and/or their contributing emissions are not identified or are difficult to identify; (3) Exceedances on internationally influenced days are in the range of typical exceedances attributable to local sources; and (4) Exceedances occurred in association with other processes and sources of pollutants, or on days where meteorological conditions were conducive to local pollutant formation (*e.g.,* for ozone, clear skies and elevated temperatures). The San Antonio and Northern Wasatch Front nonattainment areas meet all four of these characteristics suggesting the need for a comprehensive weight of evidence showing, including multiple lines of evidence to support a CAA section 179B demonstration in these areas. The EPA recognizes that no single analysis is sufficient to support or refute a CAA section 179B demonstration definitively. Therefore, the Agency utilized multiple lines of evidence in the proposed disapproval of the submitted CAA section 179B demonstrations, which, taken together, provided a consistent and coherent conceptual model that did not support a ''but for'' finding for these areas. The EPA disagrees that the analyses the Agency recommended in the CAA section 179B Guidance and the Agency relied upon in evaluation are arbitrary or not supported by the statute.

Further, the EPA's 179B Guidance indicated that a demonstration will be stronger when international contributions are shown to be greater on NAAQS exceedance days than on non-exceedance days. Inclusion of this information will make it easier to differentiate locally versus internationally driven exceedances. However, the above interpretation from the Section 179B Guidance should not be considered as requiring that international contributions be restricted to contributions from specific international transport events. Rather, the CAA section 179B Guidance and the April 2022 proposal point to the need for a more detailed demonstration in cases where international contributions are difficult to distinguish from US contributions, including when ''[e]xceedances on internationally influenced days are in the range of typical exceedances attributable to local sources.'' In addition, as part of a thorough evaluation of the impacts of international transport, the EPA considers it appropriate to focus on analyzing the contributions on the days that contribute to an area's NAAQS violation.

Comment: A commenter claimed that the EPA used one criterion (*i.e.,* whether feasible measures have been implemented) in the Northern Wasatch Front determination that the EPA had already rejected in a prior rulemaking [22] as not being part of a CAA section 179B demonstration.

Response: The EPA disagrees with this comment. The comment seems to conflate the requirement in CAA section 182(b)(2) that areas classified as Moderate and higher must show that they have implemented RACM/RACT with the EPA's statements in the proposal that Utah's demonstration would have been strengthened through a showing that the state had attempted to implement feasible controls. The EPA explained that the proposed disapproval of the CAA section 179B demonstration for the Wasatch area relied on multiple lines of evidence. As noted in the technical support document (TSD) for the proposed disapproval of this CAA section 179B demonstration, the state did not make a compelling demonstration that it has implemented controls to mitigate local emissions contributing to ozone levels on exceedance days. Because each nonattainment area is unique, the types of analyses that would be appropriate for any particular area depend on area-specific factors. The EPA considers the weight of available evidence in assessing a state's CAA section 179B demonstration. The EPA considered the fact that the state has not attempted to implement reasonable local controls along with information indicating whether ozone exceedances had occurred predominantly as a result of emissions from local sources versus international sources. Imposition of local control measures is not a prerequisite or requirement to a Marginal area's CAA section 179B(b) demonstration. However, consideration of whether feasible controls have been implemented in an area could be a significant factor relative to information characterizing the nature of contributions on exceedance days. Such control measure information is therefore helpful in considering to what extent local versus international emissions contributed to ozone exceedances in the Northern Wasatch Front.

Comment: A commenter stated that states would benefit from further clarification of the CAA Section 179B Guidance and a concerted effort from the EPA to codify its CAA section 179B(b) interpretation through rulemaking.

Response: This action is to fulfill our statutory obligation under CAA section 181 by determining whether 28 Marginal ozone nonattainment areas attained the 2015 ozone NAAQS by August 3, 2021, the applicable attainment date for such areas. As part of the final disapproval for the San Antonio and Northern Wasatch Front CAA section 179B demonstrations, this rulemaking action is intended to clarify EPA's interpretations of CAA section 179B and apply them to certain areas of the country through regulatory action. The EPA does not intend to initiate a public notice-and-comment rulemaking to codify the provisions of CAA section 179B at this time.

E. Moderate Area SIP Submission and Controls Implementation Deadlines

Pursuant to CAA section 182(i) and after considering comments received, the EPA is finalizing its proposed

across the United States. It is clear from the legislative history that Congress intended for CAA section 179B to be limited in scope for situations where international transport is a particular problem and not applicable to situations where international emissions are merely part of the normal background level.

[21] *See* 87 FR 21842, 21852 (April 13, 2022).

[22] *See* 83 FR 62998 (December 6, 2018).

deadlines for Moderate area SIP revisions, and implementation of RACM/RACT and Basic I/M programs for the 2015 ozone NAAQS. SIP revisions required for the newly reclassified Moderate areas must be submitted no later than January 1, 2023, and RACM/RACT for these areas must be implemented as expeditiously as practicable, but no later than the same date. We acknowledge that for some states with reclassified Moderate areas, meeting a January 1, 2023, SIP submission and RACM/RACT implementation deadline will be challenging. However, the options for establishing deadlines within the CAA framework of attainment timeframes and RACT implementation requirements are constrained. We also recognize there are ways to anticipate and manage the tight timeframes for SIP development and submission, such as advance planning based on preliminary area DVs. Also, a state may at any time request—and the EPA must grant—a voluntary reclassification under CAA section 181(b)(3). The EPA remains committed to working closely with affected states to help them prepare their SIP revisions in a timely manner.

For required Basic I/M programs, the EPA is finalizing an implementation deadline of no later than 4 years after the effective date of reclassification for states that do not intend to rely upon emission reductions from their Basic I/M program in attainment or RFP SIPs. As discussed in the April 2022 proposal, the EPA realizes that implementing a brand new or revised I/M program on an accelerated timeline may be difficult to achieve in practice, especially for states with no I/M programs elsewhere within their jurisdiction.

The EPA received adverse comments on our proposed deadlines, which are addressed as follows. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to Comments document in the docket for this action.

Comment: Regarding the proposed January 1, 2023, SIP submission deadline for reclassified Moderate areas, the EPA received comments stating that the deadline was unreasonable, and/or the resulting compressed timeframe provided insufficient time for SIP development, with some commenters also noting that the EPA's delayed rulemaking in this action has contributed to the planning burden on states. Two commenters observed that the proposed deadline would be less than 12 months from final area reclassifications, with one commenter contending the EPA has long held that one year from final reclassification was an appropriate SIP submission deadline, and both commenters referencing the previous determination and reclassification action for Moderate areas under the 2008 ozone NAAQS as an example. One other commenter requested a SIP submission deadline of May 1, 2023, and two other commenters requested that the EPA provide the same planning timeframes allowed for initially designated areas (*e.g.,* 2 years for RACT SIPs, 3 years for RFP and attainment demonstration SIPs). Two additional commenters did not request a specific deadline but were concerned that the proposed submission deadline was unachievable given the timing and time demands of state legislative processes, *e.g.,* the Colorado General Assembly does not convene until mid-January each year, and the Connecticut regulatory adoption process generally takes 10–12 months and requires the approval of a legislative committee.

Response: The EPA acknowledges the short planning timeframe available to states with newly reclassified Moderate areas, and that delays in this rulemaking have reduced the time between the effective date of final area reclassifications and the proposed January 1, 2023, deadlines for SIP submissions for these areas. We further acknowledge that the available timeframe here will present significant challenges for many states. But we believe that our approaches for establishing SIP submission deadlines in prior determination and reclassification actions were case-specific and, while informative, are not determinative of our final action here. Of potential alternatives, we maintain that the deadline established in this final action best provides for consistent treatment of states in submitting SIP revisions within the constraints of attainment timeframes and RACT requirements under the Act. Further, to the extent that commenters suggested that states are confined to initiating SIP development activities only after the EPA finalizes its attainment determinations and area reclassifications, we disagree, as there are proactive and voluntary pathways by which states can anticipate and manage the tight timeframes to develop required SIP revisions for reclassified nonattainment areas. The EPA addresses specific aspects of commenters' concerns as follows.

Responding to comments that the January 1, 2023, deadline for SIP submissions for reclassified Moderate areas is unreasonable and/or provides insufficient time for state planning activities, we look to the statutory framework and context underlying our legal and policy basis. Areas initially classified as Moderate under the 2015 ozone NAAQS were required to prepare and submit SIP revisions by deadlines relative to the effective date of the nonattainment designation (*i.e.,* August 3, 2018), which ranged from 2 to 3 years after the effective date of designation (*e.g.,* 2 years for the RACT SIP, and 3 years for the attainment plan with RACM and attainment demonstration). These SIP submission deadlines preceded the RACT implementation deadline (*i.e.,* as expeditiously as practicable but no later than January 1 of the 5th year after the effective date of designations) and have the practical effect of ensuring that SIPs requiring control measures needed for attainment, including RACM, would be submitted prior to when those controls are required to be implemented—in this case, no later than the beginning of the Moderate area attainment year. *i.e.,* January 1, 2023.

Section 181(b)(2)(A) of the CAA requires that within 6 months following the applicable attainment date, the EPA shall determine whether an ozone nonattainment area attained the ozone standard, and those areas that failed to attain and were not granted a 1-year attainment date extension are reclassified by operation of law. Although Congress did not articulate specific SIP submission deadlines for reclassified areas in the Act, it provided the EPA with authority under CAA section 182(i) to adjust any related deadlines for requirements under CAA sections 182(b) through (d) ''. . . to the extent such adjustment is necessary or appropriate to assure consistency among the required submissions.'' Explicitly excluded from CAA section 182(i) is authority to adjust attainment dates, *i.e.,* ''. . . the Administrator may adjust any applicable deadlines (other than attainment dates) . . .''.

The area classifications and attainment date framework established in Table 1 of CAA section 181(a)(1) and interpreted by 40 CFR 51.1303 inherently constrains the planning and implementation timeframe for reclassified areas, particularly at lower area classifications. The time increments between the Marginal and Moderate, and the Moderate and Serious area statutory attainment dates are only three years. These short timeframes are further constrained by the RACT implementation deadline for reclassified areas. Consistent with the RACT requirements of 40 CFR 51.1312(a)(3)(ii), the EPA proposed a RACT implementation deadline for

reclassified Moderate areas corresponding with the beginning of the Moderate area attainment year (*i.e.,* January 1, 2023). Aligning the RACT implementation and SIP submission deadline for reclassified areas ensures that SIPs requiring control measures needed for attainment, including RACM, are submitted no later than when those controls are required to be implemented.[23] The combination of constraints dictated by the statutory and regulatory requirements for reclassified ozone areas, particularly at the lower classifications, are a primary cause of the compressed timeframe for SIP development and implementation. Even if the EPA had published this final determination and reclassification action by the statutory due date (*i.e.,* February 3, 2022) with an effective date 30 days after (*i.e.,* approximately March 7, 2022) there still would be less than a year between the effective date and the SIP submission deadline of January 1, 2023. We recognize that many areas may face difficulty in meeting the submission and implementation deadlines in the final rule, but this approach is consistent with the CAA and our regulations, and given the competing considerations, is a reasonable exercise of the EPA's discretion under CAA section 182(i).

Two commenters observed that the proposed deadline would be less than 12 months from final area reclassifications, with one commenter asserting that the EPA has long held that an appropriate deadline for states with reclassified areas to submit required SIP revisions is one year from final reclassification. Both commenters referenced the EPA's August 2019 final determination action that reclassified certain areas from Moderate to Serious for the 2008 ozone NAAQS and established a SIP submission deadline in August 2020. While we acknowledge that the short timeframe for SIP submittal here will present significant challenges for many states, we disagree with the commenter's general assertion that establishing a one-year SIP submission timeframe is a ''long held'' approach for the EPA. To this end, we wish to note multiple instances of the EPA establishing a SIP submission deadline of less than one year from the effective date of the final determination and reclassification action, *e.g.,* for four reclassified Moderate areas under the 1997 8-hour ozone NAAQS. Final actions for the four reclassified Moderate areas—Imperial County, California; Atlanta, Georgia; Beaumont-Port Arthur, Texas; and Baton Rouge, Louisiana—established a SIP submission deadline corresponding with the beginning of the Moderate area attainment year (*i.e.,* December 31, 2008, or January 1, 2009) and approximately eight months from the final action effective date.[24] SIP revisions for reclassified Moderate and Serious areas under the 2008 ozone NAAQS were due approximately seven and ten months from the final action effective dates, respectively.[25]

The EPA acknowledges that the referenced determination and reclassification action for Moderate areas under the 2008 ozone NAAQS established a SIP submission deadline for reclassified Serious areas of approximately one year from the final action. In that instance, the SIP submission deadline (August 3, 2020) was approximately 11 months from the final action effective date (September 23, 2019). However, we consider the final action for reclassified Serious areas under the 2008 ozone NAAQS distinguishable from this current action because the EPA proposed a SIP submission deadline of 12 months from the final action effective date, but was persuaded by comments received to finalize an aligned deadline of August 3, 2020, which corresponded with the RACT SIP submission deadline for areas initially classified Moderate and higher for the 2015 ozone NAAQS. The EPA's rationale, pursuant to the authority of CAA section 182(i), was to provide for ''consistency among submissions'' due from a nonattainment area for more than one NAAQS, which could also allow states to save limited resources by consolidating two SIP submissions into a single submission.[26] That situation does not exist for this current action and, while previous determination and reclassification actions may be informative, the EPA considers them to be case-specific and not necessarily determinative of our final rule approach for reclassified Moderate areas under the 2015 ozone NAAQS. The timeframes for the prior actions discussed here, as for the present action, were informed by the attainment date, and the different submission deadlines necessarily considered the time between the establishing action and the applicable attainment date. This timeframe varies across actions, and we cannot here apply a longer timeframe from a previous action if it would not be allowed by the applicable attainment date for this action.

Several commenters requested that EPA establish a later SIP submission deadline for reclassified Moderate areas, with one commenter requesting a specific date of May 1, 2023, and two commenters requesting deadlines that would provide the same planning timeframes allowed for initially designated areas. Two additional commenters did not request a specific deadline but were concerned that the proposed submission deadline was unachievable given the timing and time demands of state legislative processes. As discussed previously, Congress did not articulate specific SIP submission deadlines for reclassified areas in the Act, and it required that states submit all SIP revisions for initially designated Moderate areas (including RACT and the attainment plan with RACM and attainment demonstration) before their RACT implementation deadline, which is as expeditiously as practicable but no later than January 1, 2023. Further, as discussed in the proposed action, the EPA does not find it appropriate to provide deadlines of 2 and 3 years from the effective date of a final action on this determination, as those deadlines would fall after the Moderate area attainment date of August 3, 2024.[27] The January 1, 2023, submission deadline for reclassified Moderate areas may not be compatible with some state legislative processes, but nowhere in Subpart 2 did Congress indicate that state legislative processes or calendars should dictate, or even factor into, deadlines for CAA NAAQS implementation. The EPA maintains that establishing the selected SIP submission deadline ensures consistent treatment of states, consistency among SIP submissions, and balances the other considerations relevant to ozone attainment planning such as attainment dates and existing regulatory requirements.

We acknowledge again that meeting this SIP submission deadline will be challenging for many states, and that delays in this rulemaking have reduced the time between the effective date of this final action and the deadline for submission and implementation. However, to the extent that commenters suggested that states can only initiate SIP development activities only after the EPA finalizes its attainment determinations and area reclassifications, we disagree. There are

[23] *See* 87 FR 21842, 21856 (April 13, 2022).

[24] *See* final determination and reclassification actions for the 1997 8-hour ozone NAAQS for Imperial County, CA (73 FR 8209, February 13, 2008); Atlanta, GA (73 FR 12013, March 6, 2008); Beaumont-Port Arthur, TX (73 FR 14391, March 18, 2008); and Baton Rouge, LA (73 FR 15087, March 21, 2008).

[25] *See* 81 FR 26697, 26704 (May 4, 2016) and 84 FR 44238, 44245 (August 23, 2019).

[26] *See* 84 FR 44238, 44246 (August 23, 2019).

[27] *See* 87 FR 21842, 21855 (April 13, 2022).

proactive and voluntary pathways by which states can anticipate and manage the tight timeframes to develop required SIP revisions for reclassified nonattainment areas, including early planning and voluntary reclassification. The EPA is aware that many states with areas affected by this current action may be constrained in *finalizing* rulemakings that require additional emissions controls unless the state air agency can demonstrate such controls were mandated by an underlying federal requirement (*e.g.,* required pursuant to a mandatory area reclassification). However, to our knowledge most states with affected areas are not prohibited from *starting* their SIP development activities before the EPA finalizes this current action. As we noted in our 2019 attainment determination and reclassification action for the 2008 ozone NAAQS, states with Moderate areas that were proposed for reclassification as Serious had known with a reasonable amount of certainty that revised SIPs would be due in the near future to provide for expeditious attainment of the 2008 ozone NAAQS, and had the opportunity to make progress on plan development activities before issuance of the final action.[28] That remains true for this current action, where states with affected Marginal areas have been aware of preliminary 2018–2020 DVs since at least December 2020 and could have reasonably anticipated that SIP revisions for reclassified Moderate areas would again be due in the near future, consistent with previous EPA determination and reclassification actions. Nonetheless, the EPA recognizes the challenges posed by the aligned SIP submission and RACT implementation deadline of January 1, 2023, and is committed to working closely with states to help them as they prepare SIP revisions in a timely manner.

The EPA also notes that voluntary reclassification provides another way for states to anticipate and manage the tight timeframes for SIP development for nonattainment areas. An air agency can request—and the EPA *must* grant—a voluntary reclassification under CAA section 181(b)(3), which resets the area's attainment date into the future, and would therefore likely provide more time and flexibility for developing and submitting required SIP revisions. Of particular benefit for states is the longer timeframe to prepare RACT analyses and adopt SIP revisions for voluntarily reclassified areas, which could result in states determining that additional controls are reasonable and in turn help expedite air quality improvements in these areas.

Comment: Regarding the proposed January 1, 2023, RACT implementation deadline for reclassified Moderate areas, the EPA received comments stating that the deadline was unreasonable, and/or the resulting compressed timeframe provided insufficient time for RACT SIP development and implementation by affected sources. One commenter generally agreed with the EPA that measures necessary to advance attainment should be implemented by the beginning of ozone season in the attainment year but, along with other commenters, contended it would be difficult for sources to timely procure needed materials and/or install new controls. Some commenters also noted that RACT implementation could be hindered by current supply chain issues stemming from, *e.g.,* the COVID–19 pandemic. Two commenters supported RACT implementation deadlines corresponding with the start of the Moderate area attainment year ozone season for their respective areas (March 1, 2023, and May 1, 2023), and one commenter requested that states be afforded the RACT implementation timeframe for initially designated areas, *i.e.,* as expeditiously as practicable but no later than January 1 of the fifth year after the effective date of designations. Another commenter contended that the January 1, 2023, deadline would limit RACM and RACT to only those measures that are already on the books or well into the adoption process. The same commenter further characterized the RACT requirement for their reclassified Moderate area as administrative and without environmental benefit because the proposed RACT timeline would limit them to merely certifying the adequacy their recent 2008 ozone NAAQS RACT evaluation for purposes of the 2015 ozone NAAQS.

Response: As discussed in the preceding response to comments regarding submission deadlines, the EPA considers the compressed planning and RACT implementation timeframe for reclassified Moderate areas to dictated, to some degree, by the area classifications and attainment date framework established in the CAA. The regulatory RACT implementation deadline for reclassified areas, which is no later than the start of the area's attainment year ozone season, creates further constraints. In consideration of CAA section 182(i)'s direction that the EPA consider ''consistency among the required submissions'' and the EPA's interpretation that that provision may refer in part to similarly situated Marginal areas across the country subject to reclassification, the EPA did not propose, and is not finalizing an approach that would establish different RACM/RACT implementation deadlines corresponding to an area's defined ozone season starting month. We instead proposed, and are finalizing, a consistent, nationally applicable RACM/RACT implementation deadline for all newly reclassified Moderate areas corresponding with the beginning of the applicable attainment year, *i.e.,* January 1, 2023, which is also the same as the single RACT implementation deadline for all areas initially classified Moderate under the 2015 ozone NAAQS. The EPA maintains that this single deadline would provide for implementation of any identified RACM/RACT as early as possible in the attainment year to influence an area's air quality and 2021–2023 attainment DV and also treat states consistently, in keeping with CAA section 182(i). We do not think a RACT implementation deadline of as expeditiously as practicable but no later than January 1 of the fifth year after the effective date of this final action, as one commenter requested, is appropriate or reasonable, because that deadline would not only fall after the Moderate area attainment date of August 3, 2024, but also after the Serious area attainment date of August 3, 2027. Such a deadline would not serve the CAA's goal of expeditious attainment of the NAAQS by no later than the attainment date.

The EPA recognizes that measures that states identify as ''reasonably available'' and that affected sources must implement are directly tied to the amount of time provided by the EPA in establishing a due date within the statutory and regulatory constraints discussed previously. Therefore, as one commenter described, the January 1, 2023, submission and implementation deadline could limit RACM and RACT to measures that are already on the books or well into the state's adoption process, and might not generate additional emission reductions. However, delaying the implementation deadline for RACT will not make it more likely that the area will attain by its attainment date. The deadline the EPA is finalizing is already the beginning of the last year in which any emission reductions could influence an area's DV as of their next attainment date. So, to the extent that commenters do not think it will be possible to implement any controls beyond what is already on the books or well into the adoption process, but recognizes that additional controls are necessary for

[28] *See* 84 FR 44238, 44246 (August 23, 2019).

that area to reach attainment, those states, as discussed previously, may exercise their option to request a voluntary reclassification, which the EPA must approve. The EPA cannot, under the CAA, reclassify areas that it knows will not attain or are unlikely to attain by the attainment date; but states are fully within their rights to recognize this and put themselves in a better position for longer planning and implementation timeframes.

Importantly, as the commenter noted, RACT for reclassified Moderate areas could include adopted and in-progress measures that were initiated independent of the EPA's current determination and reclassification action for 2015 ozone Marginal areas. This highlights an important principle underlying the CAA, namely that of ''cooperative federalism'' where, in partnership with the EPA, states and local governments have the primary responsibility for the control of air pollution at its source (*see* CAA section 101(a)(3)). Marginal areas do not have a statutory obligation to determine and implement RACM/RACT, as required for areas classified as Moderate or higher; however, the CAA does not prevent states with Marginal areas from adopting ''SIP strengthening'' measures that improve air quality but do not address a specific CAA requirement and may potentially be determined as RACT pursuant to a mandatory area reclassification. As discussed in the preceding response to comments, we are aware that states with reclassified Moderate areas may be constrained in finalizing rulemakings that require additional emissions controls unless the state air agency can demonstrate an underlying federal requirement but, for many areas, states have had significant lead time to initiate SIP development based on their knowledge of preliminary 2018–2020 DVs and reasonable anticipation that SIP revisions would be due in the near future.

Comment: The EPA received two comments on the 4-year timeframe to implement new or revised I/M programs not tied to attainment. One commenter supported allowing up to four years to implement new I/M programs. The second commenter noted that a 4-year implementation timeline for I/M may be ambitious given the considerable community outreach and public education efforts that are necessary to start up a program that potentially impacts so many individuals. The commenter urged the EPA to give states more than four years to fully implement an I/M program.

Response: The EPA acknowledges the unique nature of I/M programs and that there are many challenges, tasks, and milestones when establishing and implementing a new or revised I/M program. For the reasons described in the April 2022 proposal, the EPA continues to maintain that a deadline of up to four years is reasonable and is using our authority under CAA section 182(i) to grant this flexibility to those areas required to implement I/M under this final rule but are not intending to rely on the I/M program for attainment or RFP reductions.

Comment: One commenter noted the EPA should clarify what technical assistance will be provided for I/M programs and when it will be provided.

Response: As stated in the NPRM, the EPA intends to provide technical assistance and guidance for I/M programs in affected ozone nonattainment areas. The EPA encourages states to contact their EPA Regional Office early in the I/M SIP development process. In addition, the EPA's Office of Transportation and Air Quality continues to provide I/M guidance; *see* the EPA's I/M website at *www.epa.gov/state-and-local-transportation/vehicle-emissions-inspection-and-maintenance-im.*

III. Environmental Justice (EJ) Impacts

As discussed in Section II.B of this notice, the EPA is finalizing its proposal to grant a request for a 1-year attainment date extension for the Uinta Basin, Utah, nonattainment area and extend the August 3, 2021, Marginal area attainment date to August 3, 2022, based on our finding that the state meets the two criteria under CAA section 181(a)(5) as interpreted by the EPA in 40 CFR 51.1307 and additional considerations do not weigh against our decision to grant UDAQ's request. For example, the EPA conducted an EJSCREEN analysis for the area to evaluate whether communities in the Uinta Basin area may be exposed to disproportionate pollution burdens. The results of our screening analysis did not indicate disproportionate exposure or burdens with respect to the non-ozone environmental indicators assessed in EJSCREEN.

As discussed in Section II.E of this notice and the April 2022 proposal, a Basic vehicle I/M SIP is required for urbanized Moderate areas under the 2015 ozone NAAQS, including for areas with and without an existing I/M program that may have been implemented to meet the CAA requirements for a previous ozone NAAQS. I/M programs ensure that vehicles are operating according to the EPA's vehicle emissions standards and adequately protecting public health. However, any Basic I/M program for the 2015 ozone NAAQS may present potential economic hardship and other concerns for low-income individuals of newly reclassified Moderate ozone nonattainment areas, and we encourage states that are not already providing vehicle repair or replacement assistance programs to work with interested parties in their nonattainment areas to address such concerns.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is exempt from review by the Office of Management and Budget (OMB) because it responds to the CAA requirement to determine whether areas designated nonattainment for an ozone NAAQS attained the standard by the applicable attainment date, and to take certain steps for areas that failed to attain.

B. Paperwork Reduction Act (PRA)

This rule does not impose any new information collection burden under the PRA not already approved by the Office of Management and Budget. This action does not contain any information collection activities and serves only to make final: (1) determinations that certain Marginal nonattainment areas listed in Table 2 attained the 2015 ozone standards by the August 3, 2021 attainment date; (2) approval to grant a certain Marginal nonattainment area listed in Table 2 a 1-year attainment date extension from the August 3, 2021, attainment date to August 3, 2022; (3) determinations that certain Marginal nonattainment areas listed in Table 2 failed to attain the 2015 ozone standards by the August 3, 2021, attainment date (September 24, 2021, for San Antonio, Texas) where such areas will be reclassified as Moderate nonattainment for the 2015 ozone standards by operation of law upon the effective date of the final reclassification action; and (4) adjust any applicable implementation deadlines.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The determinations of attainment and failure to attain the 2015 ozone standards (and resulting reclassifications), and the final approval to grant 1-year attainment date extensions do not in and of themselves create any new requirements beyond what is mandated by the CAA. Instead, this rulemaking only makes factual determinations, and does not directly regulate any entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The division of responsibility between the federal government and the states for purposes of implementing the NAAQS is established under the CAA.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law.

The EPA has identified tribal areas within the nonattainment areas covered by this rulemaking, that would be potentially affected by this final action. Specifically, eight of the nonattainment areas addressed in this final action have tribes located within their boundaries: Amador, California (Jackson Rancheria of Me-Wuk Indians), Berrien County, Michigan (Pokagon Band of Potawatomi Indians), Greater Connecticut, Connecticut (Mashantucket Pequot Tribal Nation and Mohegan Indian Tribe), Northern Wasatch Front, Utah (Skull Valley Band of Goshute Indians), Phoenix-Mesa, Arizona (Fort McDowell Yavapai Nation, Gila River Indian Community of the Gila River Indian Reservation, Salt River Pima-Maricopa Indian Community of the Salt River Reservation, and Tohono O'odham Nation), San Francisco, California (Lytton Rancheria), Uinta Basin, Utah (Ute Indian Tribe of the Uintah & Ouray Reservation), and Yuma, Arizona (Cocopah Tribe and Quechan Tribe of the Fort Yuma Indian Reservation). One of the nonattainment areas addressed in this document is a separate tribal nonattainment area (Pechanga Band of Luiseño Mission Indians of the Pechanga Reservation).

The EPA has concluded that the final rule may have tribal implications for these tribes for the purposes of Executive Order 13175 but would not impose substantial direct costs upon the tribes, nor would it preempt tribal law. As noted in our proposed rule, a tribe that is part of an area that is reclassified from Marginal to Moderate nonattainment is not required to submit a tribal implementation plan revision to address new Moderate area requirements.[29] However, the NNSR major source threshold and offset requirements will change for stationary sources seeking preconstruction permits in any nonattainment areas newly reclassified as Moderate (Section II.D.1 of this notice), including on tribal lands within these nonattainment areas. Areas that are already classified Moderate for a previous ozone NAAQS are already subject to these higher offset ratios and lower thresholds, so a reclassification to Moderate for the 2015 ozone NAAQS would have no effect on NNSR permitting requirements for tribal lands in those areas.

The EPA has communicated or intends to communicate with the potentially affected tribes located within the boundaries of the nonattainment areas addressed in this final action, including offering government-to-government consultation, as appropriate.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this determination is contained in Section III of this preamble, ''Environmental Justice (EJ) Impacts.''

K. Congressional Review Act (CRA)

This rule is exempt from the CRA because it is a rule of particular applicability. The rule makes factual determinations for specific entities and does not directly regulate any entities. The determinations of attainment and failure to attain the 2015 ozone NAAQS (and resulting reclassifications), and the approval to grant 1-year attainment date extensions do not in themselves create any new requirements beyond what is mandated by the CAA.

L. Judicial Review

Section 307(b)(1) of the CAA governs judicial review of final actions by the EPA. This section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit: (i) when the agency action consists of ''nationally applicable regulations promulgated, or final actions taken, by the Administrator,'' or (ii) when such action is locally or regionally

[29] *See* 87 FR 21842, 21846 (April 13, 2022).

applicable, but ''such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.'' For locally or regionally applicable final actions, the CAA reserves to the EPA complete discretion whether to invoke the exception in (ii).

This final action is ''nationally applicable'' within the meaning of CAA section 307(b)(1). In this final action, the EPA is applying a uniform process and standard to areas across the country to make determinations regarding attainment of the 2015 ozone NAAQS for the majority of areas that are designated and classified as Marginal nonattainment for these NAAQS. All listed areas that have failed to attain by the Marginal area attainment date [30] are reclassified to Moderate upon the effective date of this final action and are subject to the same deadlines established pursuant to CAA section 182(i) for revising state implementation plans and implementing control requirements associated with the Moderate area classification. The nonattainment areas subject to this final rulemaking are located in 19 states and the District of Columbia, nine of the ten EPA regions, and the 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th, 11th and D.C. Circuits. Given that on its face this action addresses areas in states located across a wide geographic area, and uses common, nationwide analytical methods the EPA consistently applies when making determinations regarding attainment, acting on attainment date extension requests, acting on international transport demonstrations submitted to relieve states of otherwise-applicable reclassification requirements, and adjusting deadlines for all newly reclassified areas, this is a ''nationally applicable'' action within the meaning of CAA section 307(b)(1).

In the alternative, to the extent a court finds this final action to be locally or regionally applicable, the Administrator is exercising the complete discretion afforded to him under the CAA to make and publish a finding that this action is based on a determination of ''nationwide scope or effect'' within the meaning of CAA section 307(b)(1).[31] In deciding to invoke this exception, the Administrator has taken into account a number of policy considerations, including his judgment regarding the benefit of obtaining the D.C. Circuit's authoritative centralized review, rather than allowing development of the issue in other contexts, in order to ensure consistency in the Agency's approach to implementation of the 2015 ozone NAAQS in the majority of the nonattainment areas nationwide that are classified Marginal for the 2015 ozone NAAQS. This final action treats all of the identified Marginal nonattainment areas consistently, in making determinations of whether areas attained by the attainment date, in acting on requests for extensions, in evaluating demonstrations under CAA section 179B, and in reclassifying areas as Moderate and establishing consistent deadlines for all of these areas to submit and implement control measures and other plan elements required for Moderate areas. The Administrator finds that this is a matter on which national uniformity is desirable to take advantage of the D.C. Circuit's administrative law expertise and facilitate the orderly development of the basic law under the Act. The Administrator also finds that consolidated review of this action in the D.C. Circuit will avoid piecemeal litigation in the regional circuits, further judicial economy, and eliminate the risk of inconsistent results for different states. The Administrator also finds that a nationally consistent approach to the CAA's mandate concerning reclassification of areas that fail to attain the 2015 ozone NAAQS constitutes the best use of agency resources. The Administrator is publishing his finding that this action is based on a determination of nationwide scope or effect in the **Federal Register** as part of this final rule.

For these reasons, this final action is nationally applicable or, alternatively, the Administrator is exercising the complete discretion afforded to him by the CAA and finds that this final action is based on a determination of nationwide scope or effect for purposes of CAA section 307(b)(1) and is publishing that finding in the **Federal Register**. 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 District of Columbia Circuit by December 6, 2022.

List of Subjects

40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements and Volatile organic compounds.

40 CFR Part 81

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, and Volatile organic compounds.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, parts 52 and 81, title 40, chapter 1 of the Code of Federal Regulations are amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

[30] These areas include the Northern Wasatch Front, UT area and the San Antonio, TX area because the EPA is disapproving the CAA section 179B demonstrations from those two states, consistent with its CAA section 179B Guidance.

[31] In the report on the 1977 Amendments that revised CAA section 307(b)(1), Congress noted that the Administrator's determination that the ''nationwide scope or effect'' exception applies would be appropriate for any action that has a scope or effect beyond a single judicial circuit. *See* H.R. Rep. No. 95–294 at 323–24, reprinted in 1977 U.S.C.C.A.N. 1402–03.

Subpart D—Arizona

■ 2. Section 52.153 is amended by adding paragraph (b) and reserving paragraph (c) to read as follows:

§ 52.153 Control strategy and regulations: Ozone.

* * * * *

(b) *Determination of attainment by the attainment date.* Effective November 7, 2022 the EPA has determined that the Yuma County Marginal nonattainment area in Arizona attained the 2015 8-hour ozone National Ambient Air Quality Standards (NAAQS) by the applicable attainment date of August 3, 2021, based upon complete quality-assured and certified data for the calendar years 2018–2020.

(c) [Reserved]

Subpart F—California

■ 3. Section 52.282 is amended by adding paragraph (m) to read as follows:

§ 52.282 Control strategy and regulations: Ozone.

* * * * *

(m) *Determinations of attainment by the attainment date.* Effective November 7, 2022. The EPA has determined that the Amador County and San Francisco Bay Marginal nonattainment areas in California attained the 2015 8-hour ozone National Ambient Air Quality Standards (NAAQS) by the applicable attainment date of August 3, 2021, based upon complete quality-assured and certified data for the calendar years 2018–2020.

Subpart L— Georgia

■ 4. Section 52.577 is amended by adding paragraph (e) to read as follows:

§ 52.577 Determination of attainment.

* * * * *

(e) Based upon EPA's review of the air quality data for the 3-year period 2018–2020, EPA determined that the Atlanta, Georgia, 2015 8-hour ozone nonattainment area attained the 2015 8-hour ozone NAAQS by the applicable attainment date of August 3, 2021. Therefore, EPA has met the requirement pursuant to CAA section 181(b)(2) to determine, based on the Area's air quality as of the attainment date, whether the Area attained the standard. EPA also determined that the Atlanta, Georgia, 2015 8-hour ozone nonattainment area is not subject to the consequences of failing to attain pursuant to section 181(b)(2).

Subpart TT— Utah

■ 5. Section 52.2332 is revised to read as follows:

§ 52.2332 Control strategy: Ozone.

(a) *Determinations.* EPA is determining that, as of July 18, 1995, the Salt Lake and Davis Counties ozone nonattainment area has attained the ozone standard based on air quality monitoring data from 1992, 1993, and 1994, and that the reasonable further progress and attainment demonstration requirements of section 182(b)(1) and related requirements of section 172(c)(9) of the Clean Air Act do not apply to the area for so long as the area does not monitor any violations of the ozone standard. If a violation of the ozone NAAQS is monitored in the Salt Lake and Davis Counties ozone nonattainment area, these determinations shall no longer apply.

(b) *Determination.* Effective November 7, 2022, EPA is determining that the Southern Wasatch Front, Utah Marginal nonattainment area attained the 2015 8-hour ozone National Ambient Air Quality Standards (NAAQS) by the applicable attainment date of August 3, 2021, based upon complete quality-assured and certified data for the calendar years 2018–2020.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 7. The authority citation for part 81 continues to read as follows:

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

Subpart C—Section 107 Attainment Status Designations

■ 8. Section 81.303 is amended in the table for ''Arizona-2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Phoenix-Mesa, AZ'' to read as follows:

§ 81.303 Arizona.

ARIZONA—2015 8-HOUR OZONE NAAQS
[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Phoenix-Mesa, AZ		Nonattainment	November 7, 2022	Moderate.
Gila County (part):				
T2N, R12E (except that portion in Maricopa County); T3N, R12E (except that portion in Maricopa County); T4N, R12E (Sections 25 through 29 (except those portions in Maricopa County) and 33 through 36 (except those portions in Maricopa County)).				
Mariposa County (part):				

ARIZONA—2015 8-HOUR OZONE NAAQS—Continued
[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
T1N, R1E (except that portion in Indian Country); T1N, R2E; T1N, R3E; T1N, R4E (except that portion in Indian Country); T1N, R5E (except that portion in Indian Country); T1N, R6E; T1N, R7E; T1N, R1W; T1N, R2W; T1N, R3W; T1N, R4W; T1N, R5W; T1N, R6W; T1N, R7W; T1N, R8W; T2N, R1E; T2N, R2E; T2N, R3E; T2N, R4E; T2N, R6E (except that portion in Indian Country); T2N, R7E (except that portion in Indian Country); T2N, R8E; T2N, R9E; T2N, R10E; T2N, R11E; T2N, R12E (except that portion in Gila County); T2N, R13E (except that portion in Gila County); T2N, R1W; T2N, R2W; T2N, R3W; T2N, R4W; T2N, R5W; T2N, R6W; T2N, R7W; T2N, R8W; T3N, R1E; T3N, R2E; T3N, R3E; T3N, R4E; T3N, R5E (except that portion in Indian Country); T3N, R6E (except that portion in Indian Country); T3N, R7E (except that portion in Indian Country); T3N, R8E; T3N, R9E; T3N, R10E (except that portion in Gila County); T3N, R11E (except that portion in Gila County); T3N, R12E (except that portion in Gila County); T3N, R1W; T3N, R2W T3N, R3W; T3N, R4W; T3N, R5W; T3N, R6W; T4N, R1E; T4N, R2E; T4N, R3E; T4N, R4E; T4N, R5E; T4N, R6E (except that portion in Indian Country); T4N, R7E (except that portion in Indian Country); T4N, R8E T4N, R9E; T4N, R10E (except that portion in Gila County); T4N, R11E (except that portion in Gila County); T4N, R12E (except that portion in Gila County); T4N, R1W; T4N, R2W; T4N, R3W; T4N, R4W; T4N, R5W; T4N, R6W; T5N, R1E; T5N, R2E; T5N, R3E; T5N, R4E; T5N, R5E; T5N, R6E; T5N, R7E; T5N, R8E; T5N, R9E (except that portion in Gila County); T5N, R10E (except that portion in Gila County); T5N, R1W; T5N, R2W; T5N, R3W; T5N, R4W; T5N, R5W; T6N, R1E (except that portion in Yavapai County); T6N, R2E; T6N, R3E; T6N, R4E; T6N, R5E; T6N, R6E; T6N, R7E; T6N, R8E; T6N, R9E (except that portion in Gila County); T6N, R10E (except that portion in Gila County); T6N, R1W (except that portion in Yavapai County); T6N, R2W; T6N, R3W; T6N, R4W; T6N, R5W; T7N, R1E (except that portion in Yavapai County); T7N, R2E (except that portion in Yavapai County); T7N, R3E; T7N, R4E; T7N, R5E; T7N, R6E; T7N, R7E; T7N, R8E; T7N, R9E (except that portion in Gila County); T7N, R1W (except that portion in Yavapai County); T7N, R2W (except that portion in Yavapai County); T8N, R2E (except that portion in Yavapai County); T8N, R3E (except that portion in Yavapai County); T8N, R4E (except that portion in Yavapai County); T8N, R5E (except that portion in Yavapai County); T8N, R6E (except that portion in Yavapai County); T8N, R7E (except that portion in Yavapai County); T8N, R8E (except that portion in Yavapai and Gila Counties); T8N, R9E (except that portion in Yavapai and Gila Counties); T1S, R1E (except that portion in Indian Country); T1S, R2E (except that portion in Pinal County and in Indian Country);				

ARIZONA—2015 8-HOUR OZONE NAAQS—Continued
[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
T1S, R3E; T1S, R4E; T1S, R5E; T1S, R6E; T1S, R7E; T1S, R1W; T1S, R2W; T1S, R3W; T1S, R4W; T1S, R5W; T1S, R6W; T2S, R1E (except that portion in Indian Country); T2S, R5E; T2S, R6E; T2S, R7E; T2S, R1W; T2S, R2W; T2S, R3W; T2S, R4W; T2S, R5W; T3S, R1E; T3S, R1W; T3S, R2W; T3S, R3W; T3S, R4W; T3S, R5W; T4S, R1E; T4S, R1W; T4S, R2W; T4S, R3W; T4S, R4W; T4S, R5W; T5S, R4W (Sections 1 through 22 and 27 through 34).				
Pinal County (part):				
T1N, R8E; T1N, R9E; T1N, R10E; T1S, R8E; T1S, R9E; T1S, R10E; T2S, R8E (Sections 1 through 10, 15 through 22, and 27 through 34); T2S, R9E (Sections 1 through 6); T2S, R10E (Sections 1 through 6); T3S, R7E (Sections 1 through 6, 11 through 14, 23 through 26, and 35 through 36); T3S, R8E (Sections 3 through 10, 15 through 22, and 27 through 34).				
Fort McDowell Yavapai Nation.				
Gila River Indian Community of the Gila River Indian Reservation, Arizona.				
Includes only non-contiguous areas of Indian country known as ''parcels M & N''.[3]				
Tohono O'odham Nation of Arizona.				
Salt River Pima-Maricopa Indian Community of the Salt River Reservation.				
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.
[3] See Section 3.0 of the EPA's technical support document for Arizona, titled ''Arizona Final Area Designations for the 2015 Ozone National Ambient Air Quality Standards Technical Support Document (TSD),'' for more information and a map showing the locations of ''parcels M & N'' (available in Docket ID: EPA–HQ–OAR–2017–0548).

* * * * *

■ 9. Section 81.305 is amended in the table for ''California-2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Mariposa County, CA'' and ''Pechanga Band of Luiseño Mission Indians of the Pechanga Reservation'' to read as follows:

§ 81.305 California.

* * * * *

CALIFORNIA—2015 8-HOUR OZONE NAAQS
[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
* *	*	* *	*	*
Mariposa County, CA ..... Mariposa County.	.....	Nonattainment	November 7, 2022	Moderate.
* *	*	* *	*	*
Pechanga Band of Luiseño Mission Indians of the Pechanga Reservation:	.....	Nonattainment	November 7, 2022	Moderate.
Includes the main body of the contiguous Pechanga Band Reservation and the noncontiguous area known as Pu'eska Mountain, excluding non-contiguous tribal lands in the Los Angeles-South Coast Air Basin, CA (Meadowbrook parcel). [3]				

CALIFORNIA—2015 8-HOUR OZONE NAAQS—Continued

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

[3] See Section 23.0 of the EPA's technical support document for California, titled "California Final Area Designations for the 2015 Ozone National Ambient Air Quality Standards Technical Support Document (TSD)," for more information and maps showing the locations of the main body of the reservation and the non-contiguous Pu'eska Mountain and Meadowbrook lands (available in Docket ID: EPA–HQ–OAR–2017–0548).

* * * * *

■ 10. Section 81.306 is amended in the table for "Colorado—2015 8-Hour Ozone NAAQS [Primary and Secondary]" by revising the entry for "Denver Metro/North Front Range, CO" to read as follows:

§ 81.306 Colorado.

* * * * *

COLORADO—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Denver Metro/North Front Range, CO		Nonattainment	November 7, 2022	Moderate.
Adams County.				
Arapahoe County.				
Boulder County.				
Broomfield County.				
Denver County.				
Douglas County.				
Jefferson County.				
Larimer County (part).				
Including the portion of Rocky Mountain National Park therein and that portion of the county that lies south of a line described as follows: Beginning at a point on Larimer County's eastern boundary and Weld County's western boundary intersected by 40 degrees, 42 minutes, and 47.1 seconds north latitude, proceed west to a point defined by the intersection of 40 degrees, 42 minutes, 47.1 seconds north latitude and 105 degrees, 29 minutes, and 40.0 seconds west longitude, thence proceed south on 105 degrees, 29 minutes, 40.0 seconds west longitude to the inter-section with 40 degrees, 33 minutes and 17.4 seconds north latitude, thence proceed west on 40 degrees, 33 minutes, 17.4 seconds north latitude until this line intersects Larimer County's western boundary and Grand County's eastern boundary.				
Weld County	12/30/2021 [3].			
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

[3] EPA revised the nonattainment boundary in response to a court decision, which did not vacate any designations for the 2015 ozone NAAQS, but which remanded the designation for the identified county. Because this additional area is part of a previously designated nonattainment area, the implementation dates for the overall nonattainment area (*e.g.,* the August 3, 2021 attainment date) remain unchanged regardless of this later designation date.

* * * * *

■ 11. Section 81.307 is amended in the table for ''Connecticut—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Greater Connecticut, CT'' to read as follows:

§ 81.307 Connecticut.

* * * * *

CONNECTICUT—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
* *	*	* *	*	*
Greater Connecticut, CT Hartford County. Litchfield County. New London County. Tolland County. Windham County.		Nonattainment	November 7, 2022	Moderate.
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 12. Section 81.308 is amended in the table for ''Delaware—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE'' to read as follows:

§ 81.308 Delaware.

* * * * *

DELAWARE—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE. New Castle County.		Nonattainment	November 7, 2022	Moderate.
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 13. Section 81.309 is amended in the table for ''District of Columbia—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Washington, DC-MD-VA'' to read as follows:

§ 81.309 District of Columbia.

* * * * *

DISTRICT OF COLUMBIA—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Washington, DC-MD-VA District of Columbia.		Nonattainment	November 7, 2022	Moderate.

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 14. Section 81.314 is amended in the table for ''Illinois—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Chicago, IL-IN-

WI'' and ''St. Louis, MO-IL'' to read as follows:

§ 81.314 Illinois.

* * * * *

ILLINOIS—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Chicago, IL-IN-WI		Nonattainment	November 7, 2022	Moderate.
Cook County.				
DuPage County.				
Grundy County (part).				
Aux Sable Township and Goose Lake Township:				
Kane County.				
Kendall County (part).				
Oswego Township:				
Lake County.				
McHenry County	July 14, 2021.[3]			
Will County.				
St. Louis, MO-IL:				
Madison County.				
Monroe County	July 14, 2021.[3]			
St. Clair County.				
* *	*	*	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

[3] EPA revised the nonattainment boundary in response to a court decision, which did not vacate any designations for the 2015 ozone NAAQS, but which remanded the designation for the identified county. Because this additional area is part of a previously designated nonattainment area, the implementation dates for the overall nonattainment area (*e.g.,* the August 3, 2021 attainment date) remain unchanged regardless of this later designation date.

* * * * *

■ 15. Section 81.315 is amended in the table for ''Indiana—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Chicago, IL-IN-WI'' to read as follows:

§ 81.315 Indiana.

* * * * *

INDIANA—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Chicago, IL-IN-WI		Nonattainment	November 7, 2022	Moderate.
Lake County (part).				
Calumet Township, Hobart Township, North Township, Ross Township, and St. John Township.				
Porter County (part)	July 14, 2021[3].			
Center Township, Jackson Township, Liberty Township, Pine Township, Portage Township, Union Township, Washington Township, and Westchester Township.				
* *	*	*	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

[3] EPA revised the nonattainment boundary in response to a court decision, which did not vacate any designations for the 2015 ozone NAAQS, but which remanded the designation for the identified county. Because this additional area is part of a previously designated nonattainment area, the implementation dates for the overall nonattainment area (*e.g.,* the August 3, 2021 attainment date) remain unchanged regardless of this later designation date.

* * * * *

■ 16. Section 81.318 is amended in the table for ''Kentucky—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Cincinnati, OH-KY'' and ''Louisville, KY-IN'' to read as follows:

§ 81.318 Kentucky.

* * * * *

KENTUCKY—2015 8-HOUR OZONE NAAQS

(Primary and secondary)

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Cincinnati, OH-KY		Nonattainment	November 7, 2022	Moderate.
Boone County (part):				
The entire county except for 2010 US Census Tracts 706.01 and 706.04.				
Campbell County (part):				
The entire county except for 2010 US Census Tracts 520.01 and 520.02.				
Kenton County (part):				
The entire county except for 2010 US Census Tracts 637.01 and 637.02.				
Louisville, KY-IN		Nonattainment	November 7, 2022	Moderate.
Bullitt County.				
Jefferson County.				
Oldham County.				
* *	*	*	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 17. Section 81.321 is amended in the table for ''Maryland—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Baltimore, MD'', ''Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE'' and ''Washington, DC-MD-VA'' to read as follows:

§ 81.321 Maryland.

* * * * *

MARYLAND—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Baltimore, MD		Nonattainment	November 7, 2022	Moderate.
Anne Arundel County.				
Baltimore County.				
Carroll County.				
Harford County.				
Howard County.				
City of Baltimore.				
Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE.		Nonattainment	November 7, 2022	Moderate.
Cecil County.				
Washington, DC-MD-VA		Nonattainment	November 7, 2022	Moderate.
Calvert County.				
Charles County.				
Fredrick County.				
Montgomery County.				
Prince George's County.				
* *	*	*	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 18. Section 81.323 is amended in the table for ''Michigan—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for

''Allegan County, MI'', ''Berrien County, MI'' and ''Muskegon County, MI'' to read as follows:

§ 81.323 Michigan.

* * * * *

MICHIGAN—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Allegan County, MI		Nonattainment	November 7, 2022	Moderate.
Allegan County (part):				
Casco Township, Cheshire Township, City of Douglas, City of Holland, City of Saugatuck, Clyde Township, Fillmore Township, Ganges Township, Heath Township, Laketown Township, Lee Township, Manilus Township, Overisel Township, Saugatuck Township, and Valley Township.				
Berrien County, MI		Nonattainment	November 7, 2022	Moderate.
Berrien County.				
* *	*	* *	*	*
Muskegon County, MI		Nonattainment	November 7, 2022	Moderate.
Muskegon County (part):				
Blue Lake Township, City of Montague, City of Muskegon, City of Muskegon Heights, City of North Muskegon, City of Roosevelt Park, City of Whitehall, Dalton Township, (incl. Village of Lakewood Club), Fruitland Township, Fruitport Township, (incl. Village of Fruitport) Laketon Township, Montague Township, Muskegon Township, Norton Shores Township, White River Township, and Whitehall Township.				
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 19. Section 81.326 is amended in the table for ''Missouri—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''St. Louis, MO-IL'' to read as follows:

§ 81.326 Missouri.

* * * * *

MISSOURI—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
St. Louis, MO-IL:		Nonattainment	November 7, 2022	Moderate.
Franklin County (part).				
Boles Township:				
Jefferson County	July 14, 2021 [3].			
St. Charles County.				
St. Louis County.				
City of St. Louis.				
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

[3] EPA revised the nonattainment boundary in response to a court decision, which did not vacate any designations for the 2015 ozone NAAQS, but which remanded the designation for the identified county. Because this additional area is part of a previously designated nonattainment area, the implementation dates for the overall nonattainment area (*e.g.,* the August 3, 2021 attainment date) remain unchanged regardless of this later designation date.

* * * * *

■ 20. Section 81.331 is amended in the table for ''New Jersey—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE'' to read as follows:

§ 81.331 New Jersey.

* * * * *

NEW JERSEY—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
* *	*	* *	*	*
Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE.	.....	Nonattainment	November 7, 2022	Moderate.
Atlantic County.				
Burlington County.				
Camden County.				
Cape May County.				
Cumberland County.				
Gloucester County.				
Mercer County.				
Ocean County.				
Salem County.				

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 21. Section 81.336 is amended in the table for ''Ohio—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Cleveland, OH'' to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Cleveland, OH	.....	Nonattainment	November 7, 2022	Moderate.
Cuyahoga County.				
Geauga County.				
Lake County.				
Lorain County.				
Medina County.				
Portage County.				
Summit County.				
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 22. Section 81.339 is amended in the table for ''Pennsylvania—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE'' to read as follows:

§ 81.339 Pennsylvania.

* * * * *

PENNSYLVANIA—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE.	.....	Nonattainment	November 7, 2022	Moderate.
Bucks County.				
Chester County.				
Delaware County.				
Montgomery County.				
Philadelphia County.				
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 23. Section 81.344 is amended in the table for ''Texas—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Dallas-Fort Worth, TX'', ''Houston-Galveston-Brazoria, TX'' and ''San Antonio, TX'' to read as follows:

§ 81.344 Texas.

* * * * *

TEXAS—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Dallas-Fort Worth, TX	.....	Nonattainment	November 7, 2022	Moderate.
Collin County.				
Dallas County.				
Denton County.				
Ellis County.				
Johnson County.				
Kaufman County.				
Parker County.				
Tarrant County.				
Wise County.				
* *	*	* *	*	*
Houston-Galveston-Brazoria, TX	.....	Nonattainment	November 7, 2022	Moderate.
Brazoria County.				
Chambers County.				
Fort Bend County.				
Galveston County.				
Harris County.				
Montgomery County.				
San Antonio, TX	9/24/2018	Nonattainment	November 7, 2022	Moderate.
Bexar County.				
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 24. Section 81.345 is amended in the table for ''Utah—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Northern Wasatch Front, UT'' and ''Uinta Basin, UT'' to read as follows:

§ 81.345 Utah.

* * * * *

UTAH—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Northern Wasatch Front, UT		Nonattainment	November 7, 2022	Moderate.
Weber County (part):				
All portions of Weber County west of and including Townships 5, 6, and that portion of 7 North Range 1 West that are west of the ridgeline that traces the Wasatch Mountains from the southeast corner of the township to the easternmost extension of the county boundary within the township.				
Tooele County (part):				
In Tooele County, the following Townships or portions thereof as noted (including Tooele City):				
Township 1 South Range 3 West.				
Township 2 South Range 3 West.				
Township 3 South Range 3 West				
Township 3 South Range 4 West.				
Township 2 South Range 4 West.				
Township 2 South Range 5 West.				
Township 3 South Range 5 West.				
Township 3 South Range 6 West.				
Township 2 South Range 6 West.				
Township 1 South Range 6 West.				
Township 1 South Range 5 West.				
Township 1 South Range 4 West.				
Township 1 South Range 7 West.				
Township 2 South Range 7 West.				
Township 3 South Range 7 West.				
All Sections within Township 4 South Range 7 West except for Sections 29, 30, 31 and 32.				
Township 4 South Range 6 West.				
Township 4 South Range 5 West.				
Township 4 South Range 4 West.				
Township 4 South Range 3 West.				
Salt Lake County.				
Davis County.				
* * * * * * *				
Uinta Basin, UT [3] [4]	8/03/22	Nonattainment	November 7, 2022	Marginal.
Duchesne County (part):				
All land in Duchesne County below a contiguous external perimeter of 6,250 ft. in elevation. All areas within that contiguous external perimeter are included in the nonattainment area—including mesas and buttes which may have an elevation greater than 6,250 ft., but which are surrounded on all sides by land lower than 6,250 ft. Additionally, areas that fall outside the 6,250 ft. contiguous external perimeter that have elevations less than 6,250 ft. are excluded from the nonattainment area. The boundary is defined by the 6,250 ft. contour line created from the 2013 USGS 10-meter seamless Digital Elevation Model (USGS NED n41w110⅓ arc-second 2013 1 × 1 degree IMG).				
Uintah County (part):				

UTAH—2015 8-HOUR OZONE NAAQS—Continued

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
All land in Uintah County below a contiguous external perimeter of 6,250 ft. in elevation. All areas within that contiguous external perimeter are included in the nonattainment area—including mesas and buttes which may have an elevation greater than 6,250 ft., but which are surrounded on all sides by land lower than 6,250 ft. Additionally, areas that fall outside the 6,250 ft. contiguous external perimeter that have elevations less than 6,250 ft. are excluded from the nonattainment area. The boundary is defined by the 6,250 ft. contour line created from the 2013 USGS 10-meter seamless Digital Elevation Model (USGS NED n41w110⅓ arc-second 2013 1 × 1 degree IMG).				
* * * * * * *				

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

[3] The EPA is designating portions of the Uinta Basin as ''nonattainment,'' including both Tribal and State lands. The Ute Indian Tribe has air quality planning jurisdiction in the areas of Indian country included in the Uinta Basin nonattainment area, while the State of Utah has air quality planning jurisdiction in the areas of State land included in the Uinta Basin nonattainment area.

[4] Attainment date is extended to August 3, 2022 for the Uinta Basin, UT, nonattainment area.

* * * * *

■ 25. Section 81.347 is amended in the table for ''Virginia—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entry for ''Washington, DC-MD-VA'' to read as follows:

§ 81.347 Virginia.

* * * * *

VIRGINIA—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Washington, DC-MD-VA Arlington County. Fairfax County. Loudoun County. Prince William County. Alexandria City. Fairfax City. Falls Church City. Manassas City. Manassas Park City.		Nonattainment	November 7, 2022	Moderate.
* * * * * * *				

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

■ 26. Section 81.350 is amended in the table for ''Wisconsin—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' by revising the entries for ''Chicago, IL-IN-WI'', ''Milwaukee, WI'' and ''Sheboygan County, WI'' to read as follows:

§ 81.350 Wisconsin.

* * * * *

WISCONSIN—2015 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
* *	*	* *	*	*
Chicago, IL-IN-WI		Nonattainment	November 7, 2022	Moderate.
Kenosha County (part)	July 14, 2021 [5].			
The portion of Kenosha County bounded by the Lake Michigan shoreline on the East, the Kenosha County boundary on the North, the Kenosha County boundary on the South, and the I–94 corridor (including the entire corridor) on the West.				
* *	*	* *	*	*
Milwaukee, WI		Nonattainment	November 7, 2022	Moderate.
Milwaukee County	July 14, 2021 [5].			
Ozaukee County	July 14, 2021 [5].			
Racine County (part)	July 14, 2021 [5].			
Inclusive and east of the following roadways going from the northern county boundary to the southern county boundary: Highway 45 to Washington Ave. to South Beaumont Ave.				
Washington County (part)	July 14, 2021 [5].			
Inclusive and east of the following roadways going from the northern county boundary to the southern county boundary: Highway 45 to Washington Ave. to South Beaumont Ave.				
Waukesha County (part)	July 14, 2021 [5].			
Going from the western county boundary to the southern county boundary: Inclusive and north of I–94 and inclusive and east of Highway 67.				
Sheboygan County, WI	July 14, 2021 [5]	Nonattainment	November 7, 2022	Moderate.
Sheboygan County (part):				
Inclusive and east of the following roadways with the boundary starting from north to south: Union Road which turns into County Road Y which turns into Highland Drive, to Lower Road which turns into Monroe Street, to Broadway/Main Street to Highway 32 which turns into Giddings Avenue to County Road W to County Road KW.				
* *	*	* *	*	*

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

[2] This date is August 3, 2018, unless otherwise noted.

* * * * * * *

[5] EPA revised the nonattainment boundary in response to a court decision, which did not vacate any designations for the 2015 ozone NAAQS, but which remanded the designation for the identified county. Because this additional area is part of a previously designated nonattainment area, the associated implementation dates for the overall nonattainment area (*e.g.,* the August 3, 2021 attainment date) remain unchanged regardless of this later designation date.

* * * * *

[FR Doc. 2022–20460 Filed 10–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–HQ–OAR–2021–0741; FRL–8426–02–OAR]

Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Areas Classified as Serious for the 2008 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is finalizing actions pursuant to section 181(b)(2) of the Clean Air Act (CAA or Act) for most remaining areas in the country classified as ''Serious'' for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS) of 0.075 parts per million (ppm). Applying a uniform methodology, the Agency is determining that one Serious area attained the standards by the July 20, 2021, applicable attainment date and that five Serious areas failed to attain the standards by the applicable attainment date. The effect of failing to attain by the applicable attainment date is that these areas will be reclassified by operation of law to ''Severe'' nonattainment for the 2008 ozone NAAQS on November 7, 2022, the effective date of this final rule. Pursuant to its authority under the CAA, the Agency is establishing new, consistent deadlines by which the responsible state air agencies for the reclassified areas must submit State Implementation Plan (SIP) revisions and implement controls to satisfy the statutory and regulatory requirements for Severe areas for the 2008 ozone NAAQS. Additionally, in areas reclassified as Severe, where not already prohibited, the CAA will prohibit the sale of conventional gasoline and require that federal reformulated gasoline instead be sold beginning 1 year after the effective date of this final rule, November 7, 2023.

DATES: The effective date of this rule is November 7, 2022.

ADDRESSES: The EPA has established a public docket for these ozone designations at *https://www.regulations.gov* under Docket ID No. EPA–HQ–OAR–2021–0741. Although listed in the docket index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form.

FOR FURTHER INFORMATION CONTACT: For general questions concerning this action, contact Robert Lingard, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, C539–01 Research Triangle Park, NC 27709; by telephone number: 919–541–5272; email address: *lingard.robert@epa.gov;* or Emily Millar, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Policy Division, C539–01 Research Triangle Park, NC 27709; telephone number: 919–541–2619; email address: *millar.emily@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

The following is an outline of the Preamble.

I. Review of Proposed Actions

A. Background and Proposed Determinations

On March 12, 2008, the EPA revised both the primary and secondary NAAQS for ozone to a level of 0.075 ppm to provide increased protection of public health and the environment.[1] When the EPA promulgates a new or revised NAAQS, the EPA is required to designate areas as nonattainment, attainment, or unclassifiable, pursuant to section 107(d)(1) of the CAA. The CAA requires the EPA to complete the initial area designation process within 2 years of promulgating the NAAQS, with authority to extend the deadline for designations decisions by 1 additional year if the Administrator has insufficient information to make the designations within the initial 2-year timeframe. The final designations for the 2008 ozone NAAQS were based primarily on certified air quality monitoring data from calendar years 2008–2010, *i.e.,* area design values as of the time of designations.[2]

In accordance with CAA section 181(a)(1), each area designated as nonattainment for the 2008 ozone NAAQS was also classified by operation of law at the same time as the area was designated by the EPA.[3] In a separate Classifications Rule, the ozone nonattainment areas were classified as Marginal, Moderate, Serious, Severe, or Extreme, based on the severity of their ozone levels, which is also determined by available area design values at the time of designation.[4] Subpart 2 of the CAA requires ozone nonattainment areas to achieve the NAAQS as expeditiously as practicable, but not later than the maximum attainment date. Higher classifications, or more polluted areas, receive more time to attain compliance. When the EPA determines that an area has failed to attain by the maximum attainment date, that area is automatically reclassified to the next highest classification, allowing more time for compliance with the NAAQS but imposing additional mandatory controls under the Act.

Consequently, as each attainment date for each 2008 ozone NAAQS classification established under the

[1] *See* 73 FR 16436 (March 27, 2008).

[2] The air quality design value for the 8-hour ozone NAAQS is the 3-year average of the annual 4th highest daily maximum 8-hour average ozone concentration. *See* 40 CFR part 50, appendix I.

[3] *See* CAA section 181(a)(1), tbl. 1.

[4] 77 FR 30160 (May 21, 2012). *NRDC* v. *EPA,* 777 F.3d 456 (D.C. Cir. 2014) overturned parts of the EPA's Classifications Rule but did not impact the EPA's methodology for classifying areas and the levels at which the EPA classified the 2008 ozone NAAQS nonattainment areas.

statute and regulations has passed, the EPA has made the required determinations as to whether areas across the country attained the NAAQS by those dates based on the areas' design values as of the attainment dates.[5] As areas across the country have implemented more stringent controls and as federal measures have required emission reductions of precursors of ozone pollution from mobile sources and stationary point sources, air quality in the nonattainment areas under the 2008 ozone NAAQS has improved, and areas have come into attainment of the NAAQS. For this reason, the EPA has had to address fewer areas in each successive notice determining whether areas attained by the attainment date, and the number of areas that have failed to attain by the attainment date and been reclassified has decreased over time.[6]

Accordingly, on April 13, 2022, the EPA proposed actions to fulfill its statutory obligation under Clean Air Act (CAA or the Act) section 181 to determine whether the remaining Serious ozone nonattainment areas across the country attained the 2008 ozone NAAQS by July 20, 2021, the applicable attainment date for such areas.[7] As noted there, the EPA's proposal addressed seven of the nine remaining Serious nonattainment areas for the 2008 ozone NAAQS—specifically, (1) Chicago-Naperville, IL-IN-WI; (2) Dallas-Fort Worth, TX; (3) Denver-Boulder-Greeley-Ft. Collins-Loveland, CO; (4) Greater Connecticut, CT; (5) Houston-Galveston-Brazoria, TX; (6) Morongo Band of Mission Indians; and (7) New York-N. New Jersey-Long Island, CT-NJ-NY. The two other Serious nonattainment areas located in California were addressed in a separate proposal, which considered exceptional events demonstrations submitted by the California Air Resources Board.[8]

First, the EPA proposed to find that the Greater Connecticut, CT, nonattainment area attained the 2008 ozone NAAQS by the applicable attainment date based on complete, quality-assured and certified ozone air quality monitoring data for the 2018–2020 calendar years.

Second, the EPA proposed to deny the state of Texas's request for a 1-year extension of the attainment date from July 20, 2021, to July 20, 2022, for the Houston-Galveston-Brazoria, TX, nonattainment area (Houston area). The proposed denial of Texas Commission of Environmental Quality's (TCEQ's) request was based, in part, on our consideration of air quality trends in the Houston area that indicated the area would not timely attain by the extended attainment date, nor even qualify for a second 1-year extension of the attainment date. Our proposed denial was also based, in part, on our consideration of existing pollution burdens for some communities within the area. Taken together, these considerations weighed in favor of not delaying the imposition of more stringent requirements associated with reclassification, and the EPA, therefore, proposed to deny the state's request for an extension.[9]

Third, the EPA proposed to find that six areas failed to attain the 2008 ozone NAAQS by the applicable attainment date. The six areas were: (1) Chicago-Naperville, Illinois-Indiana-Wisconsin (IL-IN-WI) (Chicago area); (2) Dallas-Fort Worth, TX; (3) Denver-Boulder-Greeley-Ft. Collins-Loveland, Colorado (CO) (Denver Area); (4) Houston-Galveston-Brazoria, TX (Houston area); (5) Morongo Band of Mission Indians; and (6) New York-North New Jersey-Long Island, Connecticut-New Jersey-New York (CT-NJ-NY) (New York Metropolitan area). The proposed determination for each of these areas was based upon complete, quality-assured and certified ozone air quality monitoring data that showed that the 8-hour ozone design value (DV) for the area exceeded 0.075 ppm for the period 2018–2020, *i.e.,* the area's DV as of the attainment date. The EPA proposed that these six areas would be reclassified as Severe nonattainment areas by operation of law on the effective date of a final action finding that these areas failed to attain the 2008 ozone NAAQS by the applicable attainment date for Serious areas.[10] Since EPA issued its proposal in April, the Agency redesignated the Chicago area to attainment for the 2008 ozone NAAQS based on attaining air quality for the period 2019–2021 and a determination that the other statutory criteria for redesignation were met, and, therefore, we are not finalizing our proposed determination of failure to attain and reclassification for this area.[11]

A summary of the actions proposed for the six areas covered by this final action is provided in Table 1 in this action.

TABLE 1—2008 OZONE NAAQS SERIOUS NONATTAINMENT AREA PROPOSED ACTION SUMMARY

2008 NAAQS nonattainment area	2018–2020 design value (DV) (ppm)	2008 NAAQS attained by the serious attainment date	2020 4th highest daily maximum 8-hr average (ppm)	Area failed to attain 2008 NAAQS but state requested 1-year attainment date extension based on 2020 4th highest daily maximum 8-hr average ≤0.075 ppm
Dallas-Fort Worth, TX*	0.076	Failed to Attain	0.077	No.
Denver-Boulder-Greeley-Ft. Collins-Loveland, CO.	0.081	Failed to Attain	0.087	No.
Greater Connecticut, CT	0.073	Attained	0.071	N/A.
Houston-Galveston-Brazoria, TX	0.079	Failed to Attain	0.075	Yes.
Morongo Band of Mission Indians	0.099	Failed to Attain	0.103	No.

[5] *See, e.g.,* 86 FR 26697 (May 4, 2016); 84 FR 44238 (August 23, 2019).

[6] 86 FR 26697 (addressing 36 Marginal areas subject to the July 20, 2015, Marginal area attainment date, finding 11 failed to attain); 84 FR 44238 (addressing 11 Moderate areas subject to the July 20, 2018, Moderate area attainment date, finding 7 failed to attain).

[7] *See* 87 FR 21825 (April 13, 2022).

[8] On July 14, 2022, the EPA proposed to determine that Nevada County (Western part), CA, and Ventura County, CA, areas attained by the 2008 ozone Serious area attainment date (87 FR 42126).

[9] *See* 87 FR 21825, 21835 (April 13, 2022).

[10] *See* CAA section 181(b)(2)(A).

[11] Final redesignation actions for the three state portions of the Chicago area were effective upon publication in the **Federal Register:** Indiana portion (87 FR 30821, May 20, 2022); Illinois portion (87 FR 30828, May 20, 2022); and the Wisconsin portion (87 FR 21027, April 11, 2022).

TABLE 1—2008 OZONE NAAQS SERIOUS NONATTAINMENT AREA PROPOSED ACTION SUMMARY—Continued

2008 NAAQS nonattainment area	2018–2020 design value (DV) (ppm)	2008 NAAQS attained by the serious attainment date	2020 4th highest daily maximum 8-hr average (ppm)	Area failed to attain 2008 NAAQS but state requested 1-year attainment date extension based on 2020 4th highest daily maximum 8-hr average ≤0.075 ppm
New York-N. New Jersey-Long Island, CT-NJ-NY.	0.082	Failed to Attain	0.080	No.

* In a letter to the Texas Commission on Environmental Quality dated June 30, 2021, EPA Region 6 indicated that it did not concur on EE demonstrations for the Dallas-Fort Worth area submitted to the EPA on May 28, 2021; a copy of this letter and the supporting EPA technical review is provided in the docket for this rulemaking.

B. Proposed Severe Area SIP Submission and Controls Implementation Deadlines

In the April 2022 proposal, the EPA also solicited comment on adjusting the due dates, in accordance with CAA section 182(i), for SIP submissions and implementation deadlines for all SIP requirements that would apply to newly reclassified Severe areas (*see* CAA sections 172(c)(1) and 182(a)(b)(c) and (d), and 40 CFR 51.1100 *et seq.*). Under CAA section 181(b)(2), Serious nonattainment areas that fail to attain the 2008 ozone NAAQS by the applicable attainment date for such areas will be reclassified as Severe by operation of law upon the effective date of the final reclassification action. Each responsible state air agency must subsequently submit a SIP revision that satisfies the air quality planning requirements for a Severe area under CAA section 182(d), and they must attain the standard by July 20, 2027 (within 15 years of initial designation). For areas reclassified as Severe, SIP submissions must apply the more stringent major source threshold of 25 tons per year (tpy) [12] for reasonably available control technology (RACT) and nonattainment new source review (NNSR), and the more stringent NNSR emissions offset ratio of 1.3:1.[13] In order to fulfill their Severe area SIP submission requirements, states may, where appropriate, certify that existing SIP provisions for an area are adequate to address one or more Severe area requirement(s). Such certifications must be submitted as SIP revisions.

On July 20, 2012, when final nonattainment designations became effective for the 2008 ozone NAAQS, states responsible for areas initially classified as Severe were required to prepare and submit SIP revisions by deadlines relative to that effective date. For those areas, the submission deadlines ranged from 2 to 10 years after July 20, 2012, depending on the SIP element (*e.g.,* 2 years for the RACT SIP and vehicle miles traveled (VMT) offset demonstration, 4 years for the attainment demonstration, 10 years for the CAA section 185 fee program). Initial Severe areas were also required to implement RACT as expeditiously as practicable but no later than January 1 of the 5th year after July 20, 2012 (*i.e.,* January 1, 2017). Those deadlines have all now passed, and the EPA proposed to use its discretion under CAA section 182(i) to adjust the SIP deadlines that would otherwise apply.[14]

1. Submission Deadlines for SIP Revisions

The EPA proposed a SIP submission deadline of 18 months after the effective date of reclassification to address the CAA section 185 fee program, VMT offset demonstration, and reasonably available control measures (RACM) and RACT requirements. This deadline is consistent with that for all other Severe area plan elements required under CAA sections 172(c)(1) and 182(a)(b)(c) and (d), and 40 CFR 51.1100 *et seq.*

2. Implementation Deadline for Required Controls

As required by 40 CFR 51.1108(d) the state must provide for implementation of all control measures needed for attainment no later than the beginning of the attainment year ozone season.[15] Further, the EPA proposed that any controls that air agencies determine are needed for meeting CAA requirements must be implemented as expeditiously as practicable but no later than 18 months from the proposed SIP submission deadline. These controls include any identified RACT, and any needed transportation control strategies or transportation control measures (TCMs) indicated in the VMT offset demonstration. The EPA requested comment on (1) aligning the implementation deadlines for RACT and transportation-related controls; (2) on requiring that any controls needed for meeting reasonable further progress (RFP) or timely attainment of the 2008 ozone NAAQS be implemented as expeditiously as practicable but no later than 18 months after the proposed SIP submission deadline, and (3) on providing an overall 36-month schedule for SIP submission and controls implementation.

II. Responses To Comments and Final Actions

The public comment period for the EPA's April 2022 proposal closed on June 13, 2022, and included a public hearing held on May 9, 2022. The comments received during this period and the public hearing transcript can be found in the docket for this action. A majority of commenters supported the EPA's proposal to determine that one area attained the 2008 ozone NAAQS by the applicable attainment date, to deny a requested 1-year attainment date extension for the Houston area, and to reclassify to Severe the nonattainment areas that did not attain the 2008 ozone NAAQS by the applicable attainment date and do not qualify for an attainment date extension. Our final

[12] ''For any Severe Area, the terms 'major source' and 'major stationary source' include (in addition to the sources described in section 7602 of this title) any stationary source or group of sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 25 tons per year of volatile organic compounds.'' CAA section 182(d).

[13] *See* CAA section 182(d)(2). If a state's plan requires all existing major sources in the nonattainment area to use best available control technology for VOCs consistent with CAA section 169(3), the required offset ratio is 1.2 to 1.

[14] For additional discussion on certain Severe area requirements, *see* 87 FR 21825 (April 13, 2022).

[15] ''Attainment year ozone season'' is defined as the ozone season immediately preceding a nonattainment area's maximum attainment date (*see* 40 CFR 51.1100(h)), with the attainment year being the calendar year corresponding with that final ozone season for determining attainment.

actions are summarized in Table 2 of this action.

TABLE 2—2008 OZONE SERIOUS NONATTAINMENT AREA FINAL ACTION SUMMARY

2008 NAAQS nonattainment area	Attained by the attainment date	Failed to attain by the attainment date	Extension of the serious area attainment date to July 20, 2022
Dallas-Fort Worth, TX		X	
Denver-Boulder-Greeley-Ft. Collins-Loveland, CO		X	
Greater Connecticut, CT	X		
Houston-Galveston-Brazoria, TX		X	
Morongo Band of Mission Indians		X	
New York-N. New Jersey-Long Island, CT-NJ-NY		X	

The EPA is responding to certain comments in this section of the preamble. The remaining comments and the EPA's responses can be found in the Response to Comments document, which is found in the docket for this rulemaking. To access the Response to Comments document, please go to *http://www.regulations.gov,* and search for Docket No. EPA–HQ–OAR–2021–0741, or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

A. Determinations of Attainment by the Attainment Date

Pursuant to section 181(b)(2)(A) of the CAA and 40 CFR 51.1103 and after considering comments received, the EPA is making a final determination that the Greater Connecticut Serious nonattainment area listed in Table 2 of this action attained the 2008 ozone NAAQS by the applicable attainment date of July 20, 2021. Once effective, this final action satisfies the EPA's obligation pursuant to CAA section 181(b)(2)(A) to determine, based on an area's air quality as of the attainment date, whether the area attained the standard by the applicable attainment date. The effect of a final determination of attainment by an area's attainment date is to discharge the EPA's obligation under CAA section 181(b)(2)(A), and to establish that, in accordance with CAA section 181(b)(2)(A), the area will not be reclassified for failure to attain by the applicable attainment date.

This determination of attainment does not constitute a redesignation to attainment as provided for under CAA section 107(d)(3). The EPA may redesignate an area if the state meets additional statutory criteria, including the EPA approval of a state plan demonstrating maintenance of the air quality standard for 10 years after redesignation, as required under CAA section 175A. As for all NAAQS, the EPA is committed to working with states that choose to submit redesignation requests for areas that are attaining the 2008 ozone NAAQS.

The EPA did not receive adverse comments on its proposed determination of attainment for the Greater Connecticut area. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to Comments document in the docket for this action.

B. Determinations of Failure To Attain and Reclassification, and Denial of Requested 1-Year Attainment Date Extension

Pursuant to CAA section 181(b)(2) and after considering comments received, the EPA is finalizing its proposed determinations that the five Serious nonattainment areas listed in Table 2 of this action failed to attain the 2008 ozone NAAQS by the applicable attainment date of July 20, 2021. Therefore, upon the effective date of this final action, these five areas will be reclassified, by operation of law, as Severe for the 2008 ozone NAAQS. Once reclassified as Severe, these areas will be required to attain the standard ''as expeditiously as practicable'' but no later than 15 years after the initial designation as nonattainment, which in this case would be no later than July 20, 2027. If any of these areas attains the 2008 ozone NAAQS, the relevant state may request redesignation to attainment, provided the state can demonstrate that the criteria under CAA section 107(d)(3)(E) are met.[16]

Included in these five areas is the Houston area, for which the EPA is finalizing its proposed denial of the TCEQ request to extend the Houston Serious area attainment date by one year from July 20, 2021, to July 20, 2022.[17] A majority of commenters supported the EPA's proposal to deny the Houston area attainment date extension request, to determine that the area failed to attain by the applicable attainment date, and to reclassify the area as Severe. We also received an adverse comment from TCEQ on our proposed action, which is addressed in the Response to Comments document in the rulemaking docket for this action. As detailed in the Response to Comments document, TCEQ acknowledged that the CAA grants the EPA discretion in acting on attainment date extension requests, but urged the EPA to grant Texas's request on the basis that the area had met the two qualifying criteria. We think it is reasonable, given the statute's goal of expeditious attainment of the NAAQS in order to protect public health and the environment, to consider available information that demonstrates that Houston could not have attained by an extended attainment date or qualified for a second extension, and that indicates that the population impacted by the Agency's decision already bears a disproportionate burden of pollution. Specifically, as discussed in the proposal, the EPA's analysis of existing pollution burden found that there are communities residing and working near violating ozone monitors in the Houston area and the Houston Ship Channel that are exposed to a significant and disproportionate burden of ozone pollution and other sources of pollution (*e.g.,* vehicle traffic and particulate matter emissions) compared to the greater Houston area and the U.S. as a whole.[18] The existing pollution burden on the population that would be impacted by the EPA's action on the state's request is a relevant consideration where the EPA is exercising its judgment about whether or not to issue a determination that

[16] More information about redesignation is available at *https://www.epa.gov/ozone-pollution/redesignation-and-clean-data-policy-cdp.*

[17] Baer, Tonya, Director, Office of Air, TCEQ. ''Request for a One-Year Extension of the Houston-Galveston-Brazoria (HGB) 2008 Eight-Hour Ozone Standard Attainment Date.'' April 5, 2021.

[18] *See* 87 FR 21825, 21834 (April 13, 2022).

would have the effect of immediately requiring more stringent pollution controls or providing additional time to see whether air quality would resolve without those controls.

The EPA recognizes that delays in issuing this final rulemaking have had the practical effect of providing an extra year for the Houston area to attain the 2008 ozone NAAQS, because the contemplated extended attainment date would have been July 20, 2022. Regardless, the EPA continues to have an obligation to act on TCEQ's request, and the basis articulated in the proposal and in the RTC for denying TCEQ's request is reasonable and consistent with the Agency's analytic approach when evaluating requests from other states seeking extensions under the same statutory provision for other ozone NAAQS.[19] We also note that certified data now available for the period 2019–2021 confirm the preliminary assessment on air quality trends in the proposal, showing that the Houston area did not attain by the extended date, and does not qualify for a second extension. The import of the air quality information in the record alone would support a denial. The EPA is, therefore, finalizing its denial of TCEQ's requested 1-year attainment date extension for the Houston area based upon the Agency's analysis of air quality trends. Denying the *extension* request and determining that the Houston area failed to attain the 2008 ozone NAAQS by its July 20, 2021, attainment date will, by operation of law, include the Houston area among the other areas being reclassified to Severe for the 2008 ozone NAAQS and trigger the deadlines associated with the set of more protective attainment planning and control requirements for those areas.

With respect to the remaining areas included in this final action, a majority of commenters supported the EPA's proposal to determine that they failed to attain by the applicable attainment date and to reclassify those areas as Severe. We also received several adverse comments on our proposed determinations, some of which are addressed below. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to Comments document in the rulemaking docket for this action.

Comment: Several commenters opposed reclassifying the Denver area to Severe nonattainment, claiming that the environmental benefits of the action do not outweigh the economic costs. One commenter claimed that the EPA is ''required to determine whether the benefits of a regulation justify the costs'' and that the EPA should not adopt the regulation because ''the programs required by a downgrade will not achieve any reduction in ozone.'' The commenter claims that E.O. 12866 gives the EPA an option to decline to reclassify the area, and that the E.O. requires the EPA to assess the costs and benefits of the reclassification as a ''significant regulatory action'' because it will cost individuals and companies in Colorado more than $1 billion annually. The commenter also stated that it is time for the EPA to consider alternative regulations that would ''give Colorado an incentive to achieve the ozone standard, while imposing the least burden on society'' and cited to E.O. 12866 for performance objectives rather than programs.

Response: The EPA disagrees with these comments. CAA section 181(b)(2)(A) states that ''the Administrator shall determine, based on the area's design value (as of the attainment date), whether the area attained the standard by that date. Except for any Severe or Extreme area, any area that the Administrator finds has not attained the standard by that date shall be reclassified by operation of law . . . to the higher of—(i) the next higher classification for the area or (ii) the classification applicable to the area's design value . . . .'' This provision unambiguously requires the EPA to determine whether an area timely attained ''based on the area's design value (as of the attainment date).'' The area's design value as of its attainment date is the sole criterion that the EPA is permitted to consider in determining whether an area has timely attained. With respect to reclassification, the statute is similarly restrictive: *any* area that the Administrator finds has not attained by its attainment date *shall* be reclassified *by operation of law.* The Act exempts from reclassification Severe or Extreme areas and limited other areas (*e.g.,* an area that can demonstrate, under CAA section 179B(b), that the area would have attained by the applicable attainment date, but for emissions emanating from outside of the United States). Outside of limited explicit exceptions, Congress made the judgment that reclassification would apply to areas that fail to attain the NAAQS on time and left no determination or even action for the EPA to carry out. The reclassification happens ''by operation of law'' when the EPA makes the determination that an area has failed to attain by its attainment date, and there is no Agency judgment or consideration of factors—cost, benefit, or otherwise. *Cf. Sierra Club* v. *EPA,* 294 F.3d 155 (D.C. Cir. 2002) (rejecting the EPA's decision not to reclassify a downwind nonattainment area that failed to timely attain due to transported pollution from upwind states). Accordingly, the EPA does not consider cost in the reclassification of areas that fail to attain the ozone standard. We also do not agree that E.O. 12866 provides the EPA with any option not to reclassify. Nothing in the E.O. purports to override the mandatory duty established in the Clean Air Act, nor could it. E.O. 12866 (*see* 58 FR 51735, October 4, 1993) gives the Office of Management and Budget (OMB) the authority to review regulatory actions that are categorized as ''significant'' under section 3(f) of E.O. 12866. In their corresponding E.O. 12866 guidance, OMB listed types of regulatory actions that are exempt from OMB review, including ''area designations of air quality planning purposes.'' [20] The EPA has historically interpreted its ozone determination of attainment actions to fall in this exempted category because these action involve determinations based on air quality, responding to the CAA requirement to determine whether areas designated nonattainment for an ozone NAAQS attained the standard by the applicable attainment date, and to take certain steps for areas that failed to attain.[21] Findings of failure to attain under CAA section 181(b)(2) are based on air quality considerations, and reclassifications must occur by operation of law in light of certain air quality conditions. The statutory requirements are clearly defined with respect to the differently classified areas, and those requirements are automatically triggered by classifications that, in turn, are triggered by air quality values. Congress has not authorized or directed the EPA to consider cost in this process, and E.O. 12866 does not provide any further authority or requirement to do so. With respect to the concern that the reclassification will cost individuals and companies in Colorado more than $1 billion annually, the commenter bases that estimate on information he obtained related to the cost of providing federal RFG in the Denver area. We respond to this comment in detail in the Response to Comments document in the docket for this action. In that response

[19] *See* 87 FR 21842 (April 13, 2022).

[20] *See* ''Guidance for Implementing E.O. 12866'' (October 12, 1993) at p. 8 and Appendix C; available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/assets/inforeg/eo12866_implementation_guidance.pdf.*

[21] *See, e.g.,* 81 FR 26697, 26707 (May 4, 2016).

we conclude that the cost of implementing the federal RFG program in the Denver area will be approximately $13.3 million per year.

Comment: Several commenters opposed the reclassification of the Denver area because Colorado has undertaken many efforts to reduce ozone precursor emissions. One commenter asserted that the economic impacts from reclassifying the area will be ''felt across communities and industries for years to come.'' Two commenters pointed to VMT growth offset requirements for Severe nonattainment areas, with one contending that the ''EPA should not mandate air quality measures that Colorado residents have so recently rejected.'' Two commenters stated that the EPA should use incentives, not mandates, to improve air quality. Commenters pointed to federal actions that will reduce ozone as justification for not reclassifying the Denver area.

Response: The EPA agrees that the state has taken significant regulatory steps to reduce ozone precursor emissions but disagrees that these steps are a basis to refrain from reclassifying the area. Regardless of ozone trends or of the state's actions to date, the EPA has a mandatory duty under CAA section 181(b)(2)(A) to determine whether the Denver area attained by its July 20, 2021, attainment date based on the area's design value as of that date. As previously stated, the CAA does not allow the EPA to consider economic impacts in assessing whether an area has attained the NAAQS by the applicable date. Instead, CAA section 181(b)(2) requires the EPA to make the determination of attainment based solely on the area's DV, which is derived entirely from monitored air quality data.

Regarding VMT growth offsets, CAA section 182(d)(1)(A) requires that Severe and Extreme ozone nonattainment areas identify and adopt specific and enforceable transportation control measures to offset any growth in emissions associated with an increase in VMT. The first steps for addressing the CAA's VMT offset provision are for the state to determine if there has been any growth in emissions due to increased VMT and, if there has been an increase in emissions, to quantify the magnitude of that increase. If there is any increase in emissions, the state would select the control measures to offset the identified growth in emissions. The EPA has issued guidance on these calculations and provided a tool to be used with the MOVES3 emission factor model.[22] [23] In this final notice, the EPA is not prescribing that any specific measures be adopted by areas being reclassified as Severe, nor would it be appropriate to do so. The nonattainment area requirements in the CAA include a range of measures to reduce emissions that are to be implemented throughout the entire nonattainment area. The VMT offset guidance referenced above provides for including emission reductions from ''clean car technology'' in demonstrations for meeting CAA section 182(d)(1)(A) requirements. State air agencies continue to have flexibility in how they can tailor and implement emission reduction measures within each nonattainment area in order to attain the standard as expeditiously as practicable.

C. Severe Area SIP Submission and Controls Implementation Deadlines

Pursuant to CAA section 182(i) and after considering comments received, the EPA is finalizing, with one exception for the CAA section 185 fee program, its proposed deadlines for Severe area SIP revisions, and implementation of RACT and any needed transportation control strategies or TCMs indicated in the VMT offset demonstration. Specifically, SIP revisions required for all newly reclassified Severe areas must be submitted no later than 18 months after the effective date of reclassification. Any controls that air agencies determine are needed for meeting CAA requirements must be implemented as expeditiously as practicable but no later than 18 months from the SIP submission deadline, which would provide an overall 36-month schedule for SIP submission and controls implementation for reclassified Severe areas. For the CAA section 185 fee program SIP, the EPA is finalizing a submittal deadline of 36 months after the effective date of reclassification.

The EPA received several significant adverse comments on our proposed deadlines, which are addressed as follows. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to Comments document in the docket for this action.

Comment: The EPA received several comments requesting that we modify the SIP submission and/or controls implementation deadlines for reclassified Severe areas. One commenter considered the overall 36-month schedule as adequate for regulatory development and SIP preparation and submission, but insufficient for new major sources to plan, budget and install new emissions controls, and requested 48–60 months to allow the owners of affected sources to comply. Another commenter stated that any control measures that can be implemented prior to the 2026 ozone season will contribute to compliance of the standard by the July 20, 2027, attainment date, and requested that the EPA extend the controls implementation deadline to the beginning of their area's attainment year ozone season (March 1, 2026) in order to maximize the time to get additional reductions implemented before the final ozone season used for compliance with the ozone NAAQS.

Response: The EPA disagrees with the commenters' requested extensions to the proposed deadlines for SIP submissions and controls implementation, which we contend would unduly delay emissions reductions and improvements to air quality in reclassified Severe areas. The request of 48–60 months to allow for source compliance did not specify whether this time allowance was inclusive of, or in addition to, their suggested 36 months for SIP preparation and submission. Assuming an effective date for this final action in November 2022, and the commenter's request for 48–60 months for SIP submission and implementation, the requested schedule would extend the controls implementation deadline to almost the end of the Severe area attainment year in the case of 48 months (*i.e.,* November 2026); and past the July 20, 2027, Severe area attainment date in the case of 60 months (*i.e.,* November 2027). The EPA's overall 36-month schedule would result in a controls implementation deadline of approximately November 2025, shortly before the beginning of Severe area attainment year and just a few months before the other commenter's requested implementation deadline of March 1, 2026.

The EPA maintains that the adopted SIP submission and implementation schedule balances the goals of robust SIP revisions, expeditious and meaningful emissions reductions, and consistency across submissions (per CAA section 182(i)) for areas reclassified as Severe. SIP revisions to

[22] *Implementing Clean Air Act Section 182(d)(1)(A): Transportation Control Measures and Transportation Control Strategies to Offset Growth in Emissions Due to Growth in Vehicle Miles Travelled,* EPA–420–B–12–053, Aug. 2012; available at *https://www.epa.gov/state-and-local-transportation/vehicle-miles-travelled-vmt-offset-demonstration-guidance.*

[23] The MOVES3 VMT offset tool can be found under ''Tools to develop special case MOVES3 inputs'' at *https://www.epa.gov/moves/tools-develop-or-convert-moves-inputs.*

address RACM/RACT requirements and other required Severe area plan elements will be due 18 months after the effective date of reclassification, which provides more planning time than the submission deadlines in previous 2008 ozone reclassification actions (approximately 12 months after the effective date of reclassification) and could contribute to states determining that additional controls are reasonable (compared to a shorter planning timeframe). We do not find it appropriate to provide a SIP submission deadline of 36 months from the effective date of this final action and an overall schedule of 48–60 months for controls implementation because this would unduly delay implementation late into the Severe area DV period (2024–2026) or beyond the Severe area attainment date of July 20, 2027. Further, the EPA considers it reasonable to require that any controls determined as needed for meeting CAA requirements must be implemented as expeditiously as practicable but no later than 18 months from the proposed SIP submission deadline. This implementation deadline in November 2025 will correspond approximately with the beginning of the Severe are attainment year (January 1, 2026) and will treat areas with varying ozone season start dates consistently per CAA section 182(i).

Comment: The EPA received a comment from an air agency asserting that the proposed 18-month deadline for submittal of CAA section 185 penalty fee programs, at the same time as the attainment demonstration, RFP, and RACT SIP revisions, is unnecessary and imposes undue burden on states. They further argue that it is unnecessary, noting that for initial Severe areas, the Act specifically sets a later deadline for the CAA section 185 fee program than for the other elements. The commenter suggests the EPA provide at least an additional 18 months, because implementation of a CAA section 185 fee program is a penalty for failing to attain the NAAQS by the attainment date. The program therefore could not become effective until the calendar year following the July 20, 2027, attainment date, at the earliest. Therefore, extending the submittal deadline would not create significant implementation issues and would not significantly limit the EPA's review time to act on the submittal prior to the attainment date.

Response: As noted previously, the EPA is finalizing a later submittal date for the CAA section 185 fee program than what was proposed, setting the due date 3 years from the effective date of reclassification (18 months longer than the proposed deadline). The EPA agrees with the commenter that under this new deadline it will still be possible to establish approved CAA section 185 fee programs for reclassified areas ahead of when they are needed, which in this case is the Severe attainment date of July 20, 2027. The new due date would be in approximately mid-2025, nearly 2 years ahead of the attainment date. Although this is not as much lead time as the CAA provides for initial Severe areas, the CAA allows the EPA to adjust deadlines as appropriate for reclassified areas per CAA section 182(i), and we agree that this deadline will not create implementation issues or unreasonably limit EPA's review time ahead of the attainment date. Although we do not believe the development of the CAA 185 program will pose an undue burden on states, we do believe, in light of related comments about the challenges with completing other Severe area requirements within the 18 months provided, that allowing more time for the CAA section 185 program could allow more focused attention to those other elements in the first 18 months following reclassification. To the degree that states want to take advantage of the administrative efficiency of adopting the CAA section 185 program element along with other required Severe area SIP elements, which was a benefit the EPA noted at proposal, they would still have the option to submit their CAA section 185 programs with the other elements.

D. Reformulated Gasoline

As discussed in the April 2022 proposal, the CAA prohibits the sale of conventional gasoline in any ozone nonattainment area that is reclassified as Severe and requires that federal reformulated gasoline (RFG) must be sold instead.[24] The prohibition on the sale of conventional gasoline takes effect one year after the effective date of the reclassification (*see* CAA section 211(k)(10)(D); 211(k)(5)), November 7, 2023. The primary difference between conventional gasoline and federal RFG is that federal RFG must comply with a maximum Reid Vapor Pressure (RVP) per-gallon standard of 7.4 pounds per square inch during the summer season.[25] [26] Higher maximum RVP per-gallon standards apply to conventional gasoline during the summer season.[27] Also, as discussed in the proposal, the reclassification of certain areas to Severe will not result in any changes to where federal RFG is sold because the sale of federal RFG is already required in the following nonattainment areas: New York Metropolitan area, the Houston area, and the Morongo Band of Mission Indians area. A SIP revision is not required in order for the prohibition on the sale of conventional gasoline to take effect.

The EPA proposed to reclassify the Chicago area as Severe for the 2008 ozone NAAQS in the April 2022 proposal. However, the area attained the 2008 ozone NAAQS based on 2019–2021 air quality data, and as discussed in Section I of this action, the EPA has redesignated the Chicago area to attainment since its April proposal. Therefore, federal RFG is not required for this area for the 2008 ozone NAAQS, although federal RFG continues to be required in the area for other reasons.

The reclassification of the Dallas-Fort Worth area as Severe results in the current federal RFG area being expanded to include all 10 counties in the 2008 ozone NAAQS nonattainment area effective one year after the effective date of this final rule.[28] *See* Section I of this action for more information on this area.

The reclassification of the Denver area as Severe for the 2008 ozone NAAQS results in the prohibition of the sale of conventional gasoline throughout the entire nonattainment area under CAA section 211(k)(10)(D) and section 211(k)(5) effective 1 year after the effective date of this final rule, November 7, 2023. This is a new requirement for the area as federal RFG is not currently required to be sold in any part of the Denver 2008 ozone NAAQS nonattainment area.

The EPA received comments on the CAA requirement to sell federal RFG in the Denver area, which are addressed as follows. For a discussion of additional comments received on the proposal and responses to those comments, please see the Response to Comments document in the docket for this action.

Comment: One commenter raised concerns about making the transition from conventional gasoline to federal RFG if the transition was required to occur during the summer of 2023. The commenter noted that such a transition presented two challenges: first, because it would occur during the summer, which is peak season for gasoline

[24] *See* 87 FR 21825 (April 13, 2022).

[25] *See* 40 CFR 1090.215(a)(3).

[26] The summer season means the period from June 1 through September 15 for retailers and wholesale purchaser-consumers, and May 1 through September 15 for all other persons, or an RVP control period specified in a SIP if it is longer (*see* 40 CFR 1090.80).

[27] *See* 40 CFR 1090.215(a)(1) and (2).

[28] The sale of conventional gasoline is already prohibited in Collin, Dallas, Denton, and Tarrant Counties because Texas chose to opt the 4-county Dallas-Fort Worth 1-hour ozone nonattainment area into federal RFG (57 FR 46316, October 8, 1992, and 40 CFR 1090.285(c)).

demand and a time during which the current pipeline system supplying the market operates at a very high utilization rate, and second, because requiring RFG to be implemented during the summer of 2023 would not provide fuel suppliers with sufficient time to complete necessary projects to implement the transition to RFG. The commenter pointed to several actions that fuel suppliers need to complete in order to supply RFG to the Denver area including analyzing their ability to produce fuel choices, their unique market structure, and the existing fuel distribution network and obtaining permits for construction projects and rail loading. The commenter opined that the 1-year clock for the implementation of RFG should start after the end of the 2022 summer fuel season ends on September 15, 2022.

Response: The EPA understands the concerns that the commenter raised concerning the challenges that would be presented if the transition to RFG were to occur during the summer season that runs from June 1 to September 15 for wholesale purchaser-consumers and from May 1 to September 15 for all other persons.[29] The EPA also understands the type of analyses and work that will need to be completed in order to supply RFG to the Denver area. With respect to areas that are reclassified as Severe for the ozone NAAQS, CAA section 211(k)(10)(D) states that, ''Effective one year after the reclassification of any ozone nonattainment area as a Severe ozone nonattainment area under section 7511(b) of this title, such Severe area shall also be a ''covered area'' for purposes of this subsection.'' [30] The reclassification of the Denver area to Severe for the 2008 ozone NAAQS will not be effective until after the 2022 summer season for fuel sales ends on September 15, 2022. While the CAA requires that Denver be an RFG covered area one year after the effective date of the reclassification, the RFG maximum Reid Vapor Pressure (RVP) per-gallon standard of 7.4 pounds per square inch (psi) will not apply for the first time until June 1, 2024, for wholesale purchaser-consumers and May 1, 2024, for all other persons.[31] This will provide fuel suppliers with approximately 18 months after the effective date of the reclassification to complete preparations for the sale of RFG in the Denver area. It will also be approximately two years after EPA proposed to reclassify the Denver area as Severe for the 2008 ozone NAAQS.[32]

III. Environmental Justice (EJ) Impacts

As discussed in Section II.B of this action, the EPA is finalizing its proposal to deny a request for a 1-year attainment date extension for the Houston area and to determine that the area failed to attain the 2008 ozone NAAQS by the attainment date. Denying the extension request is based on our assessment of air quality trends in the Houston area. Given our findings that the area is not likely to attain by an extended attainment date or qualify for a second extension, we also considered the impact of our action on existing air pollution burdens in the area. Screening-level EJ analyses indicate an already disproportionate air pollution burden for communities near the Houston Ship Channel and communities around violating ozone regulatory monitor sites in the Houston area. The area's reclassification to Severe will result in more timely application in this area of the Act's more stringent controls associated with that higher classification. Expeditious attainment of the NAAQS will protect all those residing, working, attending school, or otherwise present in those areas, including communities of color and low-income communities.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is exempt from review by the Office of Management and Budget (OMB) because it responds to the CAA requirement to determine whether areas designated nonattainment for an ozone NAAQS attained the standard by the applicable attainment date, and to take certain steps for areas that failed to attain.

B. Paperwork Reduction Act (PRA)

This rule does not impose any new information collection burden under the PRA not already approved by the OMB. This action does not contain any information collection activities and serves only to make final: (1) a determination that a certain Serious nonattainment area listed in Table 2 in this action attained the 2008 ozone standards by the July 20, 2021, attainment date; (2) determinations that certain Serious nonattainment areas listed in Table 2 in this action failed to attain the 2008 ozone standards by the July 20, 2021, attainment date where such areas will be reclassified as Severe nonattainment for the 2008 ozone standards by operation of law upon the effective date of the final reclassification action; and (3) adjust any applicable implementation deadlines.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The determinations of attainment and failure to attain the 2008 ozone standards (and resulting reclassifications) do not in and of themselves create any new requirements beyond what is mandated by the CAA. Instead, this rulemaking only makes factual determinations, and does not directly regulate any entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The division of responsibility between the federal government and the states for purposes of implementing the NAAQS is established under the CAA.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law.

The EPA has identified tribal areas within the nonattainment areas covered by this rulemaking that would be potentially affected by this final action. Specifically, two of the nonattainment areas addressed in this action have tribes located within their boundaries: the Greater Connecticut, CT, area (Mashantucket Pequot Tribal Nation and Mohegan Indian Tribe), and the New York-Northern New Jersey-Long Island, CT-NJ-NY area (Shinnecock Indian

[29] *See* 40 CFR 1090.80 for the definition of ''summer season.''

[30] *See* CAA section 211(k)(10)(D).

[31] Other requirements that apply to RFG such as benzene and sulfur content are identical to requirements that apply to conventional gasoline.

[32] *See* 87 FR 21825 (April 13, 2022).

Nation). One of the nonattainment areas addressed in this document is a separate tribal nonattainment area (Morongo Band of Mission Indians area).

The EPA has concluded that the final rule may have tribal implications for these tribes for the purposes of Executive Order 13175 but would not impose substantial direct costs upon the tribes, nor would it preempt tribal law. As noted in our proposed rule, a tribe that is part of an area that is reclassified from Serious to Severe nonattainment is not required to submit a tribal implementation plan revision to address new Severe area requirements.[33] However, the NNSR major source threshold and offset requirements will change for stationary sources seeking preconstruction permits in any nonattainment areas newly reclassified as Severe (Section II.D.1 of this notice), including on tribal lands within these nonattainment areas. Areas that are already classified Severe for a previous ozone NAAQS are already subject to these higher offset ratios and lower thresholds, so a reclassification to Severe for the 2008 ozone NAAQS would have no effect on NNSR permitting requirements for tribal lands in those areas.

The EPA has communicated or intends to communicate with the potentially affected tribes located within the boundaries of the nonattainment areas addressed in this final action, including offering government-to-government consultation, as appropriate.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this determination is contained in Section III of this preamble, ''Environmental Justice (EJ) Impacts,'' and the relevant documents have been placed in the public docket for this action.

With respect to the determinations of whether areas have attained the NAAQS by the attainment date, the EPA has no discretionary authority to address EJ in these determinations. The CAA directs that within 6 months following the applicable attainment date, the Administrator shall determine, based on the area's design value as of the attainment date, whether the area attained the standard by that date. CAA section 181(b)(2)(A). Except for any Severe or Extreme area, any area that the Administrator finds has not attained the standard by that date shall be reclassified by operation of law to either the next higher classification or the classification applicable to the area's design value. *Id.*

K. Congressional Review Act (CRA)

This rule is exempt from the CRA because it is a rule of particular applicability. The rule makes factual determinations for specific entities and does not directly regulate any entities. The determinations of attainment and failure to attain the 2008 ozone NAAQS (and resulting reclassifications) and the denial of a 1-year attainment date extension request do not in and of themselves create any new requirements beyond what is mandated by the CAA.

L. Judicial Review

Section 307(b)(1) of the CAA governs judicial review of final actions by the EPA. This section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit: (i) when the agency action consists of ''nationally applicable regulations promulgated, or final actions taken, by the Administrator,'' or (ii) when such action is locally or regionally applicable, but ''such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.'' For locally or regionally applicable final actions, the CAA reserves to the EPA complete discretion whether to invoke the exception in (ii).

This final action is ''nationally applicable'' within the meaning of CAA section 307(b)(1). In this final action, the EPA is applying a uniform process and standard to areas across the country to make determinations regarding attainment of the 2008 ozone NAAQS for the majority of areas that remain designated and classified as Serious nonattainment for these NAAQS. All listed areas that have failed to attain by the Serious area attainment date[34] are reclassified to Severe upon the effective date of this final action and are subject to the same deadlines established pursuant to CAA section 182(i) for revising state implementation plans and implementing control requirements associated with the Severe area classification. While many areas that were initially designated nonattainment for the 2008 ozone NAAQS in 2012 have, in the intervening decade, come into attainment of the NAAQS, the remaining nonattainment areas subject to this final rulemaking are located in six states across a wide geographic area and fall within four of the ten EPA regions and six judicial circuits. The areas affected by this notice comprise major metropolitan areas in the American South, West, and Northeast, as well as a tribal area in the West. Given that on its face this action addresses areas in states located across a wide geographic area, and uses common, nationwide analytical methods the EPA consistently applies when making determinations regarding attainment, acting on attainment date extension requests, and adjusting deadlines for all newly reclassified areas, this is a ''nationally applicable'' action within the meaning of CAA section 307(b)(1).

In the alternative, to the extent a court finds this final action to be locally or regionally applicable, the Administrator is exercising the complete discretion afforded to him under the CAA to make and publish a finding that this action is based on a determination of ''nationwide scope or effect'' within the meaning of CAA section 307(b)(1).[35] In

[33] *See* 87 FR 21825, 21828 (April 13, 2022).

[34] These areas include the Houston area because the EPA is denying Texas's request to extend the attainment date by one year.

[35] In the report on the 1977 Amendments that revised CAA section 307(b)(1), Congress noted that the Administrator's determination that the ''nationwide scope or effect'' exception applies would be appropriate for any action that has a

deciding to invoke this exception, the Administrator has taken into account a number of policy considerations, including his judgment regarding the benefit of obtaining the D.C. Circuit's authoritative centralized review, rather than allowing development of the issue in other contexts, in order to ensure consistency in the Agency's approach to implementation of the 2008 ozone NAAQS in the majority of the nonattainment areas nationwide that remain classified Serious for the 2008 ozone NAAQS. This final action treats all of the identified Serious nonattainment areas consistently by reclassifying them to Severe and establishing consistent deadlines for all of these areas to submit and implement control measures and other plan elements required for Severe areas. The Administrator finds that this is a matter on which national uniformity is desirable to take advantage of the D.C. Circuit's administrative law expertise and facilitate the orderly development of the basic law under the Act. The Administrator also finds that consolidated review of this action in the D.C. Circuit will avoid piecemeal litigation in the regional circuits, further judicial economy, and eliminate the risk of inconsistent results for different states. The Administrator also finds that a nationally consistent approach to the CAA's mandate concerning reclassification of areas that fail to attain the 2008 ozone NAAQS constitutes the best use of agency resources. The Administrator is publishing his finding that this action is based on a determination of nationwide scope or effect in the **Federal Register** as part of this final rule.

For these reasons, this final action is nationally applicable or, alternatively, the Administrator is exercising the complete discretion afforded to him by the CAA and finds that this final action is based on a determination of nationwide scope or effect for purposes of CAA section 307(b)(1) and is publishing that finding in the **Federal Register**. 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 District of Columbia Circuit by December 6, 2022.

List of Subjects

40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements and Volatile organic compounds.

40 CFR Part 81

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, and Volatile organic compounds.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, parts 52 and 81, title 40, chapter 1 of the Code of Federal Regulations are amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart H—Connecticut

■ 2. Section 52.377 is amended by revising paragraph (u) to read as follows:

§ 52.377 Control strategy: Ozone.

* * * * *

(u) *Determination of attainment for the 2008 ozone standard.* Effective November 7, 2022 EPA is determining that complete, quality-assured and certified ozone monitoring data for 2018–2020 show the Greater Connecticut, CT ozone nonattainment area attained the 2008 ozone NAAQS by its July 20, 2021, attainment deadline. Therefore, EPA has met the requirement pursuant to CAA section 181(b)(2)(A) to determine, based on the area's air quality data as of the attainment date, whether the area attained the standard.

* * * * *

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

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

Subpart C—Section 107 Attainment Status Designations

■ 4. In § 81.305, in the table entitled ''California-2008 8-Hour Ozone NAAQS [Primary and Secondary]'' revise the entry ''Morongo Band of Mission Indians[3]'' to read as follows:

§ 81.305 California.

* * * * *

CALIFORNIA—2008 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date[1]	Type	Date[1]	Type
* * *	*	*	*	*
Morongo Band of Mission Indians[3]	.....	Nonattainment ..	November 7, 2022	Severe.
* * *	*	*	*	*

[1] This date is July 20, 2012, unless otherwise noted.

* * * * * *

[3] Includes Indian country of the tribe listed in this table located in the identified area. Information pertaining to areas of Indian country in this table is intended for CAA planning purposes only and is not an EPA determination of Indian country status or any Indian country boundary. The EPA lacks the authority to establish Indian country land status, and is making no determination of Indian country boundaries, in this table.

scope or effect beyond a single judicial circuit. *See* H.R. Rep. No. 95–294 at 323–24, reprinted in 1977 U.S.C.C.A.N. 1402–03.

* * * * *

■ 5. In § 81.306, in the table entitled ''Colorado-2008 8-Hour Ozone NAAQS [Primary and Secondary]'' revise the entry ''Denver-Boulder-Greeley-Ft. Collins-Loveland, CO: [2]'' to read as follows:

§ 81.306 Colorado.

* * * * *

COLORADO—2008 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
Denver-Boulder-Greeley-Ft. Collins-Loveland, CO: [2]		Nonattainment	November 7, 2022	Severe.
Adams County				
Arapahoe County				
Boulder County				
Broomfield County				
Denver County				
Douglas County				
Jefferson County				
Larimer County (part)				
That portion of the county that lies south of a line described as follows: Beginning at a point on Larimer County's eastern boundary and Weld County's western boundary intersected by 40 degrees, 42 minutes, and 47.1 seconds north latitude, proceed west to a point defined by the intersection of 40 degrees, 42 minutes, 47.1 seconds north latitude and 105 degrees, 29 minutes, and 40.0 seconds west longitude, thence proceed south on 105 degrees, 29 minutes, 40.0 seconds west longitude to the intersection with 40 degrees, 33 minutes and 17.4 seconds north latitude, thence proceed west on 40 degrees, 33 minutes, 17.4 seconds north latitude until this line intersects Larimer County's western boundary and Grand County's eastern boundary.				
Weld County (part)				
That portion of the county that lies south of a line described as follows: Beginning at a point on Weld County's eastern boundary and Logan County's western boundary intersected by 40 degrees, 42 minutes, 47.1 seconds north latitude, proceed west on 40 degrees, 42 minutes, 47.1 seconds north latitude until this line intersects Weld County's western boundary and Larimer County's eastern boundary.				
* * * * * * *				

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

■ 6. In § 81.307, in the table entitled ''Connecticut—2008 8-Hour Ozone NAAQS [Primary and Secondary]'' revise the entry ''New York-N. New Jersey-Long Island, NY-NJ-CT: [2]'' to read as follows:

§ 81.307 Connecticut.

* * * * *

CONNECTICUT—2008 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
* * * * * * *				
New York-N. New Jersey-Long Island, NY-NJ-CT: [2]		Nonattainment	November 7, 2022	Severe.
Fairfield County				
Middlesex County				
New Haven County				

[1] This date is July 20, 2012, unless otherwise noted.

[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

■ 7. In § 81.331, in the table entitled ''New Jersey—2008 8-Hour Ozone NAAQS [Primary and Secondary]'' revise the entry ''New York-N. New Jersey-Long Island, NY-NJ-CT: [2]'' to read as follows:

§ 81.331 New Jersey.

* * * * *

NEW JERSEY—2008 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
New York-N. New Jersey-Long Island, NY-NJ-CT: [2]	.....	Nonattainment ..	November 7, 2022	Severe.
Bergen County				
Essex County				
Hudson County				
Hunterdon County				
Middlesex County				
Monmouth County				
Morris County				
Passaic County				
Somerset County				
Sussex County				
Union County				
Warren County				
* * * * * * *				

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

■ 8. In § 81.333, in the table entitled ''New York—2008 8-Hour Ozone NAAQS [Primary and Secondary]'' revise the entry ''New York-N. New Jersey-Long Island, NY-NJ-CT: [2]'' to read as follows:

§ 81.333 New York.

* * * * *

New York—2008 8-Hour Ozone NAAQS

[Primary and Secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
* * * * * * *				
New York-N. New Jersey-Long Island, NY-NJ-CT: [2]	.....	Nonattainment ..	November 7, 2022	Severe.
Bronx County				
Kings County				
Nassau County				
New York County				
Queens County				
Richmond County				
Rockland County				
Suffolk County				
Westchester County				
Shinnecock Indian Nation [3]				
* * * * * * *				

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.
[3] Includes Indian country of the tribe listed in this table located in the identified area. Information pertaining to areas of Indian country in this table is intended for CAA planning purposes only and is not an EPA determination of Indian country status or any Indian country boundary. The EPA lacks the authority to establish Indian country land status, and is making no determination of Indian country boundaries, in this table.

* * * * *

■ 9. In § 81.344, in the table entitled ''Texas—2008 8-Hour Ozone NAAQS [Primary and Secondary]'' revise the entries ''Dallas-Fort Worth, TX: [2]'' and ''Houston-Galveston-Brazoria, TX: [2]'' to read as follows:

§ 81.344 Texas.

* * * * *

TEXAS—2008 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
Dallas-Fort Worth, TX: [2]		Nonattainment ..	November 7, 2022	Severe.
Collin County				
Dallas County				
Denton County				
Ellis County				
Johnson County				
Kaufman County				
Parker County				
Rockwall County				
Tarrant County				
Wise County				
Houston-Galveston-Brazoria, TX: [2]		Nonattainment ..	November 7, 2022	Severe.
Brazoria County				
Chambers County				
Fort Bend County				
Galveston County				
Harris County				
Liberty County				
Montgomery County				
Waller County				
* * * * * * *				

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

[FR Doc. 2022–20458 Filed 10–6–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 220523–0119; RTID 0648–XC420]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries; General Category October Through November Quota Transfer

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS is transferring 125 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the General category. With this transfer, the adjusted General category October through November 2022 subquota is 177.9 mt. This action is intended to account for an accrued overharvest of 23.5 mt from previous time period subquotas and to provide further opportunities for General category fishermen to participate in the October through November General category fishery, based on consideration of the regulatory determination criteria regarding inseason adjustments. This action applies to Atlantic Tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

DATES: Effective October 5, 2022, through November 30, 2022.

FOR FURTHER INFORMATION CONTACT: Larry Redd, Jr., *larry.redd@noaa.gov,* 301–472–8503, Ann Williamson, *ann.williamson@noaa.gov,* 301–427–8503, or Nicholas Velseboer, *nicholas.velseboer@noaa.gov,* 978–281–9260.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries, including BFT fisheries, are managed under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Atlantic HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

The baseline General and Reserve category quotas are 587.9 mt and 31.2 mt, respectively. The General category baseline subquota is further suballocated to different time periods. Relevant to this action, the subquota for the October through November time period is 76.4 mt. To date for 2022, NMFS has published several actions that have resulted in adjustments to the General and Reserve category quotas, including the allowable carryover of underharvest from 2021 to 2022 (87 FR 5737, February 2, 2022; 87 FR 33049, June 1, 2022; 87 FR 43447, July 21, 2022; 87 FR 54910, September 8, 2022). The current adjusted Reserve category quota is 186.2 mt.

Transfer of 125 mt From the Reserve Category to the General Category

Under § 635.27(a)(9), NMFS has the authority to transfer quota among fishing categories or subcategories after considering the determination criteria provided under § 635.27(a)(8). NMFS has considered all of the relevant determination criteria and their

applicability to this inseason quota transfer. These considerations include, but are not limited to, the following.

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

Regarding the likelihood of closure of the General category fishery if no adjustment is made (§ 635.27(a)(8)(ii) and (ix)), NMFS considered the catches and catch rates of the General category quota to date (including during the summer/fall and winter fisheries in the last several years). NMFS also took into consideration the final rule that set restricted-fishing days for the General Category through November 30, 2022 (87 FR 33056, June 1, 2022). While the General category October through November time period subquota has not yet been exceeded, without a quota transfer at this time, based on catch rates in the last three years in comparison to the available quota, NMFS anticipates it would likely need to close the General category fishery in October. Once the fishery is closed, participants would have to stop BFT fishing activities even though commercial-sized BFT remain available in the areas where General category permitted vessels operate at this time of year. Transferring 125 mt of BFT quota from the Reserve category would account for the 23.5 mt (640.4 mt − 616.9 mt = 23.5 mt) of accrued overharvest from the prior time periods and result in an additional 101.5 mt (125 mt − 23.5 mt = 101.5 mt) being available for the October through November 2022 subquota time period, thus effectively providing limited additional opportunities to harvest the U.S. BFT quota while avoiding exceeding it.

Regarding the projected ability of the vessels fishing under the General category quota to harvest the additional amount of BFT quota transferred before the end of the fishing year (§ 635.27(a)(8)(iii)), NMFS considered General category landings over the last several years and landings to date this year. Landings are highly variable and depend on access to commercial-sized BFT and fishing conditions, among other factors. A portion of the transferred quota covers the 23.5 mt overharvest in the category to date, and NMFS anticipates that General category participants will be able to harvest the additional 101.5 mt of transferred BFT quota by the end of the subquota time period. NMFS may adjust each time period's subquota based on overharvest or underharvest in the prior period and may transfer subquota from one time period to another time period. By allowing for such quota adjustments and transfers, NMFS anticipates that the General category quota would be used before the end of the fishing year. Thus, this quota transfer would allow fishermen to take advantage of the availability of BFT on the fishing grounds and provide a reasonable opportunity to harvest the available U.S. BFT quota.

NMFS also considered the estimated amounts by which quotas for other gear categories of the fishery might be exceeded (§ 635.27(a)(8)(iv)) and the ability to account for all 2022 landings and dead discards. In the last several years, total U.S. BFT landings have been below the available U.S. quota such that the United States has carried forward the maximum amount of underharvest allowed by ICCAT from one year to the next. NMFS recently took such an action to carry over the allowable 127.3 mt of underharvest from 2021 to 2022 (87 FR 33049). NMFS will need to account for 2022 landings and dead discards within the adjusted U.S. quota, consistent with ICCAT recommendations, and anticipates having sufficient quota to do that.

NMFS also considered the effects of the adjustment on the BFT stock and the effects of the transfer on accomplishing the objectives of the FMP (§ 635.27(a)(8)(v) and (vi)). This transfer would be consistent with established quotas and subquotas, which are implemented consistent with ICCAT recommendations (established in Recommendation 21–07), ATCA, and the objectives of the 2006 Consolidated HMS FMP and amendments. In establishing these quotas and subquotas and associated management measures, ICCAT and NMFS considered the best scientific information available, objectives for stock management and status, and effects on the stock. This quota transfer is in line with the established management measures and stock status determinations. Another principal consideration is the objective of providing opportunities to harvest the available General category quota without exceeding the annual quota, based on the objectives of the 2006 Consolidated HMS FMP and amendments, including to achieve optimum yield on a continuing basis and to optimize the ability of all permit categories to harvest available BFT quota allocations (related to § 635.27(a)(8)(x)). Specific to the General category, this includes providing opportunities equitably across all time periods.

Given these considerations, NMFS is transferring 125 mt of the available 186.2 mt of Reserve category quota to the General category. Of this amount, 23.5 mt accounts for preliminary overharvest of the June through August and September time period subquotas, and 101.5 mt is added to the October through November subquota to provide further opportunities for General category fishermen to participate in the October through November General category fishery. Therefore, NMFS adjusts the General category October through November 2022 subquota to 177.9 mt (76.4 mt + 101.5 mt = 177.9 mt) after accounting for the 23.5 mt of overharvest for the prior 2022 time periods and adjusts the Reserve category quota to 61.2 mt (186.2 mt − 125 mt = 61.2 mt). The General category fishery will remain open until November 30, 2022, or until the adjusted General category quota is reached, whichever comes first.

Monitoring and Reporting

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

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

quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act and regulations at 50 CFR part 635 and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that pursuant to 5 U.S.C. 553(b)(B), it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons. Specifically, the regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Providing prior notice and opportunity for public comment on the quota transfer for the October through November 2022 time period is impracticable. The General category fishery is underway, there was an exceedance of the September subquota, and while the October through November subquota has not yet been exceeded, NMFS anticipates that it will likely need to close the General category soon. Delaying the action is contrary to the public interest, not only because it would likely result in a General category closure and associated costs to the fishery, but also administrative costs due to further agency action needed to re-open the fishery after quota is transferred. The delay would preclude the fishery from harvesting BFT that are available on the fishing grounds and that might otherwise become unavailable during a delay. This action does not raise conservation and management concerns. Transferring quota from the Reserve category to the General category does not affect the overall U.S. BFT quota, and available data show the adjustment would have a minimal risk of exceeding the ICCAT-allocated quota. NMFS notes that the public had an opportunity to comment on the underlying rulemakings that established the U.S. BFT quota and the inseason adjustment criteria.

For all of the above reasons, the AA also finds that pursuant to 5 U.S.C. 553(d), there is good cause to waive the 30-day delay in effectiveness.

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

Dated: October 4, 2022.

Jennifer M. Wallace,

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

[FR Doc. 2022–21975 Filed 10–5–22; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 194
Friday, October 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 ENERGY

10 CFR Part 430

[EERE–2017–BT–STD–0023]

RIN 1904–AE00

Energy Conservation Program: Energy Conservation Standards for Microwave Ovens; Extension of Public Comment Period

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

ACTION: Notice of public meeting and extension of public comment period.

SUMMARY: On August 24, 2022 the U.S. Department of Energy (''DOE'') published a supplemental notice of proposed rulemaking (''SNOPR'') to amend the energy conservation standards for microwave ovens. (''August 2022 SNOPR'') This document announces a public meeting to be held in support of that SNOPR and extends the public comment period for the SNOPR by 14 days to allow public comments to be submitted until November 7, 2022.

DATES: DOE will hold a public meeting via webinar on Tuesday, October 11, 2022, from 1:00 p.m. to 3:00 p.m. See section, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants. The comment period for the published August 2022 SNOPR (87 FR 52282) is also extended. DOE will accept comments, data, and information regarding the SNOPR that are received no later than November 7, 2022.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov* under docket number EERE–2017–BT–STD–0023. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–STD–0023, by any of the following methods:

(1) *Email: MWO2017STD0023@ee.doe.gov.* Include the docket number EERE–2017–BT–STD–0023 in the subject line of the message.

(2) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted.

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-2017-BT-STD-0023.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

Dr. Stephanie Johnson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. *Email: ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–6122. *Email: Celia.Sher@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE published a notice of proposed determination (''NOPD'') on August 12, 2021, in which DOE initially determined that current standards for microwave ovens do not need to be amended. 86 FR 44298. DOE provided opportunities for stakeholders to provide written comments and held a public meeting on September 13, 2021, to solicit additional feedback on the analysis. In response to comments received on the NOPD, DOE conducted further investigative testing and manufacturer discussions resulting in an updated engineering analysis. Based on this revised analysis, on August 24, 2022, DOE published the August 2022 SNOPR proposing amended energy conservation standards for microwave ovens. 87 FR 52282. The August 2022 SNOPR provided for the written submission of comments by October 24, 2022.

This notice announces a public meeting that will be held to facilitate discussions among interested parties with regards to DOE's analysis supporting the August 2022 SNOPR and also extends the comment period for that notice until November 7, 2022.

Public Participation

A. Participation in the Webinar

The time and date for the webinar meeting are listed in the **DATES** section at the beginning of this document. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *www.energy.gov/eere/buildings/public-meetings-and-comment-deadlines.* 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. Such persons may submit such request to *ApplianceStandardsQuestions@ee.doe.gov.* Persons who wish to speak should include with their request a computer file in 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 document 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 Webinar

DOE will designate a DOE official to preside at the webinar 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. 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 and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The webinar will be conducted in an informal, conference style. DOE will present a general overview of the topics addressed in the SNOPR, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting the SNOPR. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time allows, 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 the SNOPR. The official conducting the webinar will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the webinar.

A transcript of the webinar will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document. In addition, any person may buy a copy of the transcript from the transcribing reporter. DOE invites public participation in this process through participation in the submission of written comments and information. After the closing of the comment period, DOE will consider all timely-submitted comments and additional information obtained from interested parties, as well as information obtained through further analyses.

Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of public meeting and extension of public comment period.

Signing Authority

This document of the Department of Energy was signed on October 3, 2022, by Mr. Francisco Alejandro Moreno, Acting 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 October 4, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–21922 Filed 10–6–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

10 CFR Part 431

[EERE–2022–BT–STD–0015]

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Open Meetings of the Commercial Unitary Air Conditioner and Commercial Unitary Heat Pump Working Group

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

ACTION: Notice of open meetings and webinars.

SUMMARY: The U.S. Department of Energy (DOE or the Department) announces public meetings and webinars for the Commercial Unitary Air Conditioner (''CUAC'') and Commercial Unitary Heat Pump (''CUHP'') Working Group (''CUAC and CUHP Working Group'').

DATES: See the **SUPPLEMENTARY INFORMATION** section for meeting dates.

ADDRESSES: The next several rounds of public meetings will be held at the U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0121. Please see the **SUPPLEMENTARY INFORMATION** section of this notice to find the specific room in the Forrestal Building for each date. For additional information on attending the public meeting, including webinar registration information, participant instructions, and information about the capabilities available to webinar participants, see the *Public Participation* section of this notice.

FOR FURTHER INFORMATION CONTACT: Mr. Lucas Adin, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–5904. *Email ASRAC@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: If a working group of the Appliance Standards and Rulemaking Federal Advisory Committee (''ASRAC'') is undertaking negotiations, once the working group reaches consensus on the provisions of a proposed rule, a recommendation is made to ASRAC, which may then use such consensus as the basis for making a recommendation to the Department of a proposed rule. The Department, consistent with its legal obligations, may use such consensus as the basis of its proposed rule, which then is published in the **Federal Register**.

On September 1, 2022, DOE published a notice announcing initial meetings of the CUAC and CUHP Working Group, an ASRAC working group. The purpose of the CUAC and CUHP Working Group is to undertake a negotiated rulemaking to discuss and, if possible, reach consensus on a proposed rule for test procedures and energy conservation standards for CUAC and CUHP equipment, as authorized by the Energy Policy and Conservation Act of 1975, as amended. 87 FR 53699. This notice announces the upcoming meetings for this working group.

The open public meetings and webinars will be held on the following dates and times:

—Tuesday, October 11, 2022, from 9:00 a.m. to 5:00 p.m., Forrestal Building, Room 1E–245
—Wednesday, October 12, 2022, from 9:00 a.m. to 3:00 p.m., Forrestal Building, Room 1E–245
—Wednesday, November 9, 2022, from 9:00 a.m. to 5:00 p.m., Forrestal Building, Room 1E–245
—Thursday, November 10, 2022, from 9:00 a.m. to 3:00 p.m., Forrestal Building, Room 1E–245
—Tuesday, November 29, 2022, from 9:00 a.m. to 5:00 p.m., Forrestal Building, Room 1E–245
—Wednesday, November 30, 2022, from 9:00 a.m. to 3:00 p.m., Forrestal Building, Room 1E–245
—Wednesday, December 14, 2022, from 9:00 a.m. to 5:00 p.m., Forrestal Building, Room 6E–069
—Thursday, December 15, 2022, from 9:00 a.m. to 3:00 p.m., Forrestal Building, Room 6E–069

Purpose of Meetings: To negotiate in an attempt to reach consensus on proposed Federal test procedures and energy conservation standards for CUAC and CUHP equipment under the authority of the Negotiated Rulemaking Act (5 U.S.C. 561–570, Pub. L. 104–320).

Public Participation: The times, dates, and locations of the public meetings are listed previously in this **SUPPLEMENTARY INFORMATION** section. If you plan to attend the public meeting, please notify the ASRAC staff at *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals visiting DOE Headquarters are subject to advance security screening procedures. Any foreign national wishing to participate in the meetings, please notify DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *regina.washington@ee.doe.gov* so that the necessary procedures can be completed. Anyone attending the meetings will be required to present a government photo identification, such as a passport, driver's license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

Members of the public will be heard in the order in which they sign up for the Public Comment Period. Time allotted per speaker will depend on the number of individuals who wish to speak but will not exceed five minutes. Reasonable provision will be made to include the scheduled oral statements on the agenda. A third-party neutral facilitator will make every effort to allow the presentations of views of all interested parties and to facilitate the orderly conduct of business.

Participation in the meetings is not a prerequisite for submission of written comments. Written comments are welcome from all interested parties. Any comments submitted must identify the CUAC and CUHP Working Group and provide docket number EERE–2022–BT–STD–0015. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: CommPkgACHP2022STDandTP0015@ee.doe.gov.* Include docket number EERE–2022–BT–STD–0015 in the subject line of the message.

3. *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Program, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (faxes) will be accepted.

In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *https://energy.gov/eere/buildings/appliance-standards-and-rulemaking-federal-advisory-committee.* Participants are responsible for ensuring their systems are compatible with the webinar software.

Procedure for Submitting Prepared General Statements for Distribution: Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **FOR FURTHER INFORMATION CONTACT** section of this notice. The request and advance copy of statements must be received at least one week before the public meeting and may be emailed, hand-delivered, or sent by postal mail. DOE prefers to receive requests and advance copies via email. No telefacsimiles (faxes) will be accepted.

Please identify the CUAS and CUHP Working Group and provide docket number EERE–2022–BT–STD–0015 in the request. Please also include a telephone number to enable DOE staff to make a follow-up contact, if needed.

Conduct of the Public Meetings: ASRAC's Designated Federal Officer will preside at the public meetings and may also use a professional facilitator to aid discussion. The meetings will not be judicial or evidentiary-type public hearings, but DOE will conduct them 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. A transcript of each public meeting will be included on DOE's website: *https://energy.gov/eere/buildings/appliance-standards-and-rulemaking-federal-advisory-committee.* In addition, any person may buy a copy of each transcript from the transcribing reporter. Public comment and statements will be allowed prior to the close of each meeting.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials is available for review at *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.

The docket web page can be found at *www.regulations.gov/docket/EERE-2022-BT-STD-0015.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

Signing Authority

This document of the Department of Energy was signed on October 3, 2022, by Francisco Alejandro Moreno, Acting 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 October 4, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–21890 Filed 10–6–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0766; Project Identifier 2019–NE–23–AD]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: The FAA is revising a notice of proposed rulemaking (NPRM) that applied to all General Electric Company (GE) CF34–8C1, CF34–8C5, CF34–8C5A1, CF34–8C5B1, CF34–8C5A2, CF34–8C5A3, CF34–8E2, CF34–8E2A1, CF34–8E5, CF34–8E5A1, CF34–8E5A2, CF34–8E6, and CF34–8E6A1 model turbofan engines. This action revises the NPRM by updating the service information references and removing the initial and repetitive fluorescent penetrant inspections (FPIs) of the combustion chamber assembly. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions change the required actions as proposed in the NPRM, the agency is requesting comments on this SNPRM.

DATES: The FAA must receive comments on this SNPRM by November 21, 2022.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2019–0766; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, this SNPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For GE service information identified in this SNPRM, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ge.com;* website: *ge.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; email: *Scott.M.Stevenson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2019–0766; Project Identifier 2019–NE–23–AD'' at the beginning of your comments.

The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may again revise this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this SNPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this SNPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this SNPRM. Submissions containing CBI should be sent to Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to all GE CF34–8C1, CF34–8C5, CF34–8C5A1, CF34–8C5B1, CF34–8C5A2, CF34–8C5A3, CF34–8E2, CF34–8E2A1, CF34–8E5, CF34–8E5A1, CF34–8E5A2, CF34–8E6, and CF34–8E6A1 (CF34–8C and GE CF34–8E) model turbofan engines, including engine models marked on engine data plate as CF34–8C5/B, CF34–8C5/M, CF34–8C5A1/B, CF34–8C5A1/M, CF34–8C5B1/B, CF34–8C5A2/B, and CF34–8C5A2/M. The NPRM published in the **Federal Register** on December 3, 2019 (84 FR 66082). The NPRM was prompted by a predicted reduction in the cyclic life of the combustion chamber assembly aft flange. As a result, the manufacturer added a scheduled maintenance check. In the NPRM, the FAA proposed to require revisions to the airworthiness limitations section (ALS) of the manufacturer's instructions for continued airworthiness and the air carrier's approved continued airworthiness maintenance program to

incorporate initial and repetitive FPIs of the combustion chamber assembly.

Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, the manufacturer incorporated the temporary revisions (TRs) into the GE CF34–8C and GE CF34–8E engine manuals (EMs). Based on the revised service information, the FAA has revised the proposal by removing paragraph (g)(2) from the NPRM, which proposed to require initial and repetitive FPIs of the combustion chamber assembly installed on GE CF34–8C and GE CF34–8E model turbofan engines.

Comments

The following discussion presents the comments received on the NPRM and the FAA's response.

Request To Change References From TRs to EMs

Horizon Air and Japan Airlines (JAL) requested that the FAA revise the references GE CF34–8E EM TR 05–0085, dated February 21, 2019, and GE CF34–8E TR 05–0086, dated February 13, 2019, because the TRs have since been incorporated into the GE CF34–8C and GE CF34–8E EMs, as applicable.

In response to these comments, the FAA has revised this proposed AD by replacing GE CF34–8E EM TR 05–0085, dated February 21, 2019; GE CF34–8C TR 05–0141, dated February 21, 2019; GE CF34–8C TR 05–0143, dated February 13, 2019; GE CF34–8E TR 05–0086, dated February 13, 2019; and GE CF34–8C TR 05–0142, dated February 13, 2019, with the applicable tasks in the GE CF34–8C or GE CF34–8E EM.

Request To Add FPI Procedure for the Disassembled (Off-Wing) Engine

JAL requested that the FAA add the FPI procedure to paragraph (g)(2)(i) of this proposed AD, as specified in TASK 72–41–01–200–801, of GE CF34–8E EM GEK112031 for the disassembled (off-wing) engine. JAL reasoned that TASK 05–21–03–200–801 from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34–8E EM GEK112031, which incorporated GE CF34–8E TR 05–0086, dated February 13, 2019, refers to TASK 72–41–01–200–801, on-wing inspections.

The FAA disagrees with the request to add disassembled or off-wing FPI procedures to this proposed AD. Since TASK 72–41–01–200–801 and TASK 72–41–01–200–801 are not referenced in GE CF34–8E EM GEK112031, the FAA interprets JAL's comment as a request to add TASK 72–00–41–200–806, as referenced in GE CF34–8E EM GEK112031. Additionally, the FAA has determined that the FPIs proposed in the NPRM are not required to address the unsafe condition. Therefore, the FAA has removed the proposed FPI of the combustion chamber assembly, paragraph (g)(2), as proposed in the NPRM, from this proposed SNPRM.

Support for the AD

The Air Line Pilots Association, International expressed support for the AD as written.

FAA's Determination

The FAA is proposing this AD after determining the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above revise the scope of the NPRM. As a result, it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following tasks:

- TASK 05–11–05–200–801, dated March 4, 2021, from ESM 05–11–05 Static Structures—Life Limits, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022;
- TASK 05–11–05–200–801, dated March 4, 2021, from ESM 05–11–05 Static Structures—Life Limits, of GE CF34–8E EM GEK112031, Rev 43, dated April 1, 2022; and
- TASK 05–11–25–200–801, dated November 3, 2020, from ESM 05–11–25 Static Structures—BJ Life Limits, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022.

These tasks, differentiated by GE CF34–8 turbofan engine model, identify the combustion chamber assembly part number, life limit cycles, and revised inspections.

The FAA also reviewed the following tasks:

- TASK 05–21–03–200–801, dated April 1, 2019, from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022; and
- TASK 05–21–03–200–801, dated April 1, 2019, from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34–8E EM GEK112031, Rev 43, dated April 1, 2022.

These tasks, differentiated by GE CF34–8 turbofan engine model, describe revised inspection threshold limits and re-inspection interval limits for the combustion chamber assembly.

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

Proposed AD Requirements in This SNPRM

This proposed AD would require revisions to the ALS of the existing EM and the operator's existing approved maintenance or inspection program, as applicable, to incorporate initial and repetitive FPIs of the combustion chamber assembly, except as discussed under ''Differences Between this proposed SNPRM and the Service Information.''

Differences Between This SNPRM and the Service Information

TASK 05–21–03–200–801 of the GE CF34–8E EM GEK112031 and GE CF34–8C EM GEK105091, both dated April 1, 2022, specify to perform the inspection from the issuance date of the TR. This SNPRM would require performing the inspection after the effective date of this AD.

Costs of Compliance

The FAA estimates that this proposed AD affects 1,633 GE CF34–8C turbofan engine models and 857 GE CF34–8E turbofan engine models installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise the ALS of the EM and operator's existing approved maintenance or inspection program (GE CF34–8C and CF34–8E).	1 work-hour × $85 per hour = $85 ..	$0	$85	$211,650

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

General Electric Company: Docket No. FAA–2019–0766; Project Identifier 2019–NE–23–AD.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 21, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) CF34–8C1, CF34–8C5, CF34–8C5A1, CF34–8C5B1, CF34–8C5A2, CF34–8C5A3, CF34–8E2, CF34–8E2A1, CF34–8E5, CF34–8E5A1, CF34–8E5A2, CF34–8E6, and CF34–8E6A1 model turbofan engines, including engine models marked on engine data plate as CF34–8C5/B, CF34–8C5/M, CF34–8C5A1/B, CF34–8C5A1/M, CF34–8C5B1/B, CF34–8C5A2/B, and CF34–8C5A2/M.

(d) Subject

Joint Aircraft System Component (JASC) Code 7240, Turbine Engine Combustion Section.

(e) Unsafe Condition

This AD was prompted by a predicted reduction in the cyclic life of the combustion chamber assembly aft flange. The FAA is issuing this AD to prevent failure of the combustion chamber assembly. The unsafe condition, if not addressed, could result in combustion chamber assemblies failing before reaching their published life limit, uncontained release of the combustion chamber assembly, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

Within 90 days after the effective date of this AD, revise the airworthiness limitations section (ALS) of the existing engine manual (EM) and the operator's existing approved maintenance or inspection program, as applicable, to incorporate the following requirements for fluorescent penetrant inspections of the combustion chamber assembly aft flange.

(1) For combustion chamber assemblies with part numbers (P/Ns) 4145T11G08, 4145T11G09, 4180T27G01, or 4180T27G03 installed on GE CF34–8E model turbofan engines:

(i) Replace Table 801, Static Structures—Life Limits (Table 801), with the revised Table 801 in TASK 05–11–05–200–801, dated March 4, 2021, from ESM 05–11–05 Static Structures—Life Limits (TASK 05–11–05–200–801), of GE CF34–8E EM GEK112031, Rev 43, dated April 1, 2022 (GE CF34–8E EM GEK112031), and

(ii) Add TASK 05–21–03–200–801, dated April 1, 2019, including the note, from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001 (TASK 05–21–03–200–801), of GE CF34–8E EM GEK112031. Where TASK 05–21–03–200–801 of GE CF34–8E EM GEK112031 specifies to perform the inspection within 2,200 cycles from the issuance date of the temporary revision (TR), this AD requires performing the inspection within 2,200 cycles from the effective date of this AD.

(2) For combustion chamber assemblies with P/Ns 4126T87G04, 4126T87G05, 4126T87G07, 4126T87G08, 4180T27G04, 4923T82G01, or 4923T82G02 installed on GE CF34–8C1 model turbofan engines, or with P/Ns 4145T11G08, 4145T11G10, 4180T27G02, 4180T27G04, or 4923T82G02 installed on GE CF34–8C5, CF34–8C5/M, CF34–8C5A1, CF34–8C5A1/M, CF34–8C5A2, CF34–8C5A2/M, CF34–8C5A3, or CF34–8C5B1 model turbofan engines:

(i) Replace Table 801 (For –8C1) and Table 802 (For –8C5) Static Structures—Life Limits (Table 801 and Table 802), with the revised Table 801 in TASK 05–11–05–200–801 and Table 802 in TASK 05–11–25–200–801, dated November 3, 2020, from ESM 05–11–25 Static Structures—BJ Life Limits (TASK 05–11–25–200–801), of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022 (GE CF34–8C EM GEK105091); and

(ii) Add TASK 05–21–03–200–801, dated April 1, 2019, including the note, from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001 (TASK 05–21–03–200–801), of GE CF34–8C EM GEK105091. Where TASK 05–21–03–200–801 of GE CF34–8C EM GEK105091 specifies to perform the inspection within 2,200 cycles from the issuance date of the TR, this AD requires performing the inspection within 2,200 cycles from the effective date of this AD.

(3) For combustion chamber assemblies with P/Ns 4145T11G08, 4145T11G10, 4180T27G02, 4180T27G04, or 4923T82G02 installed on GE CF34–8C5B1/B, CF34–8C5/B, CF34–8C5A1/B, or CF34–8C5A2/B model turbofan engines:

(i) Replace Table 801 (For/B –8C5) Static Structures—Life Limits with the revised Table 801 in TASK 05–11–25–200–801, of GE CF34–8C EM GEK105091; and

(ii) Add TASK 05–21–03–200–801, including the note, of GE CF34–8C EM GEK105091. Where TASK 05–21–03–200–801 of GE CF34–8C EM GEK105091 specifies to perform the inspection within 2,200 cycles from the issuance date of the TR, this AD requires performing the inspection within 2,200 cycles from the effective date of this AD.

(4) After performing the actions required by paragraphs (g)(1) through (3) of this AD, except as provided in paragraph (i) of this AD, no alternative life limits may be approved.

(h) Credit for Previous Actions

You may take credit for revising the ALS of the existing EM and the operator's existing approved maintenance or inspection program, as applicable, required by paragraphs (g)(1) through (3) of this AD if the actions were completed before the effective date of this AD using GE CF34–8E EM TR

05–0085, dated February 21, 2019; GE CF34–8C TR 05–0141, dated February 21, 2019; GE CF34–8C TR 05–0143, dated February 13, 2019; GE CF34–8E TR 05–0086, dated February 13, 2019; or GE CF34–8C TR 05–0142, dated February 13, 2019.

(i) Alternative Methods of Compliance (AMOCs)

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

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

(j) Related Information

For more information about this AD, contact Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; email: *Scott.M.Stevenson@faa.gov*.

(k) Material Incorporated by Reference

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

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

(i) TASK 05–11–05–200–801, dated March 4, 2021, from ESM 05–11–05 Static Structures—Life Limits, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022.

(ii) TASK 05–11–05–200–801, dated March 4, 2021, from ESM 05–11–05 Static Structures—Life Limits, of GE CF34–8E EM GEK112031, Rev 43, dated April 1, 2022.

(iii) TASK 05–11–25–200–801, dated November 3, 2020, from ESM 05–11–25 Static Structures—BJ Life Limits, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022.

(iv) TASK 05–21–03–200–801, dated April 1, 2019, from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34–8C EM GEK105091, Rev 51, dated April 1, 2022.

(v) TASK 05–21–03–200–801, dated April 1, 2019, from ESM 05–21–03 Airworthiness Limitations—Mandatory Inspection 001, of GE CF34–8E EM GEK112031, Rev 43, dated April 1, 2022.

(3) For GE service information identified in this AD, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ge.com;* website: *ge.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on October 3, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–21860 Filed 10–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2021–N–1348]

RIN 0910–AI59

Administrative Destruction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing a regulation to implement its new authority to destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been refused admission into the United States under the Federal Food, Drug, and Cosmetic Act (FD&C Act), by providing to the owner or consignee notice and an opportunity to appear and introduce testimony prior to the destruction. Once finalized, this regulation will allow FDA to better protect the public health by preventing re-importation and deterring future shipments of refused devices subject to administrative destruction. We also discuss in this Notice of Proposed Rulemaking our intent to change FDA's procedures for administrative destruction of drugs and, if this proposed rule is finalized, these procedures will also include devices subject to administrative destruction. We described our current procedures in the proposed and final rules entitled ''Administrative Destruction of Certain Drugs Refused Admission to the United States.''

DATES: Either electronic or written comments on the proposed rule must be submitted by December 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 7, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–1348 for ''Administrative Destruction.'' 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: Ann M. Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4375, Silver Spring, MD 20993–0002, 301–796–3324.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

The proposed rule would provide to an owner or consignee notice and an opportunity to present testimony when the Agency intends to administratively destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States. The Safeguarding Therapeutics Act (STA) (Pub. L. 116–304), signed into law on January 5, 2021, amended section 801(a) of the FD&C Act (21 U.S.C. 381(a)) to provide FDA with the authority to administratively destroy certain refused devices without providing the owner or consignee with the opportunity for export. FDA proposes to amend § 1.94 (21 CFR 1.94) to provide to the owner or consignee of a refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) notice and an opportunity to present testimony to the Agency prior to destruction of the device.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would provide to an owner or consignee notice and an opportunity to present testimony when the Agency intends to administratively destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States under section 801(a) of the FD&C Act.

FDA proposes to amend part 1 (21 CFR part 1) by expanding the scope of § 1.94, which provides notice and opportunity to present testimony to the owner or consignee prior to the refusal and destruction of certain refused drugs, to also include notice and opportunity to present testimony prior to the refusal and destruction of certain refused devices.

C. Legal Authority

The legal authority for this proposed rule includes sections 701 and 801 of the FD&C Act (21 U.S.C. 371 and 381).

D. Costs and Benefits

The primary public health benefit of the proposed rule, if finalized, would be the value of preventing additional illnesses or deaths by destroying, rather than returning, refused devices valued at $2,500 or less, which may pose a public health risk. This benefit would accrue whenever FDA's existing enforcement tools would not have prevented the violative device from entering the U.S. market. The estimated primary costs of the proposed rule include the additional costs to destroy, rather than return, refused devices valued at $2,500 or less, and the additional costs to store these devices at International Mail Facilities (IMFs) prior to destruction. There would also be one-time costs to FDA to update its electronic Operational and Administrative System for Import Support (OASIS) and System for Entry Review and Import Operations (SERIO); revise its Regulatory Procedures Manual (RPM), Investigations Operations Manual (IOM), and additional FDA and inter-Agency operational procedures; and train employees on the new procedures. Express couriers would incur one-time costs to read and understand the rule. We estimate that the annualized benefits over 10 years would range from $186,000 to $941,000 at a 7 percent discount rate and a 3 percent discount rate, with a primary estimate of $397,000. The annualized costs would range from $69,000 to $1.48 million at a 7 percent discount rate, with a primary estimate of $454,000, and from $65,000 to $1.47 million at a 3 percent discount rate, with a primary estimate of $450,000.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
Agency	U.S. Food and Drug Administration.
CBP	U.S. Customs and Border Protection.
CDC	U.S. Centers for Disease Control and Prevention.
COVID–19	Disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2).

Abbreviation/acronym	What it means
FDA	U.S. Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
NIOSH	National Institute for Occupational Safety and Health.
OASIS	FDA's Operational and Administrative System for Import Support.
SERIO	FDA's System for Entry Review and Import Operations.
STA	Safeguarding Therapeutics Act.
USPS	United States Postal Service.
We, Our, Us	U.S. Food and Drug Administration.

III. Background

A. Introduction/History of the Rulemaking

Section 708 in the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), enacted in 2012, gave FDA the authority to destroy, without providing an opportunity for export, any refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) in section 801(a) of the FD&C Act. To implement that authority, FDA published a final rule in the **Federal Register** on September 15, 2015 (80 FR 55237) that revised § 1.94 to provide notice and an opportunity for the owner or consignee to appear before the Agency and introduce testimony prior to the destruction of their drug. Section 801(a) of the FD&C Act further stated that this process may be combined with the notice and opportunity to introduce testimony on the admissibility of the drug under section 801(a) of the FD&C Act, provided appropriate notice is provided to the owner or consignee.

The STA expanded FDA's administrative destruction authority to include any refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). To implement this authority, the proposed rule would amend § 1.94 to provide to the owner or consignee of any refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) notice and an opportunity to appear and introduce testimony prior to the destruction.

B. Need for the Regulation

FDA has refused devices, valued at $2,500 or less, sent to the United States via international mail or express couriers, including illegal devices that are being imported to diagnose, prevent, or treat COVID–19 such as test kits, respirators, and face masks. Other devices that pose significant public health concerns if counterfeit, unapproved, or unauthorized, or otherwise misbranded or adulterated include contact lenses and blood glucose test strips.

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) issued, pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d), a declaration of a public health emergency related to COVID–19 and mobilized the Operating Divisions of HHS (Ref. 1). Additionally, on February 4, 2020, the Secretary of HHS determined, pursuant to section 564 of the FD&C Act (21 U.S.C. 360bbb–3), that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the novel (new) coronavirus first detected in Wuhan City, Hubei Province, China in 2019 (85 FR 7316). The virus is named severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2), which causes the disease COVID–19.

Based on this determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of certain devices (85 FR 17335). On March 11, 2020, the World Health Organization declared the SARS–CoV–2 outbreak to be a pandemic. Since these events, numerous individuals and entities have tried to profit from the pandemic by selling unproven and illegally marketed products making claims that their products can be used to treat, diagnose, or prevent COVID–19. FDA is particularly concerned that these deceptive and misleading products might cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It is likely that the products do not do what they claim and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications (Ref. 2). Once COVID–19 reached the United States, FDA received complaints from American consumers ranging from bogus treatments or cures to inappropriately marketed test kits and fake or substandard personal protective equipment (Ref. 3).

In March 2020, FDA launched Operation Quack Hack to leverage Agency expertise and use advanced analytics to protect consumers from fraudulent medical products related to COVID–19. FDA's Operation Quack Hack team had reviewed thousands of websites, social media posts, and online marketplace listings. We issued hundreds of abuse complaints to online marketplaces and domain registrars about fraudulent products related to COVID–19. As of January 2022, the Agency had issued 260 warning letters to sellers of fraudulent COVID–19 products (Ref. 4).

In Fiscal Year (FY) 2021 (October 1, 2020, to September 30, 2021), CBP seized 38,154 unauthorized COVID–19 test kits and just over 35 million counterfeit face masks (Ref. 5). Particularly during a pandemic, timely access to accurate diagnostic tests is important not only for the individual patient, but for the public at large. We have observed numerous unauthorized test kits for COVID–19 being sold online. Some test developers falsely claim that their tests are FDA-approved or authorized. Others have falsely claimed that their serology tests can diagnose COVID–19 or that they are authorized for at-home testing. As of June 1, 2020, Customs and Border Protection (CBP) had seized more than 107,300 unauthorized COVID–19 test kits (Ref. 6).

As of September 2020, FDA had refused admission to more than 470 shipments of test kits offered for import into the United States, representing more than 460,000 tests overall (Ref. 7). Based on internal data, FDA refused more than 408 shipments in FY 2021. We continue to issue Warning Letters and examine shipments of COVID–19 test kits at International Mail Facilities (IMFs) and express couriers, detaining and refusing unapproved or unauthorized, counterfeit, or otherwise adulterated or misbranded test kits.

Consumers using these illegal test kits risk unknowingly spreading SARS–CoV–2 or not getting treated appropriately for COVID–19. Public

health risks from use of illegal test kits include:

- further community spread of the disease;
- a delay in the correct diagnosis and initiation of appropriate treatment for the actual cause of the tested individual's illness;
- waste of healthcare resources and additional, unnecessary evaluations based on results from inaccurate tests;
- results from inaccurate tests may lead the tested individual to take fewer precautions against virus exposure. This may increase the individual's risk of infection and may lead them to not seek testing if later infected with SARS–CoV–2, potentially increasing community spread of the disease;
- unnecessary isolation of a tested individual that might limit contact with family or friends or increase contact with other potentially SARS–CoV–2 infected individuals, and limits in their ability to work; and
- misallocation of resources used for surveillance and prevention of COVID–19 (Ref. 8).

From 2020 to 2021, CBP seized more than 34 million counterfeit face masks and respirators, most of them modeled to resemble N95 or KN95 respirators. Around 20 million of those devices were seized in 2021 (Ref. 9). The Centers for Disease Control and Prevention (CDC) has posted warnings about illegal respirators that are falsely represented to be approved by the National Institute for Occupational Safety and Health (NIOSH). These illegal respirators may not be capable of providing appropriate respiratory protection to medical professionals and frontline workers from SARS–CoV–2. When NIOSH becomes aware of marketed illegal respirators or those marketed respirators misrepresenting NIOSH approval, CDC posts these illegal respirators on its website to alert users, purchasers, and manufacturers of the legitimate respirators (Ref. 10). On March 1, 2021, CBP seized 65,280 counterfeit 3M N95 respirators at the IMF in Chicago. The shipment was from Colombia. CBP officers noticed an unfamiliar chemical smell coming from the respirators and grammatical errors on the fake 3M packaging (Ref. 11). In February 2021, more than 108,000 counterfeit N95 masks—marketed using 3M's branding—were seized by CBP in Cincinnati (Ref. 12). In June 2020, CBP seized 10,000 KN–95 respirators that were manufactured in China and shipped from Israel. The respirators appeared to be of poor quality and packaging. The manufacturer was not registered with FDA and did not have an authorization from FDA to market the respirators in the United States (Ref. 13). CBP seized 58,846 counterfeit facemasks in the fall of 2020. More than 17,000 of these facemasks were shipped from Hong Kong (Ref. 14).

The risks posed by counterfeit, unapproved, or unauthorized, or otherwise misbranded or adulterated devices are not, however, limited to devices for COVID–19. An estimated 45 million Americans wear contact lenses (Ref. 15). FDA regulates all contact lenses as prescription devices. Contact lenses sold without a prescription from unlicensed vendors, including online distributors, may be contaminated and/or counterfeit and are not safe to use. Vendors that advertise colored and decorative contact lenses as cosmetics or sell them over the counter without a prescription, are adulterating and misbranding the device in violation of the FD&C Act and are also violating Federal Trade Commission regulations (Ref. 16).

A prescription is needed for contact lenses because an eye doctor (ophthalmologist or optometrist) must measure each eye to properly fit the lenses and evaluate how the patients' eyes respond to contact lens wear. A poor fit can cause serious eye damage, including:

- scratches on the cornea;
- corneal infection (an ulcer or sore on the cornea);
- conjunctivitis (pink eye);
- decreased vision; and
- blindness.

In addition to the risks above, vendors that sell decorative lenses without a prescription may give few or no instructions on how to clean and care for the lenses. Failure to use the proper solution to keep contact lenses clean and moist can lead to infections. Bacterial infections can be extremely rapid, result in corneal ulcers, and cause blindness—sometimes within as little as 24 hours if not diagnosed and treated promptly (Ref. 17).

Chengdu Ai Qin E-commerce Co., Ltd initiated a nationwide recall of 1,362 pairs of colored contact lenses in June 2020. These contact lenses were distributed without FDA approval or clearance. The recalled products were manufactured in August 2018 in China (Ref. 18).

In January 2017, the owner and operator of Candy Color Lenses, a major online retailer of colored contact lenses in the United States, was sentenced to 46 months in prison for running an international operation importing contact lenses from suppliers in China and South Korea that he knew were counterfeit and/or unapproved for sale in the United States. Candy Color Lenses sold the contact lenses over the internet without a prescription to tens of thousands of customers in the United States. In addition to his prison sentence, the owner was ordered to remit $200,000 in restitution and forfeit $1.2 million in proceeds derived from his illegal scheme (Ref. 19).

The owner of All about Ink, a tattoo shop in Pensacola, Florida, pleaded guilty in June 2019 to misdemeanor charges of receipt of adulterated and misbranded contact lenses, and sale of contact lenses without a prescription. In May 2015, law enforcement seized approximately 600 counterfeit contact lenses that were being imported from China by All about Ink. A number of these contact lenses were tested by FDA and contained microbial contamination. We determined that the types of bacteria in the contact lenses could be hazardous. Between July 2015 and October 2015, law enforcement made several undercover purchases of contact lenses from All about Ink. Following the undercover purchases, a Federal search warrant was executed at the tattoo shop and approximately 200 pairs of contact lenses were seized. Samples of the contact lenses purchased by undercover agents and the seized contact lenses were tested by FDA and a number of these lenses contained microbial contamination. A number of the contact lenses were also counterfeit (Ref. 20).

In 2018, 34.2 million people of all ages—or 10.5 percent of the population in the United States—were estimated to have diabetes (Ref. 21). Using a glucose meter to check and monitor blood sugar is a daily part of life for millions of these Americans. Glucose meters and test strips are devices regulated by FDA. Some consumers purchase preowned or unauthorized test strips online because they are cheaper. These test strips can potentially cause infection or lead to inaccurate test results, which can cause serious harm, including death. If a consumer receives an inaccurate result from a preowned or unauthorized test strip and uses this result as a basis for their treatment, they could take too much medication or not enough medication, potentially leading to serious injury, including death. It is also possible that preowned test strips may contain small amounts of blood from the previous owner, which can put consumers at risk of infection from potential cross-contamination (Ref. 22).

FDA issued a safety communication in April 2019 warning the public against using test strips, including glucose test strips, from a previous owner (preowned) or test strips that are not authorized for sale in the United States (Ref. 23). Certain test strips require

review by FDA prior to being marketed in the United States in order to provide a reasonable assurance of safety and effectiveness when the test strips are used as intended. Test strips not authorized for sale in the United States have not been reviewed by FDA and their ability to provide an accurate result is unknown. Unauthorized test strips can also be faulty or of poor quality. When FDA reporting requirements, such as adverse event reporting, are not followed, we may not become aware of product malfunctions or safety issues associated with these test strips.

There is currently little deterrence against sellers shipping illegal devices or re-sending previously refused devices to the United States via international mail or an express courier. Devices that have been refused admission into the United States might be subsequently offered for re-importation by unscrupulous sellers who attempt to circumvent U.S. import regulatory systems. Under the proposed rule, FDA will be better able to deter such shipments by having an administrative mechanism for destroying a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission to the United States.

C. FDA's Current Regulatory Framework

Based on our internal data, the majority of devices subject to administrative destruction come into the United States via an IMF or an express courier (Ref. 24). For international mail shipments, the United States Postal Service (USPS) routes the parcels to CBP. CBP interdicts certain shipments suspected to contain FDA-regulated products and turns the packages over to FDA for examination and determination of admissibility under the laws and regulations enforced by the Agency.

A device that is imported or offered for import is subject to refusal of admission under section 801(a) of the FD&C Act if, among other reasons, it appears to be adulterated or misbranded in violation of section 501 or 502 of the FD&C Act (21 U.S.C. 351 or 352). In accordance with § 1.94, FDA issues a notice of the Agency's intention to refuse a device to the owner or consignee, as defined in 21 CFR 1.83, stating the reasons for the intended refusal. If the article was sent by international mail, FDA generally considers the addressee of that package to be the owner or consignee. The owner or consignee is given an opportunity to appear before the Agency and introduce testimony orally or in writing on why the device should not be refused admission into the United States. Under section 801(b) of the FD&C Act, the owner or consignee can also submit an application to recondition the device to bring it into compliance with the FD&C Act or to render it other than a food, drug, device, or cosmetic. If, after consideration of any testimony submitted at a § 1.94 hearing or if no hearing is requested, we determine that the device should be refused admission, the Agency issues a notice of refusal to the owner or consignee.

Devices that have been refused admission into the United States under section 801(a) of the FD&C Act are required to be destroyed by the owner or consignee unless they are exported within 90 days of the date of notice of the refusal. Refused devices that were shipped via international mail are not in the possession of the owner or consignee and currently are returned by FDA to USPS for return to the sender.

Certain illegal devices may also be destroyed if they are seized and condemned under section 304 of the FD&C Act (21 U.S.C. 334) or if they are seized and forfeited under CBP's seizure and forfeiture authority, such as 19 U.S.C. 1595a(c).

IV. Legal Authority

FDA has the legal authority under section 801(a) of the FD&C Act, as amended by the STA, to administratively destroy, without providing opportunity for export, any device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been refused admission into the United States. A device that is imported or offered for import is subject to refusal of admission under section 801(a) of the FD&C Act if, among other reasons, it appears to be adulterated or misbranded in violation of section 501 or 502 of the FD&C Act.

Section 801(a) of the FD&C Act also directs FDA to issue regulations that provide the owner or consignee of a device designated by the Agency for administrative destruction with notice and an opportunity to introduce testimony to us prior to the destruction of the device. Section 801(a) of the FD&C Act further states that this process may be combined with the notice and opportunity to appear before FDA and introduce testimony on the admissibility of the device under section 801(a) of the FD&C Act, as long as appropriate notice is provided to the owner or consignee.

Section 701(a) of the FD&C Act authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

As used throughout, the term ''device'' means those articles meeting the definition of device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)), which includes devices intended for human or animal use. Section 201(h) of the FD&C Act defines the term ''device,'' in part, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of a disease or other condition or in the cure, mitigation, treatment, or prevention of a disease or intended to affect the structure or any function of the body, and that does not achieve its primary intended purposes through chemical action within or on the body of man or other animals or by being metabolized.

V. Description of the Proposed Rule

To implement section 801(a) of the FD&C Act, as amended by the STA, the proposed rule would revise § 1.94 so that the current notice and hearing provisions that apply to the administrative destruction of certain drugs would also apply to the administrative destruction of certain devices. Specifically, the proposed rule would amend § 1.94(a) to provide the owner or consignee of a refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) with notice and an opportunity to present testimony to the Agency prior to destruction of the device. The proposed rule would also amend § 1.94(c) to specify that the notice and hearing for refusal of admission may be combined with the notice and hearing for destruction of the device.

Once the proposed rule is finalized and in effect, FDA may destroy a device that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) if, among other reasons, it is or appears to be adulterated or misbranded. As described above, FDA would provide to the owner or consignee notice and an opportunity to present testimony prior to the administrative destruction of such a device.

VI. FDA Procedures for Administrative Destruction

In the preamble of the proposed rule (79 FR 25758) and the preamble of the final rule (80 FR 55237) for ''Administrative Destruction of Certain Drugs Refused Admission to the United States,'' FDA explained that the Agency

intended to exercise its new authority in section 801(a) of the FD&C Act, added by section 708 in FDASIA, by taking the further step of destroying a drug, only in situations where, after providing the owner or consignee with notice and the opportunity to introduce testimony, the Agency has determined that the drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act.

The Agency intends to make a change to our procedures for destroying a refused drug from what was described in the preambles to the proposed and final rules for the administrative destruction of a drug. Under our revised procedures for destruction, FDA might not make a determination that a drug subject to administrative destruction is, in fact, adulterated, misbranded, counterfeit, or unapproved if the owner or consignee has not requested a hearing to contest the administrative destruction (including the basis for refusal of admission). This means that, if an owner or consignee does not request to present testimony contesting an administrative destruction, FDA might administratively destroy that drug if it appears to be adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act. FDA will continue to make a determination that a drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act when an owner or consignee requests a hearing under § 1.94 to contest the administrative destruction (including the basis for refusal of admission).

We intend to use the same procedures for devices that are subject to administrative destruction if this proposed rule is finalized and becomes effective.

At the time of the administrative destruction of refused drugs rulemaking, administrative destruction was a novel program for the Agency. The destruction program for drugs has now been in place at FDA for more than 5 years; it was implemented starting in April 2016. After careful monitoring of the program over that time, we believe that taking the further step of making a determination that a refused drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act is no longer warranted where an owner or consignee has not requested the opportunity to submit testimony to contest the destruction. Since we implemented the program, most (*e.g.,* more than 99 percent in fiscal year 2021 (Ref. 25)) of the drugs valued at $2,500 or less that FDA initially determined to be subject to administrative destruction were later determined by FDA to be, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act. Additionally, FDA has only received one request from an owner or consignee to introduce testimony to contest FDA's intention to destroy a drug since we implemented the program. Further, we have found that having our import reviewers take the further step of making and documenting a determination that a drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act can double the time it takes to designate a drug for refusal and destruction. Given our experience with the destruction program for drugs, the high volume of illegal drugs being imported via international mail and express couriers, and our limited resources to review drugs for admissibility, we intend to change our administrative destruction procedures as described above.

Comments on these revised procedures for the administrative destruction of certain drugs and devices may be submitted in accordance with the instructions above for submitting comments to this proposed rule.

VII. Proposed Effective Date

FDA intends that the effective date of the new regulatory requirements will be 30 days after publication of a final rule in the **Federal Register**.

VIII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because of the number of expected destructions per year and the very small value per event, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule, if finalized, would implement the authority of FDA to destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been offered for import and refused admission into the United States under the FD&C Act, by providing notice and opportunity to the owner or consignee to appear and introduce testimony to FDA prior to the destruction. Because our internal data show that the majority of devices offered for import, valued at $2,500 or less, and refused in FY 2022 were shipped via international mail and express couriers, FDA currently intends to implement the proposed rule, if finalized, at IMFs and express couriers (Ref. 24). We do not, therefore, consider impacts related to shipments via commercial air, land, and seaports.

The costs and benefits of the proposed rule, if finalized, would depend on the number of administrative destructions that FDA orders each year for refused devices valued at $2,500 or less. For our primary estimates, we assume that FDA would order the destruction of 65 percent of refused devices valued at $2,500 or less. We additionally assume that FDA would contract out the act of destruction to a private firm and combine the notice and hearing process for destruction with the current notice and hearing process for refusal. We summarize the costs and benefits of the proposed rule, if finalized, in table 1.

We estimate that the annualized benefits over 10 years would range from $186,000 to $941,000 at a 7 percent discount rate and a 3 percent discount rate, with a primary estimate of $397,000. The annualized costs would range from $69,000 to $1.48 million at a 7 percent discount rate, with a primary estimate of $454,000, and from

$65,000 to $1.47 million at a 3 percent discount rate, with a primary estimate of $450,000.

Over 10 years, the present value of total benefits would range from $1.31 million to $6.61 million at a 7 percent discount rate, with a primary estimate of $2.79 million, and from $1.59 million to $8.03 million at a 3 percent discount rate, with a primary estimate of $3.39 million. The present value of total costs would range from $488,000 to $10.36 million at a 7 percent discount rate, with a primary estimate of $3.19 million, and from $555,000 to $12.54 million at a 3 percent discount rate, with a primary estimate of $3.84 million.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year [1]	$0.397	$0.186	$0.941	2021	7	10 years	Benefits include cost savings to express couriers and USPS.
	0.397	0.186	0.941	2021	3	10 years	
Annualized Quantified	.....	.....	.....	.....	7	.....	
					3		
Qualitative	.....	.....	.....	.....	.....	.....	
Costs:							
Annualized Monetized $millions/year [1]	0.454	0.069	1.475	2021	7	10 years	
	0.4500	0.065	1.470	2021	3	10 years	
Annualized Quantified	.....	.....	.....	.....	7	.....	
					3		
Qualitative	.....	.....	.....	.....	.....	.....	
Transfers:							
Federal Annualized Monetized $millions/year	.....	.....	.....	.....	7	.....	
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year	.....	.....	.....	.....	7	.....	
					3		
From/To	From:			To:			

Effects:

State, Local or Tribal Government: No estimated effect.
Small Business: No estimated effect.
Wages: No estimated effect.
Growth: No estimated effect.

[1] When calculating annualized benefits and costs, we assume that payments occur at the end of each period.

The primary benefit of the proposed rule, if finalized, would be the value of additional illnesses or deaths averted from destroying, rather than returning, refused devices valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). If a destroyed device is a counterfeit or an otherwise falsified version of an approved or cleared device, the owner of the approved or cleared device may benefit through increased sales, brand value, or research and development funding. The threat of destruction additionally may have a deterrent effect, reducing the amount of adulterated or misbranded (violative) devices that are offered for import into the United States. These benefits would accrue whenever FDA's existing enforcement tools would not have prevented the violative device from entering the U.S. market; the current policy for returning refused devices does not preclude the re-importation of the device into the United States in the future. We do not have enough information to quantify these benefits. Express couriers and the USPS would incur cost savings from returning fewer refused devices to their country of origin (the current procedure for refused devices valued at $2,500 or less).

Quantified costs of the proposed rule, if finalized, would include the costs to FDA to destroy, rather than return, refused devices valued at $2,500 or less, and the additional costs to store these devices at IMFs prior to destruction. FDA would additionally incur one-time costs to update its electronic import systems, OASIS and SERIO; revise the RPM, IOM, and additional FDA and inter-Agency operational procedures; and train employees on the new procedures. Express couriers would incur one-time costs to read and understand the rule.

If our assumptions do not hold, FDA may incur additional costs, including costs to purchase equipment to destroy refused devices, costs to train employees administering the destruction of refused devices, costs to separately notify the owners or consignees of refused devices, and costs to prepare for hearings on destruction that the owners or consignees of refused devices request.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 25) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

IX. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

FDA has concluded that the requirements contained in this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)(ii)).

XI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XIII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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*22. FDA. ''The FDA Warns Against Use of Previously Owned Test Strips or Test Strips Not Authorized for Sale in the United States: FDA Safety Communication.'' Issued April 8, 2019. Content current as of April 8, 2019. *https://www.fda.gov/news-events/press-announcements/fda-warns-about-risks-using-home-use-test-strips-are-pre-owned-or-not-authorized-sale-us-including.*

*23. Id.

*24. FDA. Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS). 2022 data as of July 12, 2022.

25. FDA. Administrative Destruction: Preliminary—Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, 2022. *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting, and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is proposed to be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

■ 2. In § 1.94 revise paragraphs (a) and (c) to read as follows:

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission or that the article is a drug or device that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility or destruction of the article, and may be introduced orally or in writing.

* * * * *

(c) If the article is a drug or device that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director may give the owner or consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. The division director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

Dated: September 30, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–21809 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

GENERAL SERVICES ADMINISTRATION

41 CFR Part 105–64

[GSPMR Case 2022–105–1; Docket No. GSA–GSPMR–2022–0017; Sequence No. 1]

RIN 3090–AK62

General Services Administration Property Management Regulations, (GSPMR), Enterprise Data & Privacy Management Office (IDE); Social Security Number Fraud Prevention

AGENCY: Enterprise Data & Privacy Management Office (IDE), General Services Administration (GSA).

ACTION: Proposed rule.

SUMMARY: The General Service Administration (GSA) is proposing to amend GSA's regulations under the Privacy Act. The revisions would clarify and update the language of procedural requirements pertaining to the inclusion of Social Security account numbers (SSNs) on documents that GSA sends by mail. These revisions are necessary to implement the Social Security Number Fraud Prevention Act of 2017, which restricts the inclusion of Social Security account Numbers (SSNs) on documents sent by mail by the Federal Government.

DATES: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before December 6, 2022 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to GSA–IDE case 2202–001 to: *Regulations.gov: https://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''GSPMR Case 2022–105–1''. Select the link ''Comment Now'' that corresponds with GSPMR Case 2022–105–1. Follow the instructions provided at the ''Comment Now'' screen. Please include your name, company name (if any), and ''GSPMR Case 2022–105–1'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite GSA–IDE Case 2202–001, in all correspondence related to this case. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Laura Gerhardt, Privacy Office, Enterprise Data & Privacy Management Office (IDE), General Services Administration, at 202–322–8246 or email *gsa.privacyact@gsa.gov* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite GSPMR Case 2022–105–1.

SUPPLEMENTARY INFORMATION:

I. Background

The Social Security Number Fraud Prevention Act of 2017 (the Act) (Pub. L. 115–59; 42 U.S.C. 405 note), which was signed on September 15, 2017, restricts Federal agencies from including individuals' SSNs on documents sent by mail, unless the head of the agency determines that the inclusion of the SSN on the document is necessary (section 2(a) of the Act). The Act requires agency heads to issue regulations specifying the circumstances under which inclusion of a SSN on a document sent by mail is necessary. These regulations, which must be issued not later than five years after the date of enactment, shall include instructions for the partial redaction of SSNs where feasible, and shall require that SSNs not

be visible on the outside of any package sent by mail (section 2(b) of the Act). This proposed rule would revise the Agency regulations under the Privacy Act (41 CFR part 105–64), consistent with these requirements in the Act. The proposed revisions would clarify the language of procedural requirements pertaining to the inclusion of SSNs on documents that the Agency sends by mail.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

III. Congressional Review Act

The Office of Information and Regulatory Affairs (OIRA) has determined that this rule is not a major rule under 5 U.S.C. 804(2). Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (codified at 5 U.S.C. 801–808), also known as the Congressional Review Act or CRA, generally provides that before a ''major rule'' may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The General Services Administration 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. A major rule under the CRA cannot take effect until 60 days after it is published in the **Federal Register**.

IV. Regulatory Flexibility Act

GSA does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* This rule does not impose a requirement for small businesses to report or keep records on any of the requirements contained in this rule.

Therefore, an Initial Regulatory Flexibility Analysis has not been performed. GSA invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

GSA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (GSPMR Case 2022–105–1), in correspondence.

V. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the GSA–IDE do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

List of Subjects in 41 CFR Part 105–64

Privacy.

Laura Gerhardt,

Acting Chief Privacy Officer, Office of the Deputy Chief Information Officer, General Services Administration.

Therefore, GSA proposes to amend 41 CFR part 105–64 as set forth below:

PART 105–64–GSA PRIVACY ACT RULES

■ 1. The authority citation for 41 CFR part 105–64 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Amend § 105–64.001 by adding in alphabetical order the definition ''Un-redacted SSN Mailed Documents Listing'' to read as follows:

§ 105–64.001 What terms are defined in this part?

* * * * *

Un-redacted SSN Mailed Documents Listing (USMDL) means the Agency approved list, as posted at [GSA PRIVACY WEBSITE], designating those documents for which the inclusion of the Social Security account number (SSN) is determined to be necessary to fulfill a compelling Agency business need when the documents are requested by individuals outside the Agency or other Federal agencies, as determined by the Administrator or their designee.

■ 3. Amend § 105–64.107 by adding paragraph (c) to read as follows:

§ 105–64.107 What standards of conduct apply to employees with privacy-related responsibilities?

* * * * *

(c) In all documents sent by mail, employees shall redact SSNs if such redaction is permissible. Where full redaction is not possible due to agency requirements, partial redaction to create a truncated SSN shall be preferred to no redaction. The following conditions must be met for the inclusion of an unredacted (full) SSN or partially redacted (truncated) SSN on any document sent by mail on behalf of the agency:

(1) The inclusion of the full SSN or truncated SSN of an individual must be required or authorized by law;

(2) The inclusion of the full SSN or truncated SSN of an individual must be determined by the Administrator or their designee to be necessary to fulfill a compelling Administration business need;

(3) The full SSN of an individual may be included only on documents listed on the USMDL; and

(4) The full SSN, the truncated SSN, or any part of the SSN of an individual must not be visible from the outside of the envelope or package.

[FR Doc. 2022–21506 Filed 10–6–22; 8:45 am]

BILLING CODE 6820–34–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 22–347; RM–11932; DA 22–1009; FR ID–106914]

Television Broadcasting Services Lincoln, Nebraska

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by The University of Nebraska (Petitioner), the licensee of noncommercial educational television station KUON–TV, channel *12, Lincoln, Nebraska. The Petitioner requests the substitution of channel *27 for channel *12 at Lincoln in the Table of TV Allotments.

DATES: Comments must be filed on or before November 7, 2022 and reply comments on or before November 21, 2022.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Derek Teslik, Esq., Gray Miller Persh, 2233 Wisconsin Avenue NW, Washington, DC 20007.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202)

418–1647; or Joyce Bernstein, Media Bureau, at *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: In support, the Petitioner states that the proposed channel substitution would serve the public interest, since moving the Station to a UHF channel would improve indoor reception. In support of its assertion that viewers in Lincoln have experienced difficulty receiving a signal on channel *12, the Petitioner submits a log of approximately 80 viewer complaints and requests for help receiving the signal. According to the Petitioner, although the proposed channel *27 facilities will result in a reduction in the Station's predicted population served within its noise limited service contour, almost all of the predicted loss area is served by other PBS stations licensed to communities in Nebraska and Iowa, which largely air the same programming as KUON–TV. The Petitioner further states that once terrain-limitations are factored into the analysis, the new loss area that would be created by the proposed channel substitution would contain only 342 persons, which it asserts is below the level the Commission considers *de minimis* in the context of determining whether there would be an impermissible loss of service.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 22–347; RM–11932; DA 22–1009, adopted September 26, 2022, and released September 26, 2022. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer & Government Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a Notice of Proposed Rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in Section 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See Sections 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

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

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

§ 73.622 [Amended]

■ 2. In § 73.622 in paragraph (j), amend the Table of Allotments under Nebraska by revising the entry for Lincoln to read as follows:

§ 73.622 Table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
NEBRASKA	
* * * * *	
Lincoln	8, 10, 15, *27.
* * * * *	

[FR Doc. 2022–21888 Filed 10–6–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2022–0082; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BG07

Endangered and Threatened Wildlife and Plants; Endangered Species Status for the San Francisco Bay-Delta Distinct Population Segment of the Longfin Smelt

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the San Francisco Bay-Delta distinct population segment (DPS) of longfin smelt (*Spirinchus thaleichthys*) (Bay-Delta longfin smelt), a fish species of the Pacific Coast, as an endangered species under the Endangered Species Act of 1973, as amended (Act). After a review of the best scientific and commercial information available, we find that listing the DPS is warranted. Accordingly, we propose to list the Bay-Delta longfin smelt DPS as an endangered species under the Act. If we finalize this rule as proposed, it would add this DPS to the List of Endangered and Threatened Wildlife and extend the Act's protections to the DPS. We also find that the designation of critical habitat for the Bay-Delta longfin smelt is not determinable at this time.

DATES: We will accept comments received or postmarked on or before December 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.

We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 21, 2022.

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–2022–0082, which is the docket number for this proposed rule. 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–2022–0082, 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: Donald Ratcliff, Field Supervisor, U.S. Fish and Wildlife Service, San Francisco Bay-Delta Fish and Wildlife Office, 650 Capitol Mall Suite 8–300, Sacramento, CA 95814; telephone 916–930–5603. 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 DPS's biology, range, and population trends, including:

(a) Biological or ecological requirements of the DPS, 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 DPS, its habitat, or both.

(2) Factors that may affect the continued existence of the DPS, which may include the present or threatened destruction, modification, or curtailment of its habitat or range, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this DPS and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status of this DPS.

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. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made solely on the basis of the best scientific and commercial data available.

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 determination may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that the DPS is threatened instead of endangered, or we may conclude that the DPS 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. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. We may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On April 2, 2012, we published a 12-month finding on the status of the Bay-Delta longfin smelt (77 FR 19756), which concluded that the population of longfin smelt in the San Francisco Bay-Delta was a valid DPS and was warranted for listing under the Act. However, our completion of a proposed rule to amend the List of Endangered and Threatened Wildlife was precluded by higher priority actions. As a result, the Bay-Delta longfin smelt was added to our candidate species list. During the interim period between the DPS becoming a candidate and this proposed rule, we addressed its status through our annual candidate notices of review.

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Bay-Delta longfin smelt (Service 2022, entire). The SSA team was composed of Service biologists and State resource agency staff, who then consulted with other scientific experts during the development of the SSA report. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the DPS, including the impacts of past, present, and future factors (both detrimental and beneficial) affecting the DPS 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 sought the expert opinions of five appropriate specialists regarding the SSA. We received three responses. 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–2022–0082.

I. Proposed Listing Determination

Distinct Population Segment

As stated above, on April 2, 2012, we concluded that the population of longfin smelt in the San Francisco Bay-Delta was a valid DPS and was warranted for

listing under the Act (77 FR 19756). Since that time, additional genetic information has become available to further support our DPS conclusion that the population is both discrete and significant (Sağlam et al. 2021, p. 1793; Service 2022, chapter 2). Below is a summary of our conclusions regarding discreteness and significance for the San Francisco Bay-Delta population of the longfin smelt. For more background and details of our analysis see the 2012 12-month finding (77FR 19756).

Discreteness

Because of its limited swimming capabilities and because of the great distances between the San Francisco Bay-Delta and known breeding populations to the north, we conclude that the San Francisco Bay-Delta population is markedly separated from other longfin smelt populations, and thus meets the discreteness element of the 1996 DPS policy. The best available information indicates that longfin smelt from the San Francisco Bay-Delta population complete their life cycle moving between freshwater, brackish water, and saltwater portions of the estuary and nearby coastal ocean waters in the Gulf of Farallones. The nearest known breeding population of longfin smelt is Humboldt Bay, 420 km (260 mi) north of the San Francisco Bay-Delta. As a result, potential interchange between the San Francisco Bay-Delta population and other longfin smelt breeding populations is limited. Although the best scientific information suggests that potential movement of longfin smelt northward from the San Francisco Bay-Delta would be facilitated by ocean currents, potential movement from more northern estuaries south to the San Francisco Bay-Delta would be more difficult and unlikely because of ocean currents. Based on our review of the best scientific and commercial information available, we conclude that the San Francisco Bay-Delta population of longfin smelt is markedly separated from other longfin smelt populations as a consequence of physical, physiological, ecological, or behavioral factors.

Significance

We conclude that the San Francisco Bay-Delta population is biologically significant to the longfin smelt species because the population occurs in an ecological setting unusual or unique for the species and its loss would result in a significant truncation of the range of the species. The San Francisco Bay-Delta longfin smelt population occurs at the southern edge of the species' range and has likely experienced different natural selection pressures than those experienced by populations in middle and more northern portions of the species' range. The population may therefore possess unique evolutionary adaptations important to the conservation of the species. The San Francisco Bay-Delta also is unique because it is the largest estuary on the Pacific Coast of the United States. Because of its large size and diverse aquatic habitats, the San Francisco Bay-Delta has the potential to support a large longfin smelt population and is thus potentially important in the conservation of the species. The San Francisco Bay-Delta population also is significant to the taxon because the nearest known breeding population of longfin smelt is hundreds of miles away, so loss of the San Francisco Bay-Delta population would significantly truncate the range of the species and result in a significant gap in the species' range. Based on our review of the best available scientific and commercial information, we conclude that the San Francisco Bay-Delta population meets the significance element of the 1996 DPS policy.

Determination of Distinct Population Segment

Because we have determined that the San Francisco Bay-Delta population meets both the discreteness and significance elements of the 1996 DPS policy, we find that the San Francisco Bay-Delta longfin smelt population is a valid DPS and thus is a listable entity under the Act. As a result, we continue to find that the San Francisco Bay-Delta DPS of the longfin smelt meets the standards for determination as a DPS under our 1996 DPS policy (61 FR 4722).

Background

Below is a summary of biological information regarding the Bay-Delta longfin smelt. A thorough description and review of the range, life history, and ecology of the Bay-Delta longfin smelt is presented in the SSA report (Service 2022, entire).

Description and Distribution: The longfin smelt is a small fish species 9–11 centimeters (cm) (3.5–4.3 inches (in)) in length with a relatively short lifespan of approximately 2 to 3 years. The longfin smelt, as a species, occurs in bays and estuaries from northern California north along the coast through Alaska. The Bay-Delta longfin smelt occupies the San Francisco Bay Estuary and areas of the Pacific Ocean out to the Farallon Islands (see figure 1). The tidally influenced San Francisco Bay Estuary includes the central and south San Francisco Bay, Suisun Bay, and San Pablo Bay, and the Sacramento and San Joaquin River Delta (Delta). Longfin smelt in the San Francisco Bay-Delta are pelagic fish (fish most frequently occurring in open-water habitats) that exhibit a facultatively anadromous life history, meaning older juveniles and adults can migrate to the ocean, but are required to return to fresh water for spawning and rearing (Moyle 2002, p. 236). Bay-Delta longfin smelt spawn only once in their lifetime but may have multiple spawning events during the spawning season (generally late fall to early spring) (Service 2022, p. 12). Reproduction occurs in low-salinity to freshwater habitats beginning in late fall/early winter and extends into the spring as water temperature and low-salinity conditions allow (Service 2022, pp. 11–13).

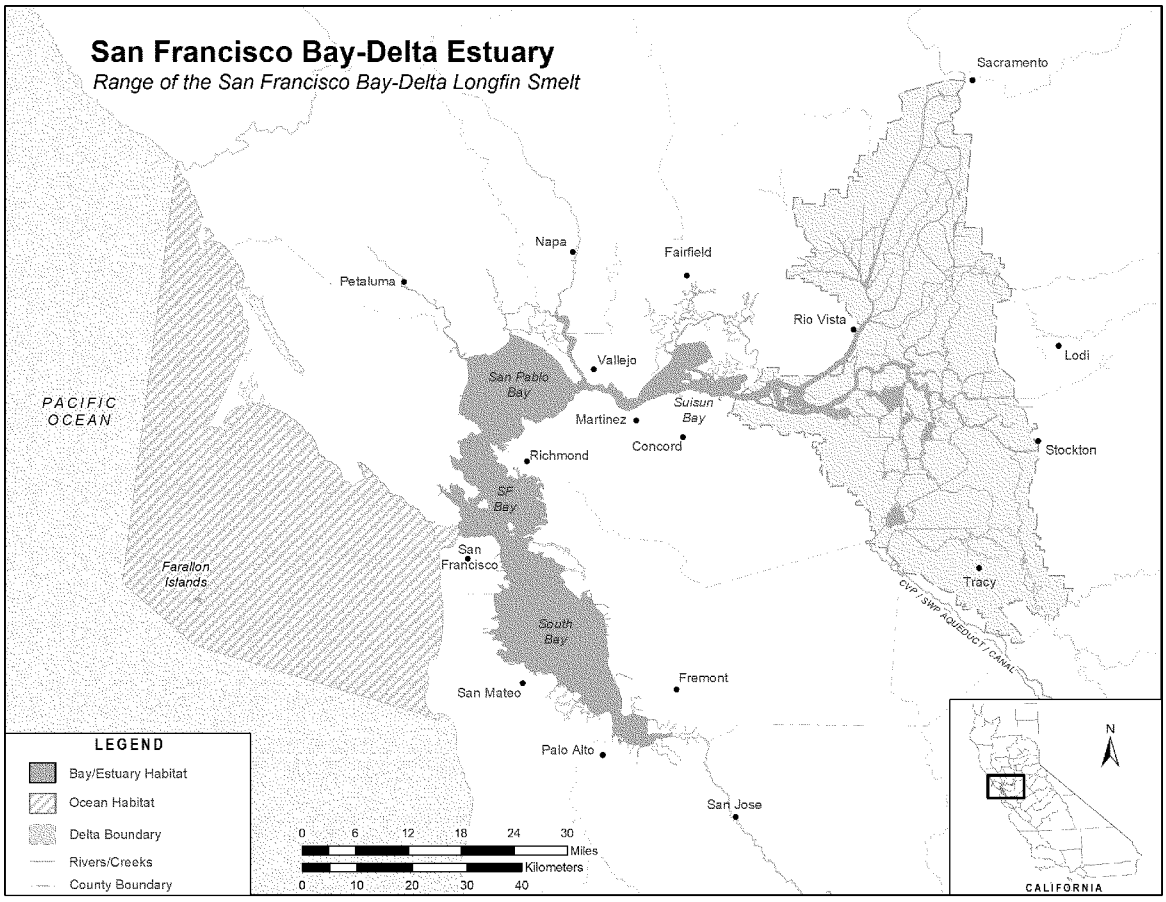

Figure 1: San Francisco Bay-Delta Longfin Smelt Distinct Population Segment Range

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 the 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 available regarding the status of the DPS, including an assessment of the potential threats to the DPS. The SSA report does not represent our decision on whether the DPS should be proposed for listing 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–2022–0082 on *https://www.regulations.gov* and by contacting the Service's Bay-Delta Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

To assess the Bay-Delta longfin smelt's 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 DPS's ecological requirements for survival and reproduction at the individual, population, and DPS level and described the beneficial and risk factors influencing the DPS's viability.

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

Summary of Biological Status and Threats

In the discussion below, we review the biological and resource needs of the Bay-Delta longfin smelt, and the threats that influence the DPS's current and future condition, in order to assess the DPS's overall viability and the risks to that viability.

Species (DPS) Needs

Below is a summary of the Bay-Delta longfin smelt's biological and ecological needs, more details of which can be found in the SSA report (Service 2022, chapter 2 entire).

The needs of the Bay-Delta longfin smelt to successfully carry out its life history are highly dependent on the freshwater inflow and resulting temperature and environmental conditions and resources of the San Francisco Bay estuary (comprising the San Francisco Bay, San Pablo Bay, Suisun Bay, and the Sacramento and San Joaquin River Delta). The amount and duration of freshwater input from rivers and tributaries flowing into the estuary greatly influences the location and extent of where the appropriate water temperature and saline conditions are present for the DPS to carry out its life functions (Service 2022, section 2.2, Ecological Setting, pp. 8–11). These freshwater flows can be natural, such as in wet years or dry years, or as a result of human-altered water management. Under high-flow conditions, the amount of low-saline/cool-water habitat is more abundant, whereas under low-flow conditions the availability, amount, extent, and duration of areas that contain the appropriate habitat conditions for the Bay-Delta longfin smelt are greatly reduced.

The needs of the Bay-Delta longfin smelt can be categorized into three main resource needs and biological condition categories, and include: (1) appropriate freshwater or low-saline water conditions; (2) appropriate water temperature conditions; and (3) adequate food resources and availability by life-stage. As the Bay-Delta longfin smelt is subject to both freshwater and saline water conditions, its habitat is extremely variable. These variable conditions along with other factors exert a strong influence on the condition of the DPS's food resources.

Interaction of Waterflow Conditions and Habitat

The San Francisco Bay estuary is one of the largest estuaries on the West Coast of the continental United States (Sommer et al. 2007, p. 271). Everywhere freshwater flow enters the San Francisco Bay estuary, it can generate variable freshwater and salinity conditions for plants and animals, such as the Bay-Delta longfin smelt, that are adapted to brackish water conditions. The San Francisco Bay estuary consists of five areas: the Sacramento-San Joaquin River Delta, Suisun Bay, San Pablo Bay in the north, as well as South San Francisco Bay and Central San Francisco Bay in the South. The northern regions receive freshwater input from the Sacramento-San Joaquin River systems, as well as lesser inputs from the Napa, Sonoma, and Petaluma Rivers. In the north, the prevailing direction of water flow is from east to west. In the south, the Central San Francisco Bay receives little freshwater from its mostly urbanized watersheds that are directly adjacent to the bay, and the South San Francisco Bay receives some freshwater input from Alviso Slough (Largier 1996, p. 69). We refer to these areas collectively as the San Francisco Bay-Delta. The Sacramento-San Joaquin River systems represent approximately 90 percent of the estuary's freshwater input, and as such, have the largest influence on estuarine habitat conditions (Jassby et al. 1995, p. 275, and fig. 4, p. 279; Monismith et al. 2002, fig. 7, p. 3010). The southern part of San Francisco Bay is generally characterized as a lagoonal system,

whereas the northern reaches function as a tidal river estuary due to the much larger freshwater flow inputs (Kimmerer 2004, p. 7). However, during large freshwater flow events and wet rainfall years, the small tributaries can have important localized effects and support conditions suitable for Bay-Delta longfin smelt spawning and larval rearing (Lewis et al. 2019, p. 3).

Numerous studies have shown the positive correlation between Bay-Delta longfin smelt juvenile abundance and freshwater flow (Stevens and Miller 1983, pp. 431–432; Jassby et al. 1995, p. 285; Kimmerer 2002, p. 47; Rosenfield and Baxter 2007, p. 1585; Sommer et al. 2007, p. 274; Kimmerer et al. 2009, p. 381; MacNally et al. 2010, p. 1422; Thomson et al. 2010, pp. 1439–1440; Maunder et al. 2015, p. 108; and Nobriga and Rosenfield 2016, p. 53). The survival of longfin smelt through their early life-stages is lower during dry or low-flow conditions and higher during wet or high-flow conditions—the evidence for this finding is that Bay-Delta longfin smelt abundance indices nearly always decline sharply during dry or low-flow periods and are higher in wet or high-flow periods (Mahardja et al. 2021, pp. 9–10). As a result, freshwater flows with appropriate magnitude, timing, and frequency (both seasonally and annually) are a significant DPS need.

Low-salinity water is an important feature for the Bay-Delta longfin smelt. Because the San Francisco Bay is connected to the Pacific Ocean, saltwater tidal flows move upstream into the estuary and mix with inflowing freshwater flows moving downstream. These tidal and stream flows present opposing hydraulic forces that interact with each other and the estuary's bathymetry (underwater contours and channels) to create extremely variable and complex currents of vertical and lateral hydrodynamic mixing of salt- and freshwater (Stacey et al. 2001, pp. 17026–17035). Depending on the strength of the tidal or freshwater inflow, the area where the saltwater and freshwater interact may move either upstream toward the Delta or downstream into the bays toward the ocean. A common term that is used to refer to where this estuarine mixing and low-salinity zone is located is ''X2''. X2 is the distance in kilometers (km) from the Golden Gate (boundary between the San Francisco Bay estuary and the Pacific Ocean) to the place where salinity near the bottom of the water column is 2 practical salinity units (PSU; also known as parts per thousand) (Jassby et al. 1995, pp. 274–275) (figure 2). Isohalines are lines (or contours) that join points of equal salinity in an aquatic system.

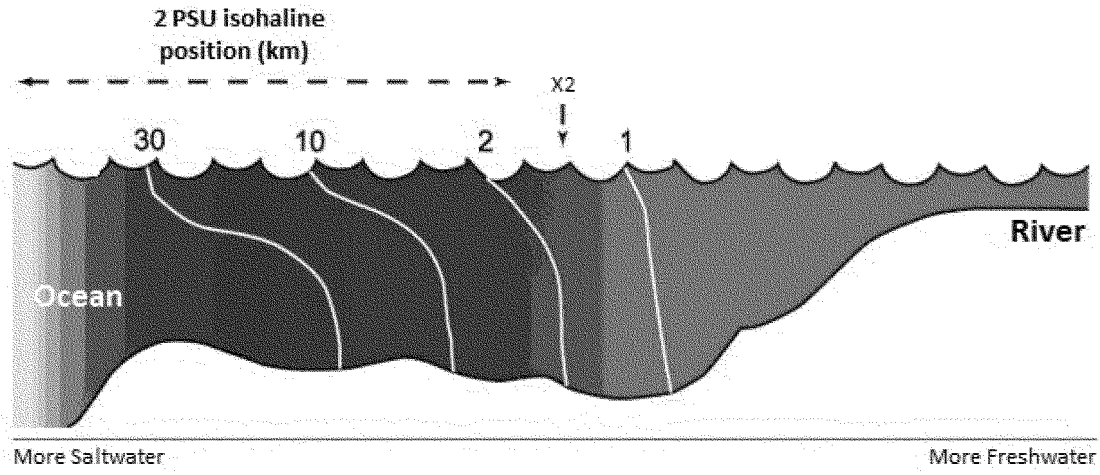

Figure 2: Illustration showing 30, 10, 2, and 1 PSU isohalines (modified from OzCoast.org.au website)

X2 is used in part because it represents the approximate upstream limit of where surface and bottom salinity differ, and because favorable turbidity conditions and high phyto- and zooplanktonic abundances are broadly associated with it. Estuarine pelagic fishes, including the Bay-Delta longfin smelt, are also associated with this location due to it being the downstream limit of the low-salinity zone for spawning and rearing and for this zone providing favorable environmental conditions and abundance of food resources (Dege and Brown 2004, fig. 3, p. 57).

The position of X2 is always moving as a result of freshwater or tidal flows. This movement results in changes to the size, shape, and ecological function of the low-salinity zone (MacWilliams et al. 2015, figs. 11–12, p. 22). Tidal flows affect the position of X2 most strongly over short time scales (hours to weeks) (Kimmerer 2004, fig. 2, p. 12). Over longer time scales, freshwater from the Sacramento-San Joaquin Delta system has the dominant influence on the position of X2 in the estuary (Jassby et al. 1995, p. 275, and fig. 4, p. 279; Monismith et al. 2002, fig. 7, p. 3010). The surface area of the low-salinity zone (and, therefore, the habitat available for Bay-Delta longfin smelt) increases very rapidly as it begins to include areas within the San Pablo Bay (X2 ≤ 55 km (34 miles (mi)), resulting in peak low-salinity zone areas of 150 to 250 square km (58 to 97 mi^2) (MacWilliams et al. 2015, fig. 12, p. 22).

Water Temperature

Bay-Delta longfin smelt require cool water conditions. Laboratory and field studies and surveys have found that hatching success, size, growth, and survivability of Bay-Delta longfin smelt are all closely dependent on water temperatures near 15 degrees Celsius (°C) (59 °F (°F)) or less. Water temperatures of 16 °C (61 °F) are the upper limit for spawning, with temperatures of 13 °C (55 °F) and potentially lower being more ideal (Baxter 2016, entire; Tempel and Burns 2021, slide 12; Service 2022, p. 21). Studies and information have identified water temperatures near 20 °C (68 °F) as the upper limit for larval fish (Jeffries et al. 2016, p. 1709). The larvae rear during the spring in the low-salinity/cool-water

locations near where they were spawned and born. Adults and juveniles have been found in water temperatures of less than 22 °C (71 °F) and likely spend the warmer periods of the year in cooler Bay habitats and the coastal ocean to escape warming temperatures that occur in much of the estuary during the summer. This movement is likely part of the DPS's adaptive capacity and could be facilitated as water temperatures rise toward 20 °C (68 °F) in the late spring. Likewise, Bay-Delta longfin smelt adults have not been known to return to most of the estuary until temperatures drop below 22 °C (71 °F) in the autumn.

Water temperatures within the estuary vary and depend on ambient air temperatures and on the amount of freshwater inflow into the system (Vroom et al. 2017, pp. 9918–9920). Because of California's Mediterranean climate of cool wet winters and hot dry summers, the majority of natural inflow and input of cooler freshwater (from cool-season rains and snowmelt) into the estuary occurs in the late fall to early spring, which coincides with the spawning period of the Bay-Delta longfin smelt. The operation of the State Water Project and Central Valley Project and the many large reservoirs that store and supply water to agricultural and municipal beneficial uses modify the flow regime and affect the volume and timing of delta freshwater inflow and outflow. As freshwater flows decrease and water temperatures warm each spring into early summer, the young fish (those >20 millimeter (mm) (0.79 in) in length) move seaward, and many individuals (both juveniles and adults) that are more tolerant of saline conditions move into the Pacific Ocean during the late spring and summer months (Service 2022, p. 17).

Food Resources

The diet of Bay-Delta longfin smelt is very specific and varies by age class and location within the estuary. Bay-Delta longfin smelt larvae select strongly for the calanoid copepod *Eurytemora affinis* as their food resource. All other prey types combined account for only about 10 percent of their diet (Barros et al. 2022, fig. 6a and 6c; Service 2022, Section 2.5 Diet). When Bay-Delta longfin smelt reach about 25 mm (1 in) in length, their diet switches and is nearly all mysids, a taxonomic group of larger crustaceans commonly called opossum shrimp (Barros et al. 2022, fig. 6b). This observation of a highly specified diet applies to fresh- and brackish-water habitats throughout the estuary (Barros et al. 2022, fig. 3). The peak abundances of these food resources have been identified as being in the estuary's largest low-salinity zone associated with X2 and generated by freshwater flow from the Delta (Kimmerer *et al.* 1998, pp. 1701–1708; Kimmerer 2002, fig. 2, p. 45). These factors explain the interrelatedness of flow with key resource needs of the DPS—such that prey, salinity, and temperature conditions facilitate the access of particular life stages to habitat areas with sufficient food resources to meet the DPS's life-history requirements.

Threats Influencing the Bay-Delta Longfin Smelt

The threats facing the Bay-Delta DPS of the longfin smelt include habitat alteration (Factor A) and changes to hydrology associated with reduced and altered freshwater flows and resulting increases in saline habitat conditions (Factor A); increased water temperatures (Factor A); reduced food resource availability (Factor E); predation (Factor C); entrainment from freshwater diversion facilities (Factor E); and contaminants (Factor E). We consider reduced and altered freshwater flows resulting from human activities and impacts associated from current climate change conditions (increased magnitude and duration of drought and associated increased temperatures) as the main threat facing the Bay-Delta longfin smelt due to the importance of freshwater flows to maintaining the life-history functions and species needs of the DPS. However, because the Bay-Delta longfin smelt is an aquatic species and the needs of the species are closely tied to freshwater input into the estuary, the impact of many of the other threats identified above are influenced by the amount of freshwater inflow into the system (*i.e.,* reduced freshwater inflows reduce food availability, increase water temperatures, and increase entrainment potential).

Reduced and Altered Freshwater Flows

The development of dams and water delivery infrastructure built throughout the Sacramento and San Joaquin River basins for flood protection and water supply for agriculture and human consumption has greatly impacted freshwater flows into the San Francisco Bay estuary (Service 2022, section 3.1.1). The creation of this water storage and delivery system, where water is stored during the wet season and conveyed to farms and cities during the dry season, has resulted in one of the largest human-altered water systems in the world (Nichols et al. 1986, p. 569). Operation of this system has resulted in a broader, flatter hydrograph with less seasonal variability, thus changing the timing, magnitude, and duration of freshwater flows into the San Francisco Bay-Delta (Kimmerer 2004, p. 15; Andrews et al. 2017, p. 72; Gross et al. 2018, p. 8). It is estimated that the State and Federal water projects annually reduce an average of about 5 million acre-feet (MAF) of freshwater into the Delta, while other municipal or private reservoirs or diverters annually decrement an additional 8 MAF of potential freshwater into the Delta (Hutton et al. 2017, fig. 4, p. 8). The cumulative effect of this annual average of about 13 MAF of freshwater supplies has resulted in a long-term decline in freshwater inflow into the estuary during the period of February through June relative to estimates of what flows would have been available absent water development (Gross et al. 2018, fig. 6, p. 12; Reis et al. 2019, fig. 3, p. 12). This situation has further increased the frequency of very low outflow years that, prior to water development, would have been very rare and associated only with extreme drought (Reis et al. 2019, fig. 3, p. 12).

In addition to the flood control and water storage and delivery systems, water diversion and export systems are also reducing freshwater inflow into the system (Kimmerer and Nobriga 2008, p. 2). From 1956 to the 1990s, water exports increased, rising from approximately 5 percent of the Delta freshwater inflow to approximately 30 percent of the Delta inflow (Cloern and Jassby 2012, p. 7). By 2012, an estimated 39 percent of the estuary's unimpaired freshwater flow in total was either consumed upstream or diverted from the estuary (Cloern and Jassby 2012, p. 8).

A reduction in freshwater flows into the estuary influences and impacts the location and extent of the low-salinity zone (spawning and rearing habitat). Freshwater inflow into the estuary and other co-linear indicators of wet versus dry conditions during the winter and spring have been statistically associated with first-year recruitment of Bay-Delta longfin smelt (Service 2022, section 3.1.1). Prior to large-scale water exports and reduced freshwater flows, the location of the low-salinity zone (X2) reached the ≤55-km (34-mi) point in the estuary (monthly averages from February through May) in about half of all years. More recently the position of the low-salinity zone reaching at least the 55-km (34-mi) point occurred only very rarely as a result of wet year conditions (Gross et al. 2018, fig. 6, p. 12 and fig. 7, p. 13) (Service 2022, section 3.1.1). In the case of Bay-Delta longfin smelt, the amount of low-

salinity habitat available for optimal growth and rearing conditions (food and water conditions (salinity, turbidity)), especially for early life stage fish, is directly linked to freshwater inflow.

Drought Conditions

California's annual weather and rainfall patterns can be extremely variable and alternate from wet to dry periods from year to year. Occasionally, several years of dry conditions have occurred over numerous extended periods (*i.e.,* varying levels of drought) (Department of Water Resources (DWR) 2020, entire). Drought periods can be characterized as having less freshwater flow, as well as shorter duration and lower magnitude of peak flows. The current trend in drought conditions has recently increased in frequency, duration, and magnitude (Swain et al. 2018, pp. 427–433). Prior to the 21st century, dry and critically dry years occurred approximately 33 percent of the time. However, since the year 2000, the dry and critically dry year frequency has increased to 43 percent. Based on soil moisture reconstruction, the period between 2000–2021 was probably the driest 22-year period on record (Williams et al. 2022, p. 1). As the existing impacts from climate change (*i.e.,* warmer temperatures) increase evapotranspiration in the watershed, the aforementioned water supply needs can exacerbate the magnitude of realized dry conditions over and above these natural patterns in precipitation and reduced delta freshwater inflow.

Bay-Delta longfin smelt exhibit poor survival and reproduction during droughts (Thomson et al. 2010, pp. 1438–1446; Mahardja et al. 2021, pp. 9–10). The survival of Bay-Delta longfin smelt through their early life-stages is lower during dry conditions and higher during wet conditions, as evidenced by Bay-Delta longfin smelt abundance indices nearly always declining sharply during dry periods then rebounding when wet weather returns (Mahardja et al. 2021, pp. 9–10). However, such recovery does not always occur after each drought cycle, leading to lower baseline numbers for the DPS (Moyle 2002, p. 237; Sommer et al. 2007, pp. 270–276). In addition, extended dry years compound the negative impacts to Bay-Delta longfin smelt as the DPS has not shown an ability to quickly recover and reoccupy upstream spawning habitats following drought. These drought conditions have exacerbated the impact of reduced freshwater flows from human activities and have been attributed to accelerating the establishment of the overbite clam (*Potamocorbula amurensis*) (see *Reduced Food Resources* and *Pelagic Organism Decline (POD),* below) by making saline water conditions more available throughout areas typically associated with more freshwater (Carlton et al. 1990, pp. 90–91).

Habitat Alteration

Large-scale habitat alteration such as channelization and dredging of streams and bays, building of levees and canals, and draining of wetlands has occurred since the 1850s. The impacts of such in-water and adjacent upland habitat alterations greatly affected and continues to impact the bathymetry of the estuary by collectively making the estuary deeper and less hydrodynamically connected to the surrounding landscape (Andrews et al. 2017, fig. 5, p. 64). The altered waterways create more space and avenues for the incoming tides to bring more saline water landward. Specifically, landscape changes since 1850 are estimated to have resulted in an average landward shift of X2 of over 3 km (2 mi) (Andrews et al. 2017, p. 68). This change along with reductions in freshwater input into the estuary (see *Reduced and Altered Freshwater Flows,* above) has caused a winter-spring upstream (landward) shift of X2 on the order of 10–20 km (6–12 mi). Taken together, the landscape changes discussed above and changes to the estuary's flow regime have changed how mixing processes function, and thus altered the habitat and food resource opportunities available for the estuary's biota, including the Bay-Delta longfin smelt

Water Temperature Alterations

The water temperature within the San Francisco Bay Estuary is also greatly influenced by freshwater inflow (Vroom et al. 2017, pp. 9918–9920). The reduction and alteration of freshwater flows into the San Francisco Bay estuary has limited the area where appropriate water temperature conditions for the Bay-Delta longfin smelt occur. As described in the Life History and Biology section of the SSA report (Service 2022, section 2.4) and summarized above, Bay-Delta longfin smelt spawning occurs within cool water conditions below 15 °C (59 °F), while larvae and young juveniles show a preference for temperatures below 12 °C (54 °F) and 20 °C (68 °F), respectively. The embryonic through early juvenile life stages are when Bay-Delta longfin smelt are believed to be most vulnerable to warming temperatures because these early life stages do not possess the ability to migrate to the cooler waters of central San Francisco Bay and the coastal ocean. Bay-Delta longfin smelt are also most abundantly detected within a narrow temperature range of cool water relative to the range that occurs in the upper estuary. Several studies and reports have found water temperatures in the Delta (the area containing favorable freshwater conditions) commonly exceeds 22 °C (72 °F) during the summer (Vroom et al. 2017, p. 9904; data from California Data Exchange Center, Central & Northern California Ocean Observing System, and U.S. Geological Survey (Blodgett et al. 2011, entire)). Increased freshwater inflow during the appropriate period of time greatly influences the amount and distribution of favorable spawning and rearing water temperature conditions (Service 2022, section 3.1.3).

Reduced Food Resources

As discussed above and in the SSA report (Service 2022, section 3.1.2), the Bay-Delta longfin smelt historically limited their diet to a relatively small number of crustacean meso- and macrozooplankton taxa. Bay-Delta longfin smelt larvae have diets dominated by a copepod, *Eurytemora affinis,* that is common in the low-salinity zone during the spring (California Department of Fish and Wildlife (CDFW), unpublished data). The two most common prey taxa for larger longfin smelt are epibenthic mysids and amphipods (Burdi 2022, pers. comm.; CDFW unpub. Diet Study Data). The copepod *E. affinis* was also at one time an important prey item for a now much-depleted mysid species, *Neomysis mercedis* (Knutson and Orsi 1983, p. 478), a prey species of juvenile and adult Bay-Delta longfin smelt.

Since the 1970s, the *Eurytemora affinis* population in the estuary has been in decline, but beginning in the late 1980s, the zooplankton community for the San Francisco Bay estuary started undergoing about a decade of rapid change in species composition, trophic structure, and utility for fish production (Winder and Jassby 2011, pp. 683–685; Kratina et al. 2014, p. 1070; Brown et al. 2016, p. 8). This decline coincided with the rapid invasion of the estuary by the nonnative overbite clam (Carlton et al. 1990, pp. 81 and 85, fig. 3) and with an extended drought in the Central Valley in the period 1987–1994 (Rosenfield and Baxter 2007, p. 1589).

The overbite clam is a filter feeder that is thought to have diverted food resources from the primary food sources of, or fed directly on, the nauplii (first larval stage) of common calanoid copepods, and resulted in their decline. These native copepods are one of the

main sources of prey of larval Bay-Delta longfin smelt (Carlton et al. 1990, pp. 90–91; Kimmerer et al. 1994, p. 87; Feyrer et al. 2003, pp. 284–286; Rosenfield and Baxter 2007, p. 1589). The invasion of the overbite clam has resulted in an over tenfold decrease in abundance of native copepods, which now account for less than 4 percent of total zooplankton biomass within the estuary after 1994 (Winder and Jassby 2011, p. 684). In addition to lower abundance, the average individual sizes of mysids in the estuary have decreased over time, with a species composition shift towards *Hyperacanthomysis longirostris,* an invasive species that reaches maturity at a smaller mass than *Neomysis* species (Hennessy 2011, entire). Although Bay-Delta longfin smelt consume these nonnative species, they are not preferred (see below) and the change in food resources most likely results in an increased effort for the DPS to meet its food resource needs.

To further exacerbate the impacts of the change in food resources, the decline of the Bay-Delta longfin smelt's historical prey base has not been accompanied by a large change in prey use by the DPS (Barros et al. 2019, p. 15; Feyrer et al. 2003, p. 285). This finding suggests that Bay-Delta longfin smelt had formed strong predator-prey interactions with their primary prey, a hypothesis supported by empirical data (MacNally et al. 2010, p. 1426). Because the DPS continues to exhibit very little variation in prey use despite the reduction in natural prey availability, they are considered more susceptible to food web changes than some other fishes (Feyrer et al. 2003, p. 281). The decline in food resources is likely affecting juvenile and adult longfin smelt growth and fitness as well as increasing the effort needed to meet food resource demands (Kimmerer and Orsi 1996, pp. 418–419; Feyrer et al. 2003, p. 281). The result of the introduction of overbite clam and reduced freshwater flows has limited abundances and availability of the Bay-Delta longfin smelt's primary food sources, especially for larval and rearing individuals that are restricted to the low-salinity zone during their development.

Predation

Little information is available on the exact predators of the Bay-Delta longfin smelt; however, Bay-Delta longfin smelt are relatively small fish, even as adults, and are thus most likely food for many fish-eating (piscivorous) predators, such as birds, jelly fish, and other fish (CDFW 2009a, p. 27). The number of piscivorous fish in the San Francisco Bay estuary is considerable (Grossman 2016, pp. 5, 12). However, studies on the diets of predatory fish in the estuary provide limited insight into predation of the Bay-Delta longfin smelt. These studies were based on visually identifying the stomach contents of numerous species of predatory fish in the estuary. In most cases, these studies did not find Bay-Delta longfin smelt (Stevens 1966, pp. 94–96; Thomas 1967, pp. 51, 57; Nobriga and Feyrer 2007, unpaginated, Results/Discussion section; CDFW 2009a, pp. 27–28; Grossman 2016, pp. 9–16). In one study in Suisun Marsh and the Sacramento-San Joaquin Delta that used DNA analysis of stomach contents, Bay-Delta longfin smelt were identified as prey of Sacramento pikeminnow (*Ptychocheilus grandis*), striped bass (*Morone saxatilis*), and largemouth bass (*Micropterus salmoides*), but only rarely (Brandl et al. 2021, tables 2 and 4). However, given the Bay-Delta longfin smelt's recent low abundance (see SSA report, section 3.2. Current DPS Survey Indices (Service 2022, pp. 41–46)) and limitations typical of field-based food-habit studies, it is expected that the Bay-Delta longfin smelt would rarely be identified in the diet of piscivorous fishes, since predatory fish feed predominantly on the fish prey that is most available (Nobriga and Feyrer 2007, unpaginated, Results/Discussion sections; CDFW 2009a, p. 27; Grossman 2016, p. 15).

Because information on direct predation is lacking, we reviewed general information about predator-prey relationships in fish food webs that are broadly applicable to situations and conditions faced by the Bay-Delta longfin smelt. The early life stages of fish are often subject to high rates of predation that play important roles in modulating abundance and amplifying the consequences of food limitation (Ahrens et al. 2012, fig. 2, p. 46, and throughout; Pangle et al. 2012, pp. 5–6). Chronic food limitation (such as those described for the Bay-Delta longfin smelt described above) and predation risk are often tightly linked in fish food webs (Ahrens et al. 2012, pp. 47–48). One way prey organisms reduce their risk to predation is to limit their foraging times, which are often relatively risky because small fishes have to behave in ways that increase their exposure or attractiveness to predators when they are actively foraging (*e.g.,* leaving sheltered habitats, moving around more actively) (Ahrens et al. 2012, fig. 1, p. 43). Thus, when food densities decline, prey fishes have two choices. They can either eat less and grow more slowly or they can increase foraging times to compensate for the lower prey densities, which may result in an increased predation risk. Other factors such as habitat or ecosystem conditions, such as turbidity and food availability, also play an important part in this relationship.

Although predation and its effects do impact the Bay-Delta longfin smelt, we do not consider the impacts to be a primary driver, but we still include this consideration as part of the cumulative impact from all threats for the DPS, especially during poor habitat conditions when food is lacking.

Entrainment

Freshwater diversion occurs throughout the estuary through pumping for agricultural, waterfowl, or municipal purposes and in some cases may lead to entrainment of Bay-Delta longfin smelt. Entrainment occurs when the suction caused by pumping creates an opportunity for fish to follow or be captured by the flow of water and become trapped and transported by the hydrodynamic footprint of those diversions. This entrainment often results in fish, especially early-life-stage fish, being killed or removed from the estuary. Bay-Delta longfin smelt can be entrained in water exported by the major pumping facilities in the South Delta (see Water Project Exports, below) when adults and commingling age-1 individuals move upstream into the freshwater portions of the Delta (CDFW 2020a, fig. 13, p. 53). Bay-Delta longfin smelt larvae and small juveniles that are either rearing or being tidally dispersed landward of X2 can also be entrained (CDFW 2020a, fig. 13, p. 53). During periods of high freshwater flow into the estuary, Bay-Delta longfin smelt (adults, juveniles, and larvae) are much less likely to be entrained by the major pumping facilities in the South Delta because the low-salinity zone (X2) is further downstream (or seaward) of the Delta. Individuals are more likely to be cued to spawn in tributaries of the San Francisco, San Pablo, and Suisun Bays rather than in the Delta since these tributaries would also be flowing high. However, changes to the estuary's bathymetry (see *Habitat Alteration,* above) have caused the tidal flows to reach further into the Old and Middle Rivers (Andrews et al. 2017, p. 66) which, as discussed below, may further impact Bay-Delta longfin smelt (see Water Project Exports, below). Below we describe the types of freshwater diversions and exports and their impacts on Bay-Delta longfin smelt.

Agricultural Diversions: Freshwater is diverted at numerous sites throughout the Delta for agricultural purposes,

particularly during the summer months (Siegfried et al. 2014, figs. 10–11, p. 11). Based on the life history of the DPS during this timeframe, the majority of Bay-Delta longfin smelt are seeking cooler water during the late spring and summer and are more seaward of the Delta and areas associated with agricultural diversions. Given the temporal mismatch between seasonal peaks in agricultural water diversions and limited use of the Delta waterways by Bay-Delta longfin smelt during this timeframe, we do not consider seasonal diversion of water for agricultural purposes and the potential for entrainment to be a high-level threat for the DPS but this activity still contributes cumulatively with other threats facing the population.

Wetland Diversions: In Suisun Marsh, the Roaring River and Morrow Island Distribution Systems (RRDS and MIDS) are California Department of Water Resources (DWR) facilities that divert water from Montezuma and Goodyear sloughs in Solano County, respectively. The water is distributed to waterfowl management wetlands in Suisun Marsh and eventually returned to marsh channels leading to Suisun Bay (minus what evaporates and is retained in wetland areas). Both diversions have been observed to entrain Bay-Delta longfin smelt (Enos et al. 2007, p. 16; CDFW 2009a, pp. 40–41). The RRDS has fish screens that were installed to reduce entrainment of fish in the vicinity of the diversion, which was recognized as a source of fish mortality (Pickard et al. 1982, pp. 4–10). The MIDS pumping facility is not screened. However, based on the results of monitoring, MIDS is considered not to have a great influence on entrainment of Bay-Delta longfin smelt (Enos et al. 2007, pp. 16–18; CDFW 2020a, p. 63).

Water Project Exports: The State of California through the DWR and the Federal Bureau of Reclamation operate freshwater diversion facilities and infrastructure associated with the State Water Project (SWP) and Central Valley Project (CVP) respectively. These facilities export freshwater from the Delta. The DWR also operates the Barker Slough Pumping Plant, which diverts water from Barker Slough into the North Bay Aqueduct (NBA) for delivery in Napa and Solano Counties. The Barker Slough diversion has positive barrier fish screens that were installed to reduce entrainment of fish in the vicinity of the diversion, which was recognized as a source of mortality for federally listed species such as the delta smelt (*Hypomesus transpacificus*), chinook salmon (*Oncorhynchus tshawytscha*) (Sacramento River winter-run, California coastal, Central Valley spring-run salmon), and steelhead salmon (*Oncorhynchus mykiss*)) (Service 2008, pp. 111–232). In dry seasons and at higher pumping rates, modeling data suggest the facilities could exhibit some level of entrainment vulnerability, despite the fish screens in place (Service 2008, p. 231). The SWP and CVP each include pumping plants in the south Delta. These pumping plants are used to export freshwater to users for municipal and agricultural purposes via the California Aqueduct to the Central Valley and Southern California. The operation of these facilities can exert a strong influence on regional hydrodynamics that has resulted in the entrainment of Bay-Delta longfin smelt, sometimes from considerable distances (Kimmerer 2008, p. 2, fig. 1, p. 3; Kimmerer and Nobriga 2008, fig. 7, p. 12; Hutton et al. 2019, fig. 7, p. 11).

Several methods have been implemented to limit and offset the entrainment impacts at these facilities, including construction of forebays (areas used to collect fish before they enter the pumps), fish screens, gate systems (used to divert fish away from pumps), and salvage operations (active collection and transport of fish back into the estuary). In most years, Bay-Delta longfin smelt have been collected (''salvaged'') in the fish facilities that are in front of each pumping plant and from screens on the pump intakes. The salvage of fish is an indicator that individuals are being entrained by pumping of water at these facilities and either being killed or removed from the estuary. The peak of salvage of age-1 and older Bay-Delta longfin smelt typically occurs in January (Grimaldo et al. 2009, fig. 5, p. 1262). These adult and age-1 fish likely represented individuals searching for spawning habitats, and immature individuals commingling with the adults. The peak of salvage of age-0 fish (fish younger than 1 year old) typically occurs in April or May as larval fish reach sizes at which they could be retained on the fish screens of the CVP and SWP fish collection facilities. However, in all likelihood some larvae begin to be entrained once they start hatching in December or January, but remain undetected until about March, with salvage efficiency increasing in April–May as the fish grow larger. Despite these salvage operations helping conserve Bay-Delta longfin smelt, the salvage operations themselves are not free from impacts on the DPS as collection, transportation, and release of salvaged fish often causes additional mortality of individuals (CDFW 2009b, pp. 4–20, table 2; CDFW 2020a, pp. 23–24, table 1).

It is possible that past entrainment and loss of Bay-Delta longfin smelt may have reached levels of concern (CDFW 2020a, fig. 10, p. 47). However, since 2009, the entrainment of longfin smelt has not been substantial (Service 2022, fig. 3.4), perhaps partly due to monitoring and management of flows in the Old and Middle Rivers (OMR) between the Sacramento/San Joaquin River confluence and the export facilities. When net OMR flow is positive, San Joaquin River water is generally moving seaward through the Delta and away from the pumping facilities. The more net negative OMR is flowing, the more the water in the Delta is moving back upstream toward the pumping plants and the faster that water is moving south, thereby increasing entrainment potential. The additional negative flow causes Sacramento River water entering the northwest portion of the Delta to be diverted southward toward the pumping facilities rather than seaward, which allows saltier tidal flows to move further toward the Delta and reduces spawning habitat for the Bay-Delta longfin smelt. In order to address and minimize effects to federally listed fish species (delta smelt, chinook salmon (Sacramento River winter-run, California coastal, Central Valley spring-run salmon), and steelhead salmon), restrictions to pumping and other water operations management strategies have been implemented by the DWR and Reclamation to limit negative OMR flows and associated entrainment through the section 7 process of the Act (Service 2008, entire; National Oceanic and Atmospheric Administration, National Marine Fisheries Service [NMFS] 2009, entire; Service 2019, entire; NMFS 2019, entire). In addition, the DWR has implemented similar measures for State-listed species (including longfin smelt) (CDFW 2009c Incidental Take Permit (ITP), entire; CDFW 2020b, ITP, entire).

The results of two different analytical approaches to the Smelt Larval Survey (SLS) data suggest that entrainment of fish has not exceeded 3 percent since 2009 (Kimmerer 2022, pers. comm.). One of the two analyses coupled particle tracking modeling with the SLS data set and found an upper 95 percent credible interval of proportional entrainment was 2.9 percent in the critically dry winter of 2013 and nearly zero in the wet winter of 2017. A second analysis (similar in approach to Kimmerer 2008, entire) analyzed all of the SLS data in the period 2009–2020. Similarly, this approach also found

proportional entrainment was unlikely to have exceeded 3 percent (range = 0.5 to 2.9 percent) (Kimmerer 2022, pers. comm., unpublished data). We interpret these findings, as well as previously published information (CDFW 2020a, entire), to indicate that the OMR management strategies in place since 2009 have been an effective conservation strategy for limiting the impact of entrainment and its consequences for the Bay-Delta longfin smelt. As a result, the best information currently available indicates that management actions for operating water diversion facilities are assisting in limiting entrainment impacts for the Bay-Delta longfin smelt.

Contaminants

The San Francisco Bay estuary has been identified as an impaired water body due to it containing numerous and persistent contaminant compounds (California State Water Resources Control Board 2018, appendix A). The list of contaminant compounds identified within the estuary includes elemental contaminants or 'metals' (*e.g.,* mercury and selenium), toxic organic compounds (dioxins, furans, polychlorinated biphenyls), and pesticides (chlordane dieldrin, DDT). Additional emerging contaminants of concern include flame retardants, nutrients, naturally occurring toxins, microplastics, and pharmaceuticals and personal care products (*i.e.,* plastic microbeads, insect repellant, sunscreen, cosmetics, etc.) (Klosterhaus et al. 2013, pp. 97–98, table 1; Sutton et al. 2017, entire). Ongoing analysis of water in the Delta suggests that on average 10 new synthetic organic pesticide chemicals are detected every year (California Department of Pesticide Regulation 2020, dataset). Water sampling in one study of the Delta indicated the presence of more than 50 chemical compounds from a single 1-liter (L) (34-ounce (oz)) water sample (Moschet et al. 2017, pp. 1557–1560).

The sources of contaminants include discharge from municipal wastewater treatment plants, agricultural outfalls, stormwater runoff, anti-fouling paints on boat and ship hulls, and direct human application of pest and aquatic plant control compounds (Service 2022, section 3.1.6). Legacy contaminants in the Bay-Delta (those from historical loading, such as organochlorine chemicals (*e.g.,* DDT) from past agricultural use and mercury from past gold mining activity), have been shown to persist in the environment and continue to impact ecosystems and can bioconcentrate through the food web, posing additional health risks (Connor et al. 2006, pp. 87–88; Marvin-DiPasquale and Cox 2007, p. 2). Regulation has reduced the use of some contaminants, only to be replaced by other more potent alternative water-soluble chemicals such as neonicotinoids, which have additional impact on nontarget species such as aquatic invertebrates and fish (Buzby et al. 2020, pp. 15–21).

Field-based toxicity is difficult to determine, as impacted fish are not recovered in order to be examined (*i.e.,* fish either die from direct exposure and resulting disease, or are eaten). Risk of exposure and effect, as determined by comparison to other species (*e.g.,* delta smelt and the introduced inland silverside (*Menidia beryllina*)), potentially include direct effects on development, growth, and reproduction; impacts resulting from impairments to bioenergetic demands; and impaired locomotion, reducing feeding success, which can lead to increased susceptibility to predation, disease, and entrainment (Connon et al. 2009, p. 12; Connon et al. 2011, p. 299; Brander et al. 2012, p. 2854; Hasenbein et al. 2014, p. 696; Jeffries et al. 2015a, p. 17407; Jeffries et al. 2015b, p. 55; Brander et al. 2016, pp. 247–260; Cole et al. 2016, p. 219; DeCourten and Brander 2017, p. 2).

Pelagic Organism Decline (POD)

Between the years 2002 through 2004, abundance indices for multiple fish species within the San Francisco Bay estuary declined abruptly in what is known as the Pelagic Organism Decline, or POD. Specifically, the POD referred to a drop in survey catches of four fish species (Bay-Delta longfin smelt, delta smelt, striped bass (*Morone saxatilis*), and threadfin shad (*Dorosoma petenense*)) (Sommer et al. 2007, p. 273). The POD event is generally recognized as a population step decline (where populations decline to lower abundance level and not rebound to previous levels) for numerous fish species in the estuary. The coincident declines of multiple species suggested a possible common cause, but a single mechanism for decline that applied to all four fish has not been identified (MacNally et al. 2010, p. 1426; Thomson et al. 2010, pp. 1442–1443). As a result, researchers have focused on multiple causes, from habitat changes, reductions in freshwater inflow, water diversions, food resource changes, competition, predation, and contaminants as contributing to the POD (Sommer et al. 2007, pp. 271–276; MacNally et al. 2010, p. 1418; Fong et al. 2016, pp. 20–21). As outlined above, all of these factors have been identified as threats impacting the Bay-Delta longfin smelt to varying degrees. Although the POD event is not a threat in itself, but is instead most likely a result of multiple threats, the subsequently smaller populations are more susceptible to poor habitat conditions and have a reduced capability of rebounding from lower abundance years.

Bay-Delta Longfin Smelt Current Condition

Current Abundance

Several long-term survey efforts have been established for monitoring San Francisco Bay estuary fish populations including the Bay-Delta longfin smelt. These established survey efforts include the Fall Midwater Trawl (FMWT), the 20-mm Survey, and the San Francisco Bay Study (Bay Study). The 20-mm Survey has been conducted since 1995, and although it does not produce an abundance index for Bay-Delta longfin smelt, we adapted the results of the survey by using the methods in the study for the delta smelt abundance index for the Bay-Delta longfin smelt. Our methods and information on how we adapted the study information is outlined in appendix B of the SSA report (Service 2022, appendix B). The longest of these survey efforts is the FMWT, which was initiated in 1967 and has surveyed pelagic waters from the Delta into San Pablo Bay monthly from September through December each year. The FMWT captures mostly juvenile and adult fish 50–150 mm (2–6 in) in length and has been used to monitor the abundance of sampled fish species since the late 1970s (Stevens and Miller 1983, pp. 431–432). In the case of Bay-Delta longfin smelt, the FMWT samples adults and juveniles, most likely those returning from more marine environments to freshwater areas associated with spawning. Figure 3 identifies FMWT abundance information for Bay-Delta longfin smelt since its inception in 1967 with emphasis on the years 2000 to 2020. Similar abundance estimates are reflected in the 20-mm Survey, Bay Study, and other modeling efforts (Service 2022, section 3.2.1).

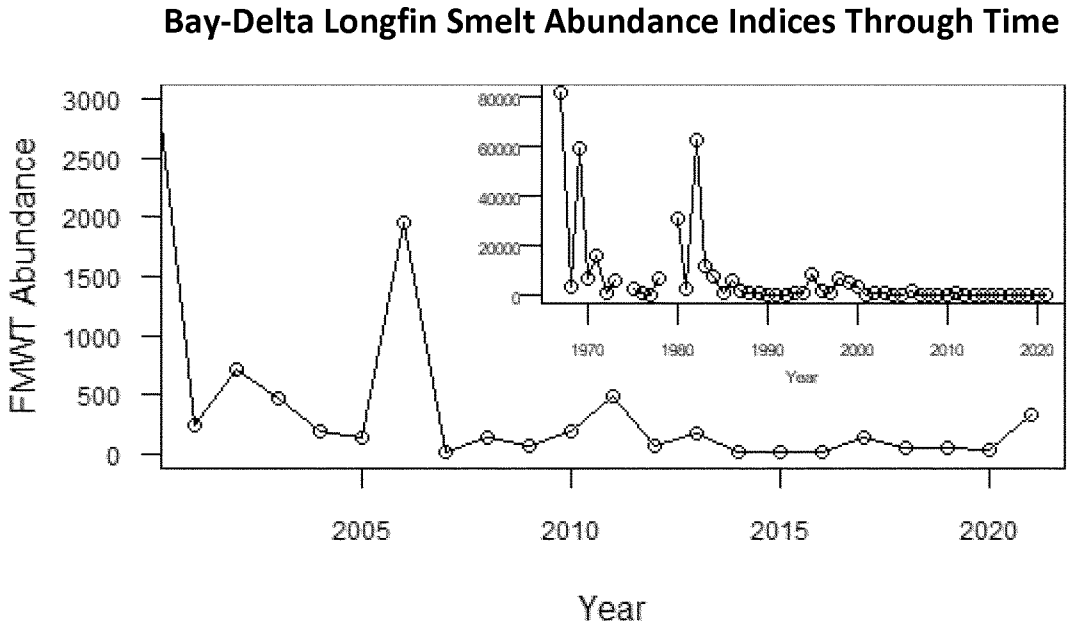

Figure 3: Bay-Delta longfin smelt abundance indices for 2000–2020 from the FMWT (Inset displays time series since 1967). Source: Adapted from California Department of Fish and Wildlife 2021

Collectively, these survey efforts encompass abundance estimates of all life stages of the Bay-Delta longfin smelt in the estuary. The data from these efforts indicate a recent and significant decline for the Bay-Delta longfin smelt throughout the estuary and across all life stages resulting in the conclusion that the current Bay-Delta longfin smelt population size is considered to be small (Service 2022, section 3.2, appendices A and B).

Population Trends

All the best available field surveys for documenting long-term abundance trends indicate Bay-Delta longfin smelt numbers have substantially declined over time, with current relative abundance reflecting small fractions of the species' historical relative abundance and representing a decline of three to four orders of magnitude over the course of available historical abundance records. Even considering the small periodic increases in numbers in occasional years in the most recent survey results (past 20 years), the general trend over time has been lower highs and lower lows in abundance for the DPS. This finding supports the conclusion that abundance of all life stages has declined substantially over the course of several decades and that the overall decline has continued in recent years (Service 2022, section 3.2). A summary of annual population growth rates derived from the monitoring data showed that, on average, abundance has declined from year to year, although some years with large growth rates contributed to variability (Service 2022, section 3.2.2).

Effects of Threats Impacting the Bay-Delta Longfin Smelt

Reduced and altered freshwater flows into the estuary greatly impact the availability, distribution, and amount of Bay-Delta longfin smelt spawning and rearing habitat. Freshwater input into the estuary provides for proper low-salinity and cooler water conditions for Bay-Delta longfin smelt to spawn and rear young and provides abundant food resources for the DPS. Reductions in availability of such habitat conditions reduces the number of young available to mature to breeding age the following year. Reduced freshwater flows also require the DPS to move farther inland to find appropriate low-salinity conditions for spawning and rearing. This movement farther inland makes the DPS's larvae and young more vulnerable to entrainment as a result of water diversion from water export facilities. These larvae and young are often not captured and returned to the estuary as a result of salvage measures due to their smaller size.

The amount of freshwater input into the estuary is dependent on natural wet/dry precipitation patterns. These patterns have been influenced by the effects of current climate change conditions, which have resulted in more frequent, prolonged, and intense drought conditions (reduced flows) and increased water temperatures (poor habitat conditions). Freshwater flows into the estuary have also been greatly influenced by human-caused alteration of rivers and streams leading into the estuary as well as diversion and export of freshwater from the estuary. These human-caused impacts of water management have exacerbated the impacts of environmental variability of natural wet/dry precipitation patterns.

In addition to altered habitat conditions for the Bay-Delta longfin smelt, the available food resources for the DPS have also been severely impacted. A rapid change to the zooplankton community in the estuary beginning in the late 1980s along with the introduction of the nonnative species such as the overbite clam and others has greatly reduced the natural prey base for the DPS and replaced it with a smaller nonnative mysid. Because the DPS continues to exhibit very little variation in prey use despite the reduction in natural prey availability, they are considered more susceptible to food web changes than some other fishes. The decline in food resources is likely affecting juvenile and adult longfin smelt growth and fitness as well as increasing the effort needed to meet food resource demands.

After the review of the threats of predation, entrainment, and contaminants, we have determined that they are not primary driving factors currently influencing the Bay-Delta longfin smelt. However, these threats are likely still contributing cumulatively to the overall impacts acting on the DPS.

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 DPS, 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 DPS. To assess the current and future condition of the DPS, 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 DPS, 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 DPS, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Resiliency, Redundancy, and Representation for the Bay-Delta Longfin Smelt

In the SSA report for the Bay-Delta longfin smelt (Service 2022, chapter 3), we evaluated the Bay-Delta longfin smelt's resiliency, redundancy, and representation under our SSA framework (Service 2016, entire).

Resiliency describes the ability of a species to withstand stochastic disturbance. Because the Bay-Delta longfin smelt is a single, intermixed population, we did not identify multiple resiliency units, but looked at the population as a whole. As discussed above, the Bay-Delta longfin smelt is subject to multiple interacting threats, including saltwater intrusion and reduced freshwater flows, that are altering and degrading habitat conditions. The resulting impact of these threats limits the extent, duration, and availability of appropriate habitat conditions needed for spawning, rearing, and ultimate recruitment of individuals into the population. These threats include anthropogenic actions (such as freshwater management, freshwater diversion, and physical alterations to the bathymetry of the estuary) or poor or altered environmental conditions (such as increased frequency and magnitude of drought resulting from current climate change conditions). Disruptions to the estuary's food web associated with reductions in freshwater flow or introductions of nonnative species are also limiting resiliency for the DPS.

Redundancy is the ability of a species to withstand catastrophic events. The Bay-Delta longfin smelt is a single intermixed population and occurs in areas within the San Francisco Bay estuary as dictated by the extremely modified and altered habitat and resource conditions. The estuary is also subject to extreme environmental variability as a result of climate change conditions resulting in increased temperatures and extreme drought. As a result of these changes, the ability of the system and organisms within the estuary to withstand catastrophic events and rebound during periods of more favorable conditions is greatly reduced. Large-scale estuary-wide ecosystem population collapses of fish and native zooplankton have occurred in the estuary. Although no single cause for the collapses has been identified, both native and nonnative fish populations have not recovered. The result has been step-declines of the Bay-Delta longfin smelt population size since the mid-1980s.

Representation describes the ability of a species to adapt to changing environmental conditions over time. This definition includes the ability of a species to adapt to both near-term and long-term changes in its physical and biological environments. The Bay-Delta longfin smelt population occurs in the San Francisco Bay estuary and is a single, genetically indistinguishable population. The Bay-Delta longfin smelt represents the southern extent of the species as a whole and most likely is a source for populations along the coast north of San Francisco Bay. Due to ocean currents and the species' poor swimming capability, populations north of the San Francisco Bay have limited ability to reestablish a population in the San Francisco Bay-Delta once they have been extirpated from the San Francisco Bay-Delta. The DPS's ability to adapt behaviorally to environmental changes (to have adaptive capacity) is also limited. This limitation is exemplified by the DPS's behavioral tendency of not adapting to food resource changes. As discussed, food resources for the DPS have changed significantly yet the DPS's behavior has not shifted to adapt to those changes.

In our evaluation of the current condition of the Bay-Delta longfin smelt, we evaluated several population viability analyses (PVAs) that quantitatively derive probabilities of extinction over time based on the DPS's historical and current abundance estimates (Service 2022, pp. 107–120; appendix B). The PVAs used information from the existing suite of surveys, including the FMWT, the 20-mm Survey, and the Bay Study, as well as others (Service 2022, figure 3.11). The PVAs modeled extinction probability based on a continuation of existing threats currently facing the DPS under varying levels of population recruitment. The results of the PVAs identified that the probability of quasi-extinction for the Bay-Delta longfin smelt exceeds 20 percent over the next 5 years and reaches 50–60 percent by 2040 (Service 2022, pp. 107–120). Applying the same assumptions over a longer time horizon (*i.e.,* 2050–2065), the suite of surveys used in the PVAs predicts that the probability of extinction for the Bay-Delta DPS under current conditions is roughly 50–80 percent (Service 2022, pp. 107–120).

As a result of our review of the best scientific and commercial data available on the Bay-Delta longfin smelt, we have determined that the DPS's resiliency is low. Numerous decades of declining abundance indices for the Bay-Delta longfin smelt document the inability of the DPS to rebound during more favorable environmental conditions and respond to the threats it is facing in the contemporary San Francisco Bay estuary. The Bay-Delta longfin smelt also has extremely limited redundancy because it effectively represents a single, small population inhabiting the San Francisco Bay-Delta and nearshore ocean environment, and because it continues to be impacted by large-scale stochastic events and is subject to catastrophic events. We have determined that the representation of the Bay-Delta longfin smelt is limited as well, reflecting that same declining abundance trend and no discernible and quantifiable compensatory adaptation to current ecological conditions. Based on our evaluation of the current resiliency, redundancy, and representation for the Bay-Delta longfin smelt, we conclude the current ability of the DPS to maintain populations in the wild is low.

Future Condition

As part of the SSA, we also developed future condition scenarios to capture the range of uncertainties regarding future threats and the projected responses by the Bay-Delta longfin smelt. To assess the future condition of the Bay-Delta longfin smelt, we used published information related to the varying environmental conditions of the San Francisco Estuary, including future climate change information and projected increases in water demand, and how these changes may impact how well the estuary can support the Bay-Delta longfin smelt into the foreseeable future. In our analyses, we considered two plausible future scenarios based on representative concentration pathways (RCP) 4.5 and 8.5 as the bookends for our analysis. The scenarios assessed climate change information (temperature increases, changes precipitation patterns, sea-level rise)

through 2100, as published information was available. The information identified that declines in Bay-Delta longfin smelt population abundance will continue into the foreseeable future under both the RCP 4.5 and 8.5 scenarios. Because we determined that the current condition of the Bay-Delta longfin smelt was consistent with an endangered species (see Determination of the Bay-Delta Longfin Smelt's Status, below), we are not presenting the results of the future scenarios in this proposed rule. Please refer to the SSA report ((Service 2022, Chapter 4) for the full analysis of future scenarios.

Conservation Efforts and Regulatory Mechanisms

Numerous efforts have been initiated regarding conservation and regulation of the San Francisco Bay estuary and its resources, including managing water flows into and export from the estuary, improving water quality, conducting habitat restoration, and implementing measures or regulations to protect native fish. This effort includes establishment of multiagency collaborations such as the Interagency Ecological Program (IEP), which focuses on coordinating and prioritizing science needs and research to meet responsibilities under State and Federal regulatory requirements (IEP 2014, entire). The State of California listed the longfin smelt in the San Francisco Bay estuary and along the California Coast as a threatened species under the California Endangered Species Act in 2009 (CDFW 2009a, entire; California Natural Diversity Database 2022, entire) and has issued restrictions and requirements for the export of water for the State Water Project (see *Entrainment,* Water Project Exports, above). Several other fish species (delta smelt, several salmonid species) are listed under both the Act and the California Endangered Species Act, and the Service and NMFS have also issued biological opinions regarding the effects to these species and their habitats for delivery and export of water from the estuary (see *Entrainment,* Water Project Exports, above). The State Water Board is responsible for issuing water quality standards and monitors contaminants within the estuary (see *Contaminants,* above). However, despite efforts such as those identified above, the current condition of the estuary and continued threats facing the estuary and Bay-Delta longfin smelt, such as reduced freshwater inflow, severe declines in population size, and disruptions to the DPS's food resources have not been ameliorated.

Determination of the Bay-Delta Longfin Smelt's Status

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 an endangered species or a 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.

Status Throughout All of Its Range

The current Bay-Delta longfin smelt abundance, density, and distribution throughout the San Francisco Bay estuary have substantially declined. Currently, the DPS exists in very low abundance despite periods when appropriate habitat conditions, which typically would allow for population rebounds, are available. Our analysis revealed that several threats are causing or contributing to this decline and currently pose a meaningful risk to the viability of the DPS. These threats have put the Bay-Delta longfin smelt largely into a state of chronic population decline due to habitat loss (reduction in freshwater flows into the estuary), which is exacerbated by limited food resources and the impacts associated with climate change, thereby limiting its resiliency and ability to withstand catastrophic events (reduced redundancy). This decline in numbers of the Bay-Delta longfin smelt is also a reflection of the DPS's ability to adapt to the ecosystem changes. As a result of the DPS's poor performance in adapting to the suite of stressors acting upon it, we consider the Bay-Delta longfin smelt's adaptive capacity and, therefore, its current representation to be low. The Bay-Delta longfin smelt's continued reduced population size makes the DPS vulnerable to varying habitat conditions (reduced freshwater flows) from year to year due to both anthropogenic and environmental conditions that are being influenced by the effects of climate change. Historically, with a larger population size, the DPS was more resilient to such stochastic and catastrophic events due to its ability to rebound in abundance when habitat conditions and resources would allow. The habitat changes, limitations to food resources, and resulting small population size now limit the DPS's ability to maintain its current population.

After evaluating threats to the DPS and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we find that the threats facing the San Francisco Bay-Delta DPS of the longfin smelt are current and ongoing and include habitat degradation and reduction from reduction of freshwater outflow from the Delta into the estuary (Factor A), increased intrusion of saltwater into spawning habitat areas (Factor A), alteration of food resources and availability (Factor E), nonnative species competition and food resource effects (Factor E), and the effects associated with climate change such as increased temperatures and frequency, magnitude, and duration of drought (Factor E). Because these threats are ongoing and currently impacting the DPS, and have already been shown to have caused a significant decline in the DPS's current resiliency, redundancy, and representation, the DPS meets the Act's definition of endangered status.

Thus, after assessing the best available information, we determine that the San Francisco Bay-Delta DPS of the longfin smelt is in danger of extinction throughout all of its range.

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 San Francisco Bay-Delta longfin smelt DPS is in danger of extinction throughout all of its range and accordingly did not undertake an analysis of any significant portion of the DPS's range. Because the DPS 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 significant portion of the range 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 San Francisco Bay-Delta longfin smelt DPS meets the definition of an endangered species. Therefore, we propose to list the San Francisco Bay-Delta longfin smelt DPS as endangered in accordance with sections 3(6) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition as a listed species, planning and implementation of 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 other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies, including the Service, 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 goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

The recovery planning process begins with development of a recovery outline made available to the public soon after a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions while a recovery plan is being developed. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) may be established to develop and implement recovery plans. The recovery planning process involves the identification of actions that are necessary to halt and reverse the species' decline by addressing the threats to its survival and recovery. The recovery plan identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or removal from protected status (''delisting''), 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. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery outline, draft recovery plan, final recovery plan, and any revisions will be available on our website as they are completed (*https://www.fws.gov/endangered*), or from our San Francisco Bay-Delta Fish and Wildlife Office (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. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this DPS is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of California would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Bay-Delta longfin smelt. Information on our grant programs that are available to aid species recovery can be found at: *https://www.fws.gov/service/financial-assistance.*

Although the Bay-Delta longfin smelt is only proposed for listing 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 proposed or 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 confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) 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 the 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 include management and any other landscape-altering activities on Federal lands or waters administered by the Service, NMFS, U.S. Bureau of Reclamation, U.S. Army Corps of Engineers, U.S. Department of Agriculture, or Federal Highway Administration.

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 NMFS, 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. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. 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) Take of the longfin smelt outside the range of the DPS as identified in figure 1;

(2) Take as a result of recreational fishing as permitted by the State of California; and

(3) Recreational boating on open water areas of the San Francisco Bay-Delta Estuary.

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; this list is not comprehensive:

Activities that the Service believes could potentially harm the Bay-Delta longfin smelt and result in ''take'' include, but are not limited to:

(1) Handling or collecting individuals of the DPS;

(2) Destruction/alteration of the Bay-Delta longfin smelt's habitat by discharge of fill material, dredging, draining, ditching, or stream channelization or diversion;

(3) Unauthorized diversion or alteration of surface flow into the San Francisco Bay-Delta estuary by removal of freshwater from rivers, streams wetlands, and other aquatic features;

(4) Pesticide applications in violation of label restrictions or introduction of other contaminants that may degrade water quality of the San Francisco Bay-Delta estuary; and

(5) Introduction of nonnative species that compete with or prey upon the Bay-Delta longfin smelt or alter food resources for the DPS.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the San Francisco Bay-Delta Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

II. Critical Habitat

Background

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in title 50 of the Code of Federal Regulations set forth the procedures for determining whether a species is an endangered species or a threatened species, issuing protective regulations for threatened species, and designating critical habitat for threatened and endangered species. In 2019, jointly with the National Marine Fisheries Service, the Service issued final rules that revised the regulations in 50 CFR parts 17 and 424 regarding how we add, remove, and reclassify threatened and endangered species and the criteria for designating listed species' critical habitat (84 FR 45020 and 84 FR 44752; August 27, 2019). At the same time the Service also issued final regulations that, for species listed as threatened species after September 26, 2019, eliminated the Service's general protective regulations automatically applying to threatened species the prohibitions that section 9 of the Act applies to endangered species (collectively, the 2019 regulations).

However, on July 5, 2022, the U.S. District Court for the Northern District of California vacated the 2019 regulations (*Center for Biological Diversity* v. *Haaland,* No. 4:19–cv–05206–JST, Doc. 168 (N.D. Cal. July 5, 2022) (*CBD* v. *Haaland*)), reinstating the regulations that were in effect before the effective date of the 2019 regulations as the law governing species classification and critical habitat decisions. Accordingly, in developing the analysis contained in this proposal, we applied the pre-2019 regulations, which may be reviewed in the 2018 edition of the Code of Federal Regulations at 50 CFR 424.12(a)(1). Because of the ongoing litigation regarding the court's vacatur of the 2019 regulations, and the resulting uncertainty surrounding the legal status of the regulations, we also undertook an analysis of whether the proposal would be different if we were to apply the 2019 regulations. That analysis, which we described in a separate memo in the decisional file and posted on *https://www.regulations.gov,* concluded that we would have reached the same proposal if we had applied the 2019 regulations because under either regulatory scheme we find that critical habitat is prudent for the DPS of Bay-Delta longfin smelt.

On September 21, 2022, the U.S. Circuit Court of Appeals for the Ninth Circuit stayed the district court's July 5, 2022, order vacating the 2019 regulations until a pending motion for reconsideration before the district court is resolved (*In re: Cattlemen's Ass'n,* No. 22–70194). The effect of the stay is that the 2019 regulations are currently the governing law. Because a court order requires us to submit this proposal to the **Federal Register** by September 30, 2022, it is not feasible for us to revise the proposal in response to the Ninth Circuit's decision. Instead, we hereby adopt the analysis in the separate memo that applied the 2019 regulations as our primary justification for the proposal. However, due to the continued uncertainty resulting from the ongoing litigation, we also retain the analysis in this preamble that applies the pre-2019 regulations and we conclude that, for the reasons stated in our separate memo analyzing the 2019 regulations, this proposal would have been the same if we had applied the 2019 regulations.

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).

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.

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.

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 a designation of critical habitat is not prudent when any of the following situations exist:

(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; or

(ii) Such designation of critical habitat would not be beneficial to the species. In determining whether a designation would not be beneficial, the factors the Services may consider include but are not limited to: Whether the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or whether any areas meet the definition of ''critical habitat.''

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 for the Bay-Delta longfin smelt, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to Bay-Delta longfin smelt. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) have been met, we have determined that the designation of critical habitat is prudent for the Bay-Delta longfin smelt.

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 Bay-Delta longfin smelt 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 DPS and habitat characteristics where this DPS 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 Bay-Delta longfin smelt 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 Rulemaking

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 proposed 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), 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. No Tribal lands were identified within the range of the Bay-Delta longfin smelt, and we did not receive any information during our development of the SSA report for the DPS. We will continue to reach out and coordinate with Tribal entities during the development of a final determination for listing the Bay-Delta longfin smelt.

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 San Francisco Bay-Delta 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 San Francisco Bay-Delta Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to 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(h) by adding an entry for ''Smelt, longfin [San Francisco Bay-Delta DPS]'' to the List of Endangered and Threatened Wildlife in alphabetical order under FISHES to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
		FISHES		
*	*	*	*	*
Smelt, longfin [San Francisco Bay-Delta DPS].	*Spirinchus thaleichthys* ..	U.S.A. (CA)	E	[**Federal Register** citation when published as a final rule].
*	*	*	*	*

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–21605 Filed 10–6–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 221003–0209]

RIN 0648–BL62

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagics Resources in the Gulf of Mexico and Atlantic Region; Framework Amendment 11

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to implement management measures described in Framework Amendment 11 to the Fishery Management Plan (FMP) for the Coastal Migratory Pelagic (CMP) Resources of the Gulf of Mexico and Atlantic Region (CMP FMP), as prepared and submitted by the Gulf of Mexico Fishery Management Council (Gulf Council). This proposed rule and Framework Amendment 11 would revise the Gulf of Mexico (Gulf) migratory group of king mackerel (Gulf king mackerel) catch limits. The purpose of this proposed rule and Framework Amendment 11 is to update catch limits to be consistent with the best scientific information available.

DATES: Written comments must be received on or before November 7, 2022.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2022–0078,'' by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter ''NOAA–NMFS–2022–0078'', in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Kelli O'Donnell, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of Framework Amendment 11, which includes a regulatory impact review, may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/framework-11-management-gulf-king-mackerel.*

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, telephone: 727–824–5305, or email: *Kelli.ODonnell@noaa.gov.*

SUPPLEMENTARY INFORMATION: Gulf king mackerel is managed under the CMP FMP prepared by the Gulf and South Atlantic Fishery Management Councils (Councils) and implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

All weights in this proposed rule are in round and eviscerated weight combined, unless otherwise specified.

Background

Under the CMP FMP, the Gulf Council manages fishing for Gulf king mackerel in Federal waters from Texas to the Florida Monroe/Miami-Dade County boundary. The Gulf king mackerel stock annual catch limit (ACL) is allocated between the commercial and recreational sectors.

The current overfishing limit (OFL) and acceptable biological catch (ABC) are 8,950,000 lb (4,059,652 kg) and 8,550,000 lb (3,878,215 kg), respectively. The current stock ACL is equal to the ABC. The OFL, ABC, and stock ACL were established in 2017 in Amendment 26 to the CMP FMP (82 FR 17387; April 11, 2017). These catch limits are based on projections from the Southeast Data Assessment and Review (SEDAR) 38 stock assessment and recommendations by the Council's Scientific and Statistical Committees (SSCs). The recreational landings estimates used in SEDAR 38 included data from the Marine Recreational Information Program's (MRIP) Coastal Household Telephone Survey (CHTS). MRIP now generates recreational landings estimates using the Fishing Effort Survey (FES) and the historical time series of king mackerel recreational landings has been calibrated to be consistent with the MRIP–FES estimates. The estimates generated using MRIP–FES are generally higher than those produced using CHTS because the new survey is designed to more accurately measure fishing activity.

In 2020, NMFS completed an update to SEDAR 38 that included calibrated MRIP–FES recreational landings. The Update indicated that Gulf group king mackerel was not overfished or undergoing overfishing, but recruitment had been low in recent years. In September 2020, the Gulf Council's SSC reviewed the SEDAR 38 Update and recommended a new OFL and ABC for Gulf group king mackerel that would address reduced recruitment and allow harvest to increase over time. The SSC's recommendation for the revised OFL is 11,050,000 lb (5,012,196 kg) for 2022, and 11,180,000 lb (5,071,163 kg) for 2023 and subsequent years. The SSC's recommendation for ABC is 9,720,000 lb (4,408,918 kg) for 2022, and 9,990,000 lb (4,531,388 kg) for 2023 and subsequent years. These OFL and ABC recommendations represent a reduction in the allowable harvest when compared to the current OFL and ABC. Had MRIP–FES data been available when SEDAR 38 was completed in 2014, the current OFL would have been 11,960,000 lb (5,424,965 kg) and the current ABC would have been 11,540,000 (5,234,456 kg). The Gulf Council and NMFS developed Framework Amendment 11 to update catch levels based on the results of the SEDAR 38 Update and Gulf SSC recommendations.

The Gulf Council manages Gulf king mackerel with sector allocations. In Amendment 1 to the FMP (50 FR 34840; August 25, 1985), the Councils allocated the total Gulf king mackerel ACL to 32 percent to the commercial sector and 68 percent to the recreational sector based on the average of available commercial and recreational landings data from 1975–1979. In Amendment 26, the Councils allocated the Gulf king mackerel total commercial ACL between the commercial Gulf zones: western zone (40 percent), northern (18 percent), and southern zone (42 percent). The southern zone was further divided by gear components with 50 percent of the southern zone allocation going to the hook and line component and 50 percent going to the gillnet component.

The fishing year for commercial harvest varies by zone: July through June for the Southern and Western zones, and October through September for the Northern zone. For the purpose

of comparing landings to the total ACL, recreational landings are monitored based on the commercial fishing year of July through June. Therefore, the sector ACLs and commercial quotas reflect that these fishing years occur in two calendar years, as noted below.

Management Measures Contained in This Proposed Rule

For Gulf king mackerel, this proposed rule would revise sector ACLs and the commercial zone quotas.

ACLs and Quotas

The current total ACL for Gulf king mackerel is equal to the ABC of 8,550,000 lb (3,878,215 kg). This rulemaking would modify the total ACL for Gulf king mackerel to 9,720,000 lb (4,408,918 kg) for 2022 and 9,990,000 lb (4,531,388 kg) for 2023 and subsequent years, which is also equal to the ABCs recommended by the Gulf Council's SSC. The 2022 total ACL would be used to establish the sector and zone catch limits for the 2022–2023 fishing year and the 2023 total ACL would be used the sector and zone catch limits for 2023–2024 and subsequent fishing years. As noted previously, the proposed ACLs represent a decrease in the allowable harvest of Gulf king mackerel because had the current total ACL been derived from an assessment using MRIP–FES data, the current total ACL would have been 11,540,000 lb (5,234,456 kg).

The current commercial ACL for the 2022–2023 fishing year is 2,740,000 lb (1,242,843 kg). Applying the current commercial allocation of 32 results in the proposed commercial ACLs of 3,110,400 lb (1,410,854 kg) for the 2022–2023 fishing year, and 3,196,800 lb (1,450,044 kg) for the 2023–2024 and subsequent years. The current recreational ACL for the 2022–2023 fishing year is 5,810,000 lb (2,635,372 kg). Applying the current recreational allocation of 68 percent results in proposed recreational ACLs of 6,609,600 lb (2,998,064 kg) for the 2022–2023 fishing year, and 6,793,200 lb (3,081,344 kg) for the 2023–2024 and subsequent years. Because the proposed recreational ACL will now be monitored using landings estimates generated by MRIP–FES this represents a decrease in the allowable recreational harvest. However, recreational landings, as estimated using MRIP–FES, have been well below the proposed ACLs since the 2016–2017 fishing year and NMFS does not expect the reduction in the recreational ACL to reduce recreational opportunities.

The current zone quotas for the 2022–2023 fishing year are 1,096,000 lb (497,137 kg) for the western zone, 493,200 lb (223,712 kg) for the northern zone, 575,400 lb (260,997 kg) for the southern zone hook-and-line component, and 575,400 lb (260,997 kg) for the southern zone gillnet component. The current total commercial hook-and-line ACL for the entire Gulf for the 2022–2023 fishing year is 2,164,600 lb (981,846 kg). Using the current commercial zone allocations, this proposed rule would revise the western zone quota to 1,244,160 lb (564,341 kg) for the 2022–2023 fishing year, and 1,278,720 lb (580,017 kg) for 2023–2024 fishing year and subsequent fishing years. The northern zone quota would be 559,872 lb (253,954 kg) for the 2022–2023 fishing year and 575,424 lb (261,008 kg) for the 2023–2024 fishing year and subsequent fishing years. The southern zone hook and line component quota would be 653,184 lb (296,279 kg) for the 2022–2023 fishing year, and 671,328 lb (304,509 kg) for the 2023–2024 fishing year and subsequent years. The southern zone gillnet component quota would be 653,184 lb (296,279 kg) for the 2022–2023 fishing year, and 671,328 lb (304,509 kg) for the 2023–2024 fishing year and subsequent fishing years. The total commercial hook and line ACL (entire Gulf) would be 2,457,216 lb (1,114,574 kg) for the 2022–2023 fishing year, and 2,525,472 lb (1,145,535 kg) for the 2023–2024 fishing year and subsequent fishing years. The southern zone gillnet component quota would be 653,184 lb (296,279 kg) for the 2022–2023 fishing year, and 671,328 lb (304,509 kg) for the 2023–2024 fishing year and subsequent fishing years.

Management Measures in Framework Amendment 11 Not Codified Through This Proposed Rule

OFL and ABC

As previously discussed, the current OFL and ABC for Gulf king mackerel of 8,950,000 lb (4,059,652 kg) and 8,550,000 lb (3,878,214 kg), are based on the Councils' SSCs' recommendations from SEDAR 38, which used recreational landings estimates from MRIP–CHTS. Framework Amendment 11 would adopt new OFLs and ABCs based on the Gulf Council's SSC recommendations from the results of the SEDAR 38 Update, which used MRIP–FES recreational landings estimates. The new OFLs would be 11,050,000 lb (5,012,196 kg) for 2022, and 11,180,000 lb (5,071,163 kg) for 2023 and subsequent years. The new ABCs would be 9,720,000 lb (4,408,918 kg) for 2022, and 9,990,000 lb (4,531,388 kg) for 2023 and subsequent years.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the framework action, the CMP FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

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

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination follows.

A description of this proposed rule, why it is being considered, and the objectives of this proposed rule are contained in this **SUPPLEMENTARY INFORMATION** section. The Magnuson-Stevens Act provides the statutory basis for this proposed rule.

This proposed rule, if implemented, would apply to all commercial vessels, charter vessels and headboats (for-hire vessels), and recreational anglers that fish for or harvest Gulf king mackerel, which occurs throughout the Gulf and off of Monroe County, Florida in the South Atlantic. The RFA does not consider recreational anglers to be small entities, so they are outside the scope of this analysis (5 U.S.C. 603). Small entities include small businesses, small organizations, and small governmental jurisdictions (5 U.S.C. 601(6) and 601(3)–(5)). Recreational anglers are not businesses, organizations, or governmental jurisdictions.

For-hire vessels sell fishing services to recreational anglers. The proposed changes to the Gulf migratory group king mackerel catch limits would not directly alter the services sold by these for-hire vessels. Any change in anglers' demand for these fishing services (and associated economic effects) as a result of the proposed action would be secondary to any direct effect on anglers and, therefore, would be an indirect effect of this proposed rule. Indirect effects fall outside the scope of the RFA. However, for-hire captains and crew are allowed to sell Gulf king mackerel harvested under the recreational bag limit when the commercial season is open, if they have both a Gulf Charter/Headboat for Coastal Migratory Pelagics permit (Gulf CMP for-hire permit) and a

valid commercial king mackerel permit. Therefore, for-hire businesses, or employees thereof, could be directly affected by this proposed rule.

During 2020, there were a total of 1,426 valid or renewable commercial king mackerel permits and 17 valid or renewable king mackerel gillnet endorsements. Only vessels with both the commercial permit and gillnet endorsement are allowed to harvest king mackerel in the southern zone using gillnet gear. On average from 2016 through 2020, there were 254 federally-permitted commercial vessels with reported landings of king mackerel in the Gulf. Their average annual vessel-level gross revenue from all species from 2016 through 2020, was approximately $93,426 (2021 dollars) and king mackerel harvested in the Gulf accounted for approximately 23 percent of this revenue. For commercial vessels that harvest Gulf king mackerel in the Gulf, it is estimated that economic profits are approximately 21.6 percent of annual gross revenue, on average. During the same period, there were 128 federally-permitted commercial vessels with reported landings of Gulf king mackerel in the South Atlantic. Their average annual vessel-level revenue from all species for 2016 through 2020 was approximately $40,035 (2021 dollars) and Gulf king mackerel harvested in the South Atlantic accounted for approximately 14 percent of this revenue. For commercial vessels that harvest Gulf king mackerel in the South Atlantic, it is estimated that economic profits are approximately 4.5 percent of annual gross revenue, on average. The maximum annual revenue from all species reported by a single one of the vessels that harvested Gulf king mackerel from 2016 through 2020, was approximately $2.44 million (2021 dollars).

For anglers to fish for or possess CMP species in or from Gulf Federal waters on for-hire vessels, those vessels are required to have a limited access Gulf CMP for-hire permit. On February 1, 2022, there were 1,299 valid (non-expired) or renewable Gulf CMP for-hire permits and 4 valid or renewable Gulf CMP historical captain for-hire permits. For anglers to fish for or possess CMP species in or from the Mid-Atlantic or South Atlantic Federal waters on for-hire vessels, those vessels are required to have an open access South Atlantic Charter/Headboat for Coastal Migratory Pelagic permit (South Atlantic CMP for-hire permit). On September 3, 2021, there were 1,825 valid South Atlantic CMP for-hire permits. Although the for-hire permit application collects information on the primary method of fishing operation, the permit itself does not identify the permitted vessel as either a headboat or a charter vessel and vessels may operate in both capacities under that permit. However, only federally permitted headboats are required to submit harvest and effort information to the NMFS Southeast Region Headboat Survey (SRHS). Participation in the SRHS is based on determination by the Southeast Fisheries Science Center (SEFSC) that the vessel primarily operates as a headboat. As of February 22, 2022, 69 Gulf headboats and 66 South Atlantic headboats were registered in the SRHS. As a result, of the 1,303 vessels with Gulf CMP for-hire permits (including historical captain permits), up to 69 may primarily operate as headboats and the remainder as charter vessels. Of the 1,825 vessels with South Atlantic CMP for-hire permits, up to 66 may primarily operate as headboats.

The average charter vessel operating in the Gulf is estimated to receive approximately $94,000 (2021 dollars) in gross revenue and $28,000 in net income (gross revenue minus variable and fixed costs) annually. The average Gulf headboat is estimated to receive approximately $451,000 (2021 dollars) in gross revenue and $84,000 in net income annually. The average charter vessel operating in the South Atlantic is estimated to receive approximately $132,000 (2021 dollars) in annual gross revenue. The average South Atlantic headboat is expected to receive approximately $234,000 (2021 dollars) in annual gross revenue. Estimates of annual net income for South Atlantic charter vessels and headboats are not available.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (North American Industry Classification System (NAICS) code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. All of the commercial fishing businesses directly regulated by this proposed rule are believed to be small entities based on the NMFS size standard.

The SBA has established size standards for all major industry sectors in the U.S., including for-hire businesses (NAICS code 487210). A business primarily involved in the for-hire fishing industry is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $8 million for all its affiliated operations worldwide. All of the for-hire vessels directly regulated by this proposed rule are believed to be small entities based on the SBA size criteria.

No other small entities that would be directly affected by this proposed rule have been identified.

CMP Framework Amendment 11 and this proposed rule would modify the Gulf king mackerel OFL, ABC, and total ACL as recommended by the Gulf's SSC for the 2021–2022 through 2023–2024 and subsequent fishing years. The total ACL would be set equal to the ABC or 9,720,000 lb (4,408,918 kg) in the 2022–2023 fishing year and then to 9,990,000 lb (4,531,388 kg) in the 2023–2024 fishing year and subsequent years. The commercial ACL would be set equal to 3,110,400 lb (1,410,854 kg) in the 2022–2023 fishing year and 3,196,800 lb (1,450,044 kg) in the 2023–2024 fishing year and subsequent fishing years. The commercial ACL is further divided into zone and gear component specific quotas with 40 percent going to the western zone quota, 18 percent going to the northern zone quota, 21 percent going to the southern zone hook-and-line quota, and 21 percent going to the southern zone gillnet quota. Overall, the proposed increase to the Gulf king mackerel commercial ACL, relative to the status quo commercial ACL of 2,740,000 lb (1,242,843 kg), would be 370,400 lb (168,011 kg) in the 2022–2023 fishing year and 456,800 lb (207,201 kg) in the 2023–2024 fishing year and subsequent years.

If commercial vessels harvest the full commercial ACL proposed for 2022–2023, it would result in an aggregate increase in annual ex-vessel revenue of $833,400 (2021 dollars). The western zone would be expected to see an increase of $333,360 (2021 dollars) in ex-vessel revenue; the northern zone would be expected to see an increase of $150,012 in ex-vessel revenue; and the southern zone would be expected to see an increase of $350,028 in ex-vessel revenue, which would be split in half among the hook-and-line vessels and gillnet vessels. On average from 2016 through 2020, there were approximately 363 federally permitted commercial vessels (Gulf and South Atlantic combined) that harvested and sold Gulf king mackerel each year. Assuming the potential aggregate increase in ex-vessel revenue from this proposed action is shared evenly by these vessels, it would result in a per-vessel increase in annual

ex-vessel revenue of approximately $2,300 (2021 dollars) for the 2022–2023 fishing year. This would represent an increase in per vessel average annual gross revenue of approximately 2 percent and 6 percent for Gulf and South Atlantic vessels, respectively. Individual vessels may experience varying levels of economic effects, depending on their fishing practices, operating characteristics, and profit maximization strategies.

In the 2023–2024 fishing year and subsequent years, the proposed increase, if harvested in full, would result in $1,027,800 in additional annual ex-vessel revenue (2021 dollars). The western zone would be expected to see an increase of $411,120 (2021 dollars) in ex-vessel revenue; the northern zone would be expected to see an increase of $185,004 in ex-vessel revenue; and the southern zone would be expected to see an increase of $431,676 in ex-vessel revenue, which would be split in half among hook-and-line vessels and gillnet vessels. Assuming the potential increase in ex-vessel revenue from this proposed action is shared evenly by the 363 vessels that harvested Gulf king mackerel (on average from 2016 through 2020), it would result in a per-vessel increase in annual ex-vessel revenue of $2,800 (2021 dollars) during the 2023–2024 fishing year and subsequent years. This would represent an increase in per vessel average annual gross revenue of approximately 3 percent and 7 percent for Gulf and South Atlantic vessels, respectively. Individual vessels may experience varying levels of economic effects, depending on their fishing practices, operating characteristics, and profit maximization strategies.

In summary, the information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this proposed rule.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 622

Annual catch limits, Fisheries, Fishing, Gulf of Mexico, King mackerel, Quotas.

Dated: October 3, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.384, revise paragraphs (b)(1)(i), (ii), and (iii) to read as follows:

§ 622.384 Quotas.

* * * * *

(b) * * *

(1) * * *

(i) *Western zone.* The quota is 1,199,360 lb (544,021 kg) for the 2021–2022 fishing year, 1,244,160 lb (564,341 kg) for the 2022–2023 fishing year, and 1,278,720 lb (580,018 kg) for the 2023–2024 fishing year and subsequent fishing years.

(ii) *Northern zone.* The quota is 539,712 lb (244,809 kg) for the 2021–2022 fishing year, 559,872 lb (253,954 kg) for the 2022–2023 fishing year, and 575,424 lb (261,008 kg) for the 2023–2024 fishing year and subsequent fishing years.

(iii) *Southern zone.* (A) The hook-and-line quota is 629,664 lb (285,611 kg) for the 2021–2022 fishing year, 653,184 lb (296,279 kg) for the 2022–2023 fishing year, and 671,328 lb (304,509 kg) for the 2023–2024 and subsequent fishing years.

(B) The run-around gillnet quota is 629,664 lb (285,611 kg) for the 2021–2022 fishing year, 653,184 lb (296,279 kg) for the 2022–2023 fishing year, and 671,328 lb (304,509 kg) for the 2023–2024 and subsequent fishing years.

* * * * *

■ 3. In § 622.388, revise paragraphs (a)(1)(ii) and (a)(2) to read as follows:

§ 622.388 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(a) * * *

(1) * * *

(ii) The commercial ACL for the Gulf migratory group of king mackerel is 2,998,400 lb (1,360,051 kg) for the 2021–2022 fishing year, 3,110,400 lb (1,410,854 kg) for the 2022–2023 fishing year, and 3,196,800 lb (1,450,044 kg) for the 2023–2024 and subsequent fishing years. The ACL is further divided into a commercial ACL for vessels fishing with hook-and-line and a commercial ACL for vessels fishing with run-around gillnets. The hook-and-line ACL (which applies to the entire Gulf) is 2,368,736 lb (1,074,441 kg) for the 2021–2022 fishing year, 2,457,216 lb (1,114,574 kg) for the 2022–2023 fishing year, and 2,525,472 lb (1,145,535 kg) for the 2023–2024 and subsequent fishing years. The run-around gillnet ACL (which applies to the southern zone) is 629,664 lb (285,611 kg) for the 2021–2022 fishing year, 653,184 lb (296,279 kg) for the 2022–2023 fishing year, and 671,328 lb (304,509 kg) for the 2023–2024 and subsequent fishing years.

* * * * *

(2) *Recreational sector.* If recreational landings, as estimated by the SRD, reach or are projected to reach the recreational ACL of 6,371,600 lb (2,890,109 kg) for the 2021–2022 fishing year, 6,609,600 lb (2,998,064 kg) for the 2022–2023 fishing year, and 6,793,200 lb (3,081,344 kg) for the 2023–2024 and subsequent fishing years, the AA will file a notification with the Office of the Federal Register to implement bag and possession limits for Gulf migratory group king mackerel of zero, unless the best scientific information available determines that a bag limit reduction is unnecessary.

* * * * *

[FR Doc. 2022–21807 Filed 10–6–22; 8:45 am]

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Notices

Federal Register
Vol. 87, No. 194
Friday, October 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

Submission for OMB Review; Comment Request

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

Comments regarding this information collection received by November 7, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *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.

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

Animal and Plant Health Inspection Service

Title: National Animal Health Reporting System (NAHRS).

OMB Control Number: 0579–0299.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. The AHPA is contained in Title X, Subtitle E, Sections 10401–18 of Public Law 107–171, May 13, 2002, of the Farm Security and Rural Investment Act of 2002. Disease prevention is the most effective method for maintaining a healthy animal population and enhancing the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Veterinary Services' (VS) ability to allow U.S. animal producers to compete in the world market of animal and animal product trade. In connection with this mission, APHIS operates NAHRS, which collects, on a national basis, data on the prevalence of important livestock and poultry diseases within the United States.

Need and Use of the Information: The NAHRS collects data monthly from State veterinarians on the presence or absence of specific diseases of interest to the World Organization for Animal Health (Office International des Epizooties) (OIE). As a member country of the OIE, the United States is required to submit reports on the status of certain diseases notifiable to the OIE. Reportable diseases are diseases that have the potential for rapid spread, irrespective of national borders, that are of serious socio-economic or public health consequence and that are of major importance in the international trade of animals and animal products. The potential benefits to trade as a result of the NAHRS include accurate reporting on the health status of the U.S. livestock industry, improved and expanded animal disease reporting infrastructure, expansion of livestock industries into new export markets, and preservation of existing markets through increased confidence in quality and disease freedom of U.S. livestock. This data collection is unique in terms of the type, quantity, and frequency of data; no other entity is collecting and reporting this type of data on the health status of U.S. livestock to the OIE.

Description of Respondents: State Governments, private laboratories.

Number of Respondents: 77.

Frequency of Responses: Reporting.

Total Burden Hours: 6,615.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–21879 Filed 10–6–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

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

Comments regarding this information collection received by November 7, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *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.

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

Foreign Agricultural Service

Title: CCC's Facility Guarantee Program (FGP).

OMB Control Number: 0551–0032.

Summary of Collection: The Commodity Credit Corporation's (CCC) Facility Guarantee Program (FGP) offers credit guarantees to facilitate the financing of U.S. manufactured goods and services to improve or establish agricultural infrastructure and/or facilities in emerging markets, with the goal of increasing U.S. agricultural commodity exports. Sales under FGP are considered normal commercial sales.

Under the authority of 7 CFR part 1493, subpart C, the Facility Guarantee Program (FGP) offers credit guarantees to facilitate the financing of U.S. manufactured goods and services to improve or establish agriculture infrastructure in emerging markets. Sales under FGP are considered normal commercial sales. The Foreign Agricultural Service (FAS) will collect information in a letter format via mail or facsimile.

Need and Use of the Information: The information collection is necessary to enable sellers and U.S. and foreign financial institutions to receive the benefits of the program. FAS will collect information to determine eligibility for FGP benefits and to ensure CCC that all participants have a business office in the U.S. and are not debarred or suspended from participating in government programs. FAS will use the application to determine a project's eligibility for FGP coverage and to determine the impact on U.S. agricultural trade. The information requested will provide CCC with adequate information to meet statutory requirements.

If the information were not collected CCC would be unable to determine if export sales under the FGP would be eligible for coverage or if coverage conformed to program requirements-thus making CCC unable to ensure appropriate and efficient use of government resources.

Description of Respondents: Business or other for-profit.

Number of Respondents: 18.

Frequency of Responses: Recordkeeping; Reporting; On occasion.

Total Burden Hours: 360.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–21874 Filed 10–6–22; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket No. RBS–22–Business–0023]

Notice of New Information Collection

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Business-Cooperative Service's (RBCS or Agency), an agency within the United States Department of Agriculture, Rural Development, requested that the Office of Management and Budget (OMB) conduct an emergency review by September 27, 2022, of a new information collection package for the Fertilizer Production Expansion Program (FPEP). In addition to the emergency clearance, the regular clearance process is hereby being initiated to provide the public with the opportunity to comment under a full comment period, as the Agency intends to request regular approval from OMB for this information collection. FPEP will support new and expanded supplies of fertilizer and nutrient alternatives that play the same role as fertilizer to United States farmers as a key input necessary for production of agricultural commodities.

DATES: Comments on this notice must be received by December 6, 2022 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: Pamela Bennett, Regulations Management Division, Innovation Center, U.S. Department of Agriculture. Email: *pamela.bennett@usda.gov.* Telephone: (202) 720–9639.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that RBCS provide public notice of its request for emergency processing and the time period within which OMB should approve or disapprove the collection of information (see 5 CFR 1320.13(d)). This notice identifies this request for an emergency review by September 27, 2022. The regulation also requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that RBCS will submit to OMB for regular approval.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Rural Business-Cooperative Service, including whether the information will have practical utility; (b) the accuracy of the Rural Business-Cooperative Service's estimate of the burden of the proposed collection of information including validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent by the Federal eRulemaking Portal: Go to *https://www.regulations.gov* and, in the ''Search'' box, type in the Docket No. RBS–22–Business–0023. A link to the Notice will appear. You may submit a comment here by selecting the ''Comment'' button or you can access the ''Docket'' tab, select the ''Notice,'' and go to the ''Browse & Comment on Documents'' Tab. Here you may view comments that have been submitted as well as submit a comment. To submit a comment, select the ''Comment'' button, complete the required information, and select the ''Submit Comment'' button at the bottom. Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''FAQ'' link at the bottom.

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. Data furnished by the applicants will be used to determine eligibility for program benefits. Furnishing the data is voluntary; however, failure to provide data could result in program benefits being withheld or denied.

Title: Fertilizer Production Expansion Program.

OMB Control Number: 0570–0081.

Type of Request: New information collection.

Abstract: The Rural Business-Cooperative Service administers the Fertilizer Production Expansion Program (FPEP). The purpose of the program is to expand capacity, improve competition, and increase supply chain resilience within the agricultural fertilizer and nutrient management sector, in connection with the production of agricultural commodities. To meet its purpose, FPEP will support the production of agricultural commodities through the manufacturing and processing of fertilizer and nutrient alternatives that are:

- Independent and outside the dominant fertilizer suppliers—The goal is to increase domestic competition. Consequently, entities that hold a Market Share (in either production or distribution) that is greater than or equal to the entity that holds the fourth largest share of the market for nitrogen, phosphate, or potash, or any combination therefore, will not be considered for funding;
- Made in America—Produced within Tribal Lands or in the U.S. and its territories by entities operating within Tribal Lands or in the U.S. and its territories, creating good-paying jobs at home, and reducing the reliance on potentially unstable or inconsistent foreign supplies;
- Innovative—To improve upon fertilizer production methods and efficient-use technologies to jump start the next generation of fertilizers and nutrient alternatives;
- Sustainable—Reduces the greenhouse gas impact of transportation, production, and use through renewable energy sources, feedstocks, formulations, and incentivizing greater precision in fertilizer use; and
- Farmer-focused—Like other CCC investments, a driving factor will be making sure the additional domestic capacity supported by USDA is dedicated to U.S. agricultural commodity production.

The reporting burden covered by this collection of information consists of forms, documents and written burden to support a request for funding for an FPEP grant. This information collection will be used to obtain information necessary to evaluate grant applications to determine the eligibility of the applicant and the project for the program and to qualitatively assess the project's technical and financial merit to determine which projects should be funded.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 10.42 hours per response.

Respondents: Respondents for this data included but are not limited to Tribes, Tribal entities, for-profit entities, corporations, non-profit entities, producer-owned cooperatives and corporations, certified benefit corporations and state or local government entities.

Estimated Number of Respondents: 135.

Estimated Number of Responses per Respondent: 13.56.

Estimated Number of Responses: 1,831.

Estimated Total Annual Burden on Respondents: 19,082 hours.

Copies of this information collection can be obtained from Pamela Bennett, Rural Development Innovation Center, Regulations Management Division, at (202) 720–9639. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Mark Brodziski,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2022–21889 Filed 10–6–22; 8:45 am]

BILLING CODE 3410–XY–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Hawai'i 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 a meeting of the Hawai'i Advisory Committee to the Commission will convene by ZoomGov on Monday, November 7, 2022, from 9:00 a.m. to 10:30 a.m. HST, to discuss and potentially vote on a project topic.

DATES: Monday, November 7, 2022, from 9:00 a.m.–10:30 a.m. HST.

Zoom Link: *https://tinyurl.com/yck26akb.*

Audio: (551) 285–1373; Meeting ID: 160 192 4110

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, Designated Federal Officer (DFO) at *kfajota@usccr.gov* or by phone at (434) 515–2395.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the Zoom link above. 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 call-in number found through registering at the web link provided for this meeting.

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 emailed to Kayla Fajota at *kfajota@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl0AAA.*

Please click on ''Committee Meetings'' tab. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. 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 phone number or email address.

Agenda

I. Welcome and Roll Call
II. Approval of August 23, 2022, Meeting Minutes
III. Discussion and Potential Vote: Potential Project Topic
IV. Next Steps
V. Public Comment
VI. Adjournment

Dated: October 4, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–21907 Filed 10–6–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Missouri Advisory Committee to the U.S. Commission on Civil Rights

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 Missouri Advisory Committee

(Committee) will hold a meeting on Wednesday, October 26, 2022 at 12 p.m.–1 p.m. central time. The Committee will continue orientation and begin identifying potential civil rights topics for their first study of the 2022–2026 term.

DATES: The meeting will take place on Wednesday, October 26, 2022 at 12 p.m. central time.

ADDRESSES:

Public Call Information: Dial: (833) 435–1820, Confirmation Code: 161 707 0170.

Zoom Link: https://www.zoomgov.com/j/1617070170.

• To join by phone only dial (833) 435–1820; Access Code: 161 707 0170.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or (312) 353–8311.

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. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. 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. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individual who is deaf, deafblind and hard of hear 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 confirmation code.

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 mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324, or emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

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, Mississippi 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 and roll call
II. Introductions
III. Discuss Civil Rights Topics
IV. Public comment
V. Next steps
VI. Adjournment

Dated: October 4, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–21901 Filed 10–6–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the U.S. Virgin Islands Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice 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 U.S. Virgin Islands Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a web meeting via Zoom at 12:00 p.m. EST (AST) on Wednesday, November 2, 2022, for the purpose of meeting for the first time as a newly appointed Committee and discussing various potential civil rights topics for the Committee's first project.

DATES: The meeting will take place on Wednesday, November 2, 2022, at 12:00 p.m. EST (AST).

Online (Audio/Visual): https://tinyurl.com/d225fmtr.

Telephone (Audio Only): Dial: 1–833–568–8864; Meeting ID: 160 967 2921.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez, DFO, at *ero@usccr.gov* or 1–202–529–8246.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the meeting link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, 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 details found through registering at the web link above. To request additional accommodations, please email *ero@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also 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 Sarah Villanueva at *svillanueva@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at 1–202–376–7533.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination 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, U.S. Virgin Islands 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 Coordination Unit at the above email or street address.

Agenda

I. Welcome
II. Introductions
III. Recap/Explanation of Stage Gate Management
IV. Concept Stage Discussion
V. Public Comment
VI. Adjourn

Dated: October 4, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–21900 Filed 10–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Economic Development Administration (EDA), National Telecommunications and Information Administration (NTIA), Bureau of Industry and Security (BIS), Minority Business Development Agency (MBDA); Membership of the Performance Review Board for EDA, NTIA, BIS and MBDA

AGENCY: EDA, NTIA, BIS, and MBDA; Department of Commerce.

ACTION: Notice of membership on the EDA, NTIA, BIS and MBDA Performance Review Board.

SUMMARY: The EDA, NTIA, BIS and MBDA, Department of Commerce (DOC), announce the appointment of those individuals who have been selected to serve as members of the Performance Review Board. The Performance Review Board is responsible for reviewing performance appraisals and ratings of Senior Executive Service (SES) members and Senior Level (SL) members and making recommendations to the appointing authority on other performance management issues, such as pay adjustments and bonuses. The appointment of these members to the Performance Review Board will be for a period of twenty-four (24) months.

DATES: The period of appointment for those individuals selected for EDA, NTIA, BIS and MBDA Performance Review Board begins on October 7, 2022.

FOR FURTHER INFORMATION CONTACT: Christine Covington, U.S. Department of Commerce, Office of Human Resources Management, Office of Executive Resources, 14th and Constitution Avenue NW, Room 50021, Washington, DC 20230, at (202)482–2613.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the EDA, NTIA, BIS, and MBDA, Department of Commerce (DOC), announce the appointment of those individuals who have been selected to serve as members of EDA, NTIA, BIS and MBDA Performance Review Board. The Performance Review Board is responsible for (1) reviewing performance appraisals and ratings of Senior Executive Service (SES) and Senior Level (SL) members and (2) making recommendations to the appointing authority on other Performance management issues, such as pay adjustments and bonuses for SES and SL members. The Appointment of these members to the Performance Review Board will be for a period of twenty-four (24) month.

The name, position title, and type of appointment of each member of the Performance Review Board are set forth below:

1. *Department of Commerce, National Telecommunications and Information Administration (NTIA), First Responder Network Authority,* Jeffrey Bratcher, Chief Technology Officer, Career SES
2. *Department of Commerce, National Telecommunications and Information Administration (NTIA),* Jaisha Wray, Associate Administrator, Office of International Affairs, Career SES
3. *Department of Commerce, Economic Development Agency (EDA),* Michele Chang, Deputy Assistant Secretary for Policy, Non-Career SES
4. *Department of Commerce, National Telecommunications and Information Administration (NTIA),* Stephanie Sykes, Senior Advisor, Non-Career SES
5. *Department of Commerce, Economic Development Agency (EDA),* Harry Phillip, Paradice Regional Director, Atlanta Regional Office, Career SES
6. *Department of Commerce, Office of the Secretary (OS),* Miguel L'Heureux, White House Liaison, Non-Career SES
7. *Department of Commerce, Bureau of Industry and Security (BIS),* Eileen Albanese, Director Office of National Security and Technology Transfer Controls, Career SES
8. *Department of Commerce, National Telecommunications and Information Administration (NTIA),* Steve Molina, Deputy Associate Administrator for Spectrum Management, Career SES
9. *Department of Commerce, Bureau of Industry and Security (BIS),* Karen H. Nies-Vogel Director, Office of Exporter Services, Career SES
10. *Department of Commerce, National Telecommunications and Information Administration (NTIA),* Douglas Kinkoph, Associate Administrator for Telecommunications and Information Applications, Career SES
11. *Department of Commerce, National Telecommunications and Information Administration (NTIA),* Philip Murphy, Senior Advisor, Non-Career SES
12. *Department of Commerce, Economic Development Agency (EDA),* Linda Cruz-Carnall, Philadelphia Regional Director, Career SES
13. *Department of Commerce, National Telecommunications and Information Administration (NTIA),* Kim Farington, Chief Financial and Administrative Officer, Career SES

Dated: September 30, 2022.

Christine Covington,

Human Resources Specialist, Office of Executive Resources, Office of Human Resources Management, Office of the Secretary, Department of Commerce.

[FR Doc. 2022–21616 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–25–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Renewing Temporary Denial of Export Privileges

Azur Air, Sharypovo Airport, 404/1 Kozhevnicheskiy Lane, Moscow, Russia

Pursuant to section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2021) (''EAR'' or ''the Regulations''),[1] I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the temporary denial order (''TDO'') issued in this matter on April 7, 2022. I find that renewal of this order is necessary in the public interest to prevent an imminent violation of the Regulations.

I. Procedural History

On April 7, 2022, I signed an order denying Azur Air's (''Azur'') export privileges for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to Section 766.24(a) of the Regulations and was effective upon issuance.[2]

On September 13, 2022, BIS, through OEE, submitted a written request for renewal of the TDO that issued on April 7, 2022. The written request was made more than 20 days before the TDO's scheduled expiration. A copy of the renewal request was sent to Azur in accordance with Sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received.

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations, or any order, license or authorization issued thereunder. 15 CFR 766.24(b)(1) and 766.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future

[1] On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. app. 2401 *et seq.* (''EAA'') (except for three sections which are inapplicable here), section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (''IEEPA''), and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

[2] The TDO was published in the **Federal Register** on April 12, 2022 (87 FR 21614).

violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

B. The TDO and BIS's Request for Renewal

The U.S. Commerce Department, through BIS, responded to the Russian Federation's (''Russia's'') further invasion of Ukraine by implementing a sweeping series of stringent export controls that severely restrict Russia's access to technologies and other items that it needs to sustain its aggressive military capabilities. These controls primarily target Russia's defense, aerospace, and maritime sectors and are intended to cut off Russia's access to vital technological inputs, atrophy key sectors of its industrial base, and undercut Russia's strategic ambitions to exert influence on the world stage. Effective February 24, 2022, BIS imposed expansive controls on aviation-related (*e.g.,* Commerce Control List Categories 7 and 9) items to Russia, including a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (ECCN) 9A991 (section 746.8(a)(1) of the EAR).[3] BIS will review any export or reexport license applications for such items under a policy of denial. *See* Section 746.8(b). Effective March 2, 2022, BIS excluded any aircraft registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia from being eligible for license exception Aircraft, Vessels, and Spacecraft (AVS) (Section 740.15 of the EAR).[4] Accordingly, any U.S.-origin aircraft or foreign aircraft that includes more than 25% controlled U.S.-origin content, and that is registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia, is subject to a license requirement before it can travel to Russia.

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO and the evidence developed over the course of this investigation, which indicate a blatant disregard for U.S. export controls, as well as the TDO. Specifically, the initial TDO, issued on April 7, 2022, was based on evidence that Azur engaged in conduct prohibited by the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991.b on flights into Russia after March 2, 2022, from destinations including Nha Trang, Vietnam, Dubai, United Arab Emirates, and Antalya, Turkey, without the required BIS authorization.[5] Further evidence submitted by BIS indicated that Azur was continuing to operate aircraft subject to the EAR both into and out of Moscow and other cities in Russia potentially in violation of Section 736.2(b)(10) of the Regulations.

In its September 13, 2022 request for renewal of the TDO, BIS has submitted evidence that Azur continues to operate in violation of the April 7, 2022 TDO and/or the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991.b on flights into and out of Russia. Specifically, BIS's evidence and related investigation indicated that Azur has continued to operate aircraft subject to the EAR, including, but not limited to, flights into and out of Russia from/to Antalya, Turkey, Bodrum, Turkey, and Dalaman, Turkey. Information about those flights includes, but is not limited to, the following:

Tail No.	Serial No.	Aircraft type	Departure/arrival cities	Dates
RA–73071	29377	757–2Q8 (B752)	Antalya, TY/Moscow, RU	September 17, 2022.
RA–73071	29377	757–2Q8 (B752)	Antalya, TY/Samara, RU	September 19, 2022.
RA–73071	29377	757–2Q8 (B752)	Antalya, TY/Moscow, RU	September 21, 2022.
RA–73075	26271	757–2Q8 (B752)	Dalaman, TY/Ufa, RU	September 17, 2022.
RA–73075	26271	757–2Q8 (B752)	Dalaman, TY/Moscow, RU	September 18, 2022.
RA–73075	26271	757–2Q8 (B752)	Bodrum, TY/Moscow, RU	September 20, 2022.
RA–73077	30045	757–2Q8 (B752)	Antalya, TY/Moscow, RU	September 18, 2022.
RA–73077	30045	757–2Q8 (B752)	Bodrum, TY/Moscow, RU	September 19, 2022.
RA–73077	30045	757–2Q8 (B752)	Dalaman, TY/Yekaterinberg, RU	September 20, 2022.

III. Findings

Under the applicable standard set forth in section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that Azur has acted in violation of the Regulations and the TDO; that such violations have been significant, deliberate and covert; and that given the foregoing and the nature of the matters under investigation, there is a likelihood of imminent violations. Therefore, renewal of the TDO is necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should avoid dealing with Azur in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

IV. Order

It is therefore ordered:

First, Azur Air, Sharypovo Airport, 404/1 Kozhevnicheskiy Lane, Moscow, Russia, when acting for or on their behalf, any successors or assigns, agents, or employees may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

[3] 87 FR 12226 (Mar. 3, 2022). Additionally, BIS published a final rule effective April 8, 2022, which imposed licensing requirements on items controlled on the Commerce Control List (''CCL'') under Categories 0–2 that are destined for Russia or Belarus. Accordingly, now all CCL items require export, reexport, and transfer (in-country) licenses if destined for or within Russia or Belarus. 87 FR 22130 (Apr. 14, 2022).

[4] 87 FR 13048 (Mar. 8, 2022).

[5] Publicly available flight tracking information shows that on March 6, 2022, serial number (SN) 27612 flew from Nha Trang, Vietnam to Moscow, Russia, and on March 10, 2022, SN 27909 flew from Dubai, UAE to Vladivostok, Russia. In addition, on March 17, 2022, SN 21614 flew from Antalya, Turkey to Kazan, Russia.

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations, or engaging in any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of Azur any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by Azur of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby Azur acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from Azur of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

D. Obtain from Azur in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by Azur, or service any item, of whatever origin, that is owned, possessed or controlled by Azur if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to Azur by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of sections 766.24(e) of the EAR, Azur may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of Section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Azur as provided in section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to Azur and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect for 180 days.

Matthew S. Axelrod,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2022–21819 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Renewing Temporary Denial of Export Privileges

PJSC Aeroflot, 1 Arbat St., 119019, Moscow, Russia

Pursuant to Section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2021) (''EAR'' or ''the Regulations''),[1] I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the temporary denial order (''TDO'') issued in this matter on April 7, 2022. I find that renewal of this order is necessary in the public interest to prevent an imminent violation of the Regulations.

I. Procedural History

On April 7, 2022, I signed an order denying PJSC Aeroflot's (''Aeroflot'') export privileges for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to Section 766.24(a) of the Regulations and was effective upon issuance.[2]

On September 13, 2022, BIS, through OEE, submitted a written request for renewal of the TDO that issued on April 7, 2022. The written request was made more than 20 days before the TDO's scheduled expiration. A copy of the renewal request was sent to Aeroflot in accordance with sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received.

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations, or any order, license or authorization issued thereunder. 15 CFR 766.24(b)(1) and 766.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future

[1] On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. App. 2401 *et seq.* (''EAA''), (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (''IEEPA''), and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

[2] The TDO was published in the **Federal Register** on April 12, 2022 (87 FR 21611).

violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

B. The TDO and BIS's Request for Renewal

The U.S. Commerce Department, through BIS, responded to the Russian Federation's (''Russia's'') further invasion of Ukraine by implementing a sweeping series of stringent export controls that severely restrict Russia's access to technologies and other items that it needs to sustain its aggressive military capabilities. These controls primarily target Russia's defense, aerospace, and maritime sectors and are intended to cut off Russia's access to vital technological inputs, atrophy key sectors of its industrial base, and undercut Russia's strategic ambitions to exert influence on the world stage. Effective February 24, 2022, BIS imposed expansive controls on aviation-related (*e.g.,* Commerce Control List Categories 7 and 9) items to Russia, including a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (ECCN) 9A991 (Section 746.8(a)(1) of the EAR).[3] BIS will review any export or reexport license applications for such items under a policy of denial. *See* section 746.8(b). Effective March 2, 2022, BIS excluded any aircraft registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia from being eligible for license exception Aircraft, Vessels, and Spacecraft (AVS) (section 740.15 of the EAR).[4] Accordingly, any U.S.-origin aircraft or foreign aircraft that includes more than 25% controlled U.S.-origin content, and that is registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia, is subject to a license requirement before it can travel to Russia.

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO and the evidence developed over the course of this investigation, which indicate a blatant disregard for U.S. export controls, as well as the TDO. Specifically, the initial TDO, issued on April 7, 2022, was based on evidence that Aeroflot engaged in conduct prohibited by the Regulations by operating multiple aircraft subject to the EAR and classified under ECCN 9A991.b on flights into Russia after March 2, 2022, from destinations including Beijing, China, Delhi, India, and Dubai, United Arab Emirates, without the required BIS authorization.[5] Further evidence submitted by BIS indicated that Aeroflot was continuing to operate aircraft subject to the EAR both domestically on flights within Russia, as well as to/from Belarus potentially in violation of section 736.2(b)(10) of the Regulations.

In its September 13, 2022, request for renewal of the TDO, BIS has submitted evidence that Aeroflot continues to operate in violation of the April 7, 2022 TDO and/or the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991.b on flights into and within Russia. Specifically, BIS's evidence and related investigation indicated that Aeroflot has continued to operate aircraft subject to the EAR, including, but not limited to, flights into and out of Russia from/to Minsk, Belarus, Delhi, India, and Istanbul, Turkey. Information about those flights includes, but is not limited to, the following:

Tail No.	Serial No.	Aircraft type	Departure/arrival cities	Dates
RA–73126	41214	737–8LJ (B738)	Moscow, RU/Minsk, BY	September 1, 2022.
RA–73126	41214	737–8LJ (B738)	Minsk, BY/Moscow, RU	September 1, 2022.
RA–73126	41214	737–8LJ (B738)	Moscow, RU/Sochi, RU	September 13, 2022.
RA–73117	44442	737–8MC (B738)	Moscow, RU/Minsk, BY	August 29, 2022.
RA–73117	44442	737–8MC (B738)	Minsk, BY/Moscow, RU	August 29, 2022.
RA–73117	44442	737–8MC (B738)	Moscow, RU/Sochi, RU	September 22, 2022.
RA–73107	44439	737–8MC (B738)	Moscow, RU/Minsk, BY	September 8, 2022.
RA–73107	44439	737–8MC (B738)	Minsk, BY/Moscow, RU	September 8, 2022.
RA–73107	44439	737–8MC (B738)	Moscow, RU/Mineralnye Vody, RU	September 21, 2022.
RA–73106	44434	737–8MC (B738)	Moscow, RU/Minsk, BY	August 25, 2022.
RA–73106	44434	737–8MC (B738)	Minsk, BY/Moscow, RU	August 25, 2022.
RA–73106	44434	737–8MC (B738)	Moscow, RU/Barnaul, RU	September 19, 2022.
RA–73144	41690	777–3M0 (ER) (B77W)	Istanbul, TR/Moscow, RU	September 20, 2022.
RA–73144	41690	777–3M0 (ER) (B77W)	Istanbul, TR/Moscow, RU	September 21, 2022.
RA–73144	41690	777–3M0 (ER) (B77W)	Delhi, IN/Moscow, RU	September 20, 2022.

III. Findings

Under the applicable standard set forth in section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that Aeroflot has acted in violation of the Regulations and the TDO; that such violations have been significant, deliberate and covert; and that given the foregoing and the nature of the matters under investigation, there is a likelihood of imminent violations. Therefore, renewal of the TDO is necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should avoid dealing with Aeroflot, in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

IV. Order

It is therefore ordered:

[3] 87 FR 12226 (Mar. 3, 2022). Additionally, BIS published a final rule effective April 8, 2022, which imposed licensing requirements on items controlled on the Commerce Control List (''CCL'') under Categories 0–2 that are destined for Russia or Belarus. Accordingly, now all CCL items require export, reexport, and transfer (in-country) licenses if destined for or within Russia or Belarus. 87 FR 22130 (Apr. 14, 2022).

[4] 87 FR 13048 (Mar. 8, 2022).

[5] Publicly available flight tracking information shows that on March 6, 2022, serial number (SN) 65309 flew from Beijing, China to Moscow, Russia, and SN 41690 flew from Dubai, UAE to Moscow, Russia. In addition, on March 7, 2022, SN 63511 flew from Delhi, India to Moscow, Russia.

First, PJSC Aeroflot, 1 Arbat St., 119019, Moscow, Russia, when acting for or on their behalf, any successors or assigns, agents, or employees may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations, or engaging in any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of Aeroflot any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by Aeroflot of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby Aeroflot acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from Aeroflot of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

D. Obtain from Aeroflot in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by Aeroflot, or service any item, of whatever origin, that is owned, possessed or controlled by Aeroflot if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to Aeroflot by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of sections 766.24(e) of the EAR, Aeroflot may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Aeroflot as provided in section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to Aeroflot, and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect for 180 days.

Matthew S. Axelrod,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2022–21818 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Renewing Temporary Denial of Export Privileges

UTair Aviation JSC, Khanty-Mansiysk Airport, Tyumen Region, Russia 628012

Pursuant to section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2021) (''EAR'' or ''the Regulations''),[1] I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the temporary denial order (''TDO'') issued in this matter on April 7, 2022. I find that renewal of this order is necessary in the public interest to prevent an imminent violation of the Regulations.

I. Procedural History

On April 7, 2022, I signed an order denying UTair Aviation JSC's (''UTair'') export privileges for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to Section 766.24(a) of the Regulations and was effective upon issuance.[2]

On September 13, 2022, BIS, through OEE, submitted a written request for renewal of the TDO that issued on April 7, 2022. The written request was made more than 20 days before the TDO's scheduled expiration. A copy of the renewal request was sent to UTair in accordance with Sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received.

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue an order temporarily denying a

[1] On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. app. 2401 *et seq.* (''EAA'') (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (''IEEPA''), and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, Section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

[2] The TDO was published in the **Federal Register** on April 12, 2022 (87 FR 21616).

respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations, or any order, license or authorization issued thereunder. 15 CFR 766.24(b)(1) and 766.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

B. The TDO and BIS's Request for Renewal

The U.S. Commerce Department, through BIS, responded to the Russian Federation's (''Russia's'') further invasion of Ukraine by implementing a sweeping series of stringent export controls that severely restrict Russia's access to technologies and other items that it needs to sustain its aggressive military capabilities. These controls primarily target Russia's defense, aerospace, and maritime sectors and are intended to cut off Russia's access to vital technological inputs, atrophy key sectors of its industrial base, and undercut Russia's strategic ambitions to exert influence on the world stage. Effective February 24, 2022, BIS imposed expansive controls on aviation-related (*e.g.,* Commerce Control List Categories 7 and 9) items to Russia, including a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (ECCN) 9A991 (section 746.8(a)(1) of the EAR).[3] BIS will review any export or reexport license applications for such items under a policy of denial. *See* section 746.8(b). Effective March 2, 2022, BIS excluded any aircraft registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia from being eligible for license exception Aircraft, Vessels, and Spacecraft (AVS) (section 740.15 of the EAR).[4] Accordingly, any U.S.-origin aircraft or foreign aircraft that includes more than 25% controlled U.S.-origin content, and that is registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia, is subject to a license requirement before it can travel to Russia.

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO and the evidence developed over the course of this investigation, which indicate a blatant disregard for U.S. export controls, as well as the TDO. Specifically, the initial TDO, issued on April 7, 2022, was based on evidence that UTair engaged in conduct prohibited by the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991.b on flights into Russia after March 2, 2022, from destinations including Jeddah, Saudi Arabia, Yerevan, Armenia, and Tashkent, Uzbekistan, without the required BIS authorization.[5] Further evidence submitted by BIS indicated that UTair was continuing to operate aircraft subject to the EAR both internationally and domestically within Russia potentially in violation of Section 736.2(b)(10) of the Regulations.

In its September 13, 2022 request for renewal of the TDO, BIS has submitted evidence that UTair continues to operate in violation of the April 7, 2022 TDO and/or the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991.b on flights into and out of Russia. Specifically, BIS's evidence and related investigation indicated that UTair has continued to operate aircraft subject to the EAR, including, but not limited to, flights into and out of Russia from/to Yerevan, Armenia, Baku, Azerbaijan, Istanbul, Turkey, Dushanbe, Tajikistan, and Tashkent, Uzbekistan. Information about those flights includes, but is not limited to, the following:

Tail No.	Serial No.	Aircraft type	Departure/arrival cities	Dates
RA–73082	30437	767–224 (ER) (B762)	Tashkent, UZ/Moscow, RU	September 14, 2022.
RA–73082	30437	767–224 (ER) (B762)	Dushanbe, TJ/Moscow, RU	September 17, 2022.
RA–73082	30437	767–224 (ER) (B762)	Tashkent, UZ/Moscow, RU	September 19, 2022.
RA–73081	30435	767–224 (ER) (B762)	Dushanbe, TJ/Moscow, RU	September 14, 2022.
RA–73081	30435	767–224 (ER) (B762)	Tashkent, UZ/Moscow, RU	September 17, 2022.
RA–73081	30435	767–224 (ER) (B762)	Yerevan, AM/Moscow, RU	September 19, 2022.
RA–73085	32779	737–8AS (B738)	Baku, AZ/Moscow, RU	September 9, 2022.
RA–73085	32779	737–8AS (B738)	Yerevan, AM/Tyumen, RU	September 11, 2022.
RA–73085	32779	737–8AS (B738)	Yerevan, AM/Moscow, RU	September 20, 2022.
RA–73086	32780	737–8AS (B738)	Baku, AZ/Moscow, RU	September 18, 2022.
RA–73086	32780	737–8AS (B738)	Dushanbe, TJ/Moscow, RU	September 19, 2022.
RA–73086	32780	737–8AS (B738)	Baku, AZ/Moscow, RU	September 21, 2022.
RA–73047	28912	737–524 (B735)	Istanbul, TY/Grozny, RU	September 14, 2022.
RA–73047	28912	737–524 (B735)	Yerevan, AM/Moscow, RU	September 15, 2022.
RA–73047	28912	737–524 (B735)	Baku, AZ/St. Petersburg, RU	September 22, 2022.

III. Findings

Under the applicable standard set forth in section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that UTair has acted in violation of the Regulations and the TDO; that such violations have been significant, deliberate and covert; and that given the foregoing and the nature of the matters under investigation, there is a likelihood of imminent violations. Therefore, renewal of the TDO is

[3] 87 FR 12226 (Mar. 3, 2022). Additionally, BIS published a final rule effective April 8, 2022, which imposed licensing requirements on items controlled on the Commerce Control List (''CCL'') under Categories 0–2 that are destined for Russia or Belarus. Accordingly, now all CCL items require export, reexport, and transfer (in-country) licenses if destined for or within Russia or Belarus. 87 FR 22130 (Apr. 14, 2022).

[4] 87 FR 13048 (Mar. 8, 2022).

[5] Publicly available flight tracking information shows that on March 5, 2022, serial number (SN) 36387 flew from Jeddah, Saudi Arabia to Grozy, Russia, and on March 30, 2022, SN 28907 flew from Yerevan, Armenia to Tyumen, Russia. In addition, on March 31, 2022, SN 30437 flew from Tashkent, Uzbekistan to Moscow, Russia.

necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should avoid dealing with UTair in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

IV. Order

It is therefore ordered:

First, UTair Aviation JSC, Khanty-Mansiysk Airport, Tyumen Region, Russia, when acting for or on their behalf, any successors or assigns, agents, or employees may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations, or engaging in any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of UTair any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by UTair of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby UTair acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from UTair of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

D. Obtain from UTair in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to section 764.3(a)(2) of the Regulations; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by UTair, or service any item, of whatever origin, that is owned, possessed or controlled by UTair if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to UTair by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of sections 766.24(e) of the EAR, UTair may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by UTair as provided in section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to UTair, and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect for 180 days.

Matthew S. Axelrod,

Assistant Secretary of Commerce Export Enforcement.

[FR Doc. 2022–21817 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–881]

Certain Cold-Rolled Steel Flat Products From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2020–2021

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that certain cold-rolled steel flat products (cold-rolled steel) from the Republic of Korea (Korea) were not sold in the United States at less than normal value during the period of review (POR), September 1, 2020, through August 31, 2021. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 7, 2022.

FOR FURTHER INFORMATION CONTACT: Fred Baker or Preston Cox, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2924, or (202) 482–5041, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 20, 2016, Commerce published in the **Federal Register** the antidumping duty order on cold-rolled steel from Korea.[1] On September 2, 2021, Commerce published a notice of opportunity to request an administrative review of the *Order*.[2] On November 5,

[1] *See Certain Cold Rolled Steel Flat Products from Brazil, India, the Republic of Korea, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Brazil and the United Kingdom and Antidumping Duty Orders,* 81 FR 64432 (September 20, 2016) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 86 FR 49311, 49312 (September 2, 2021).

2021, based on timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the *Order* with respect to four companies.[3] On December 13, 2021, Commerce selected Hyundai Steel Company (Hyundai) and POSCO/POSCO International Corporation (PIC) (collectively, POSCO/PIC) as mandatory respondents in this administrative review.[4] On May 25, 2022, Commerce extended the time period for issuing these preliminary results by 120 days, until September 30, 2022, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(h)(2).[5]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[6] A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The product covered by the *Order* is cold-rolled steel from Korea. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and (2) of the Act. Export price is calculated in accordance with section 772 of the Act, and NV is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Rate for Non-Examined Companies

The statute and Commerce's regulations do not address the establishment of a weighted-average dumping margin to be determined for companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy less-than-fair-value (LTFV) investigation, for guidance when determining the weighted-average dumping margin for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we preliminarily calculated a weighted-average dumping margin of 0.00 percent for Hyundai and a weighted-average dumping margin of 0.00 percent for POSCO/PIC. Consistent with the U.S. Court of Appeals for the Federal Circuit's decision in *Albemarle,*[7] and our practice, we are applying to KG Dongbu Steel Co., Ltd. (Dongbu), the company not selected for individual examination in this review, a margin of zero percent, because we calculated rates of zero percent for both mandatory respondents, Hyundai and POSCO/PIC. These are the only margins determined in this review for individually examined respondents and, thus, we are applying this margin to Dongbu under section 735(c)(5)(B) of the Act.[8]

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margins exist for the period September 1, 2020, through August 31, 2021:

Producer/exporter	Weighted-average dumping margin (percent)
Hyundai Steel Company	0.00
POSCO/POSCO International Corporation	0.00
KG Dongbu Steel Co., Ltd.[9]	0.00

Disclosure and Public Comment

Commerce intends to disclose the calculations performed for these preliminary results to interested parties within five days of the date of publication of this notice.[10] A timeline for the submission of case briefs and written comments will be provided to interested parties at a later date.[11] Rebuttal briefs, limited to issues raised in case briefs, may be filed no later than seven days after the date for filing case briefs.[12] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Hearing requests should contain: (1) the party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 61121 (November 5, 2021).

[4] *See* Memorandum, ''2020–2021 Administrative Review of Cold-Rolled Steel Flat Products from the Republic of Korea: Respondent Selection,'' dated December 13, 2021. Consistent with the 2019–20 administrative review, Commerce has collapsed POSCO and PIC, treating these companies as a single entity. *See Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 55584 (October 6, 2021), and accompanying Preliminary Decision Memorandum, at 1, unchanged in *Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2019–2020,* 87 FR 15371 (March 18, 2022). In the 2018–19 administrative review, Commerce determined that PIC is the successor-in-interest to POSCO Daewoo Corporation (PDW), and, as a consequence, is part of the collapsed POSCO single entity. *See Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2018–2019,* 86 FR 40808 (July 29, 2021), and accompanying Issues and Decision Memorandum at 6, n.16. We continue to refer to the collapsed entity as ''POSCO/PIC'' hereafter.

[5] *See* Memorandum, ''Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Extension of Preliminary Results of Antidumping Duty Administrative Review; 2020–21,'' dated May 25, 2022.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2020–2021 Administrative Review of the Antidumping Duty Order on Certain Cold Rolled Steel Flat Products from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See Albemarle Corp.* v. *United States,* 821 F.3d 1345 (Fed. Cir. 2016) (*Albemarle*).

[8] *See* Memorandum, ''Preliminary Results of the Antidumping Duty Administrative Review of Cold-Rolled Steel Flat Products from the Republic of Korea; 2020–21: Calculation of Margin for Respondents Not Selected for Individual Examination,'' dated September 30, 2022.

[9] This company is the only non-examined company in this review.

[10] *See* 19 CFR 351.224(b).

[11] *See* 19 CFR 351.309(c).

[12] *See* 19 CFR 351.309(d)(1); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

rebuttal briefs. If a request for a hearing is made, parties will be notified of the date and time for the hearing.[13] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

All briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5:00 p.m. Eastern Time on the due date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[14]

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in any written briefs, no later than 120 days after the date of publication of these preliminary results.

Verification

On February 14, 2022, Commerce received a timely request from Cleveland-Cliffs Inc., United States Steel Corporation, and Steel Dynamics Inc. (collectively, the petitioners) to verify the information submitted by two mandatory respondents in the course of this administrative review, pursuant to 19 CFR 351.307(b)(1)(v).[15] As provided in section 782(i)(3) of the Act, Commerce intends to verify the information relied upon in determining the final results of review.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review.[16] If the weighted-average dumping margin for an individually examined respondent is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1).[17] For any individually examined respondent whose weighted-average dumping margin is zero or *de minimis* in the final results of review, or if an importer-specific assessment rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[18]

In accordance with Commerce's ''automatic assessment'' practice,[19] for entries of subject merchandise during the POR produced by the respondents for which the producer did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate of 20.33 percent established in the LTFV investigation.[20]

For Dongbu, the one company that was not selected for individual examination, we intend to assign an assessment rate based on the cash deposit rate calculated for the companies selected for mandatory review (*i.e.,* Hyundai and POSCO/PIC).[21]

The final results of this administrative 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 cash deposits of estimated antidumping duties, where applicable.[22]

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 upon publication in the **Federal Register** of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Hyundai, POSCO/PIC, and Dongbu, will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the margin 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 merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 20.33 percent,[23] the all-others rate established in the LTFV investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing 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 and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

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

Dated: September 30, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[13] *See* 19 CFR 351.310(d).

[14] *See Temporary Rule.*

[15] *See* Petitioners' Letter, ''Cold-Rolled Steel Flat Products from the Republic of Korea: Request for Verification,'' dated February 14, 2022.

[16] *See* 19 CFR 351.212(b)(1).

[17] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in* Certain Antidumping Proceedings: Final Modification, 77 FR 8101, 8103 (February 14, 2012).

[18] *Id.,* 77 FR at 8102–03; *see also* 19 CFR 351.106(c)(2).

[19] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[20] *See Order.*

[21] *See* section 735(c)(5)(A) of the Act; *see also* Preliminary Decision Memorandum at Section IV, ''Rate for Non-Examined Companies.

[22] *See* section 751(a)(2)(C) of the Act.

[23] *See Order.*

VII. Recommendation

[FR Doc. 2022–21849 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–523–813]

Polyethylene Terephthalate Sheet From the Sultanate of Oman: Preliminary Results of Antidumping Duty Administrative Review; 2020–2021

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that sales of polyethylene terephthalate (PET) sheet from the Sultanate of Oman (Oman) were made at less than normal value (NV) during the period of review (POR) March 3, 2020, through August 31, 2021. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 7, 2022.

FOR FURTHER INFORMATION CONTACT: Brittany Bauer, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3860.

SUPPLEMENTARY INFORMATION:

Background

On November 5, 2021, Commerce initiated an administrative review of the antidumping duty order on PET sheet from Oman in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[1] This administrative review covers one producer/exporter of the subject merchandise, OCTAL SAOC–FZC (OCTAL). On May 16, 2022, Commerce extended the deadline for the preliminary results of this administrative review by 120 days, until September 30, 2022.[2]

For details regarding the events that occurred subsequent to the initiation of this review, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public 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 Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order[4]

The product covered by this *Order* is PET sheet from Oman. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Constructed export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum.

Preliminary Results of the Review

We preliminarily determine that the following weighted-average dumping margin exists for the respondent for the period March 3, 2020, through August 31, 2021:

Producer/exporter	Weighted-average dumping margin (percent)
OCTAL SAOC–FZC	4.16

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If OCTAL's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We intend to instruct CBP to assess antidumping duties where the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis.* If the respondent's weighted-average dumping margin is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[5]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by OCTAL where the company did not know that the merchandise was destined for the United States, we intend to instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[6]

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 OCTAL will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis,* in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rates published for the most recently-

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 61121 (November 5, 2021).

[2] *See* Memorandum, ''Polyethylene Terephthalate Sheet from the Sultanate of Oman: Extension of the Deadline for Preliminary Results of 2020–2021 Antidumping Duty Administrative Review,'' dated May 16, 2022.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order: Polyethylene Terephthalate Sheet from the Sultanate of Oman; 2020–2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Polyethylene Terephthalate Sheet from the Republic of Korea and the Sultanate of Oman: Antidumping Duty Orders,* 85 FR 55824 (September 10, 2020) (*Order*).

[5] *See* section 751(a)(2)(C) of the Act.

[6] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

completed segment of this proceeding in which they were examined; (3) if the exporter is not a firm covered by this review or the original less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 4.74 percent,[7] the all-others rate established in the LTFV investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose the calculations performed to parties within five days after public announcement of the preliminary results.[8] Commerce will notify interested parties when it has determined a deadline for case briefs via ACCESS. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[9] Parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[10] Case and rebuttal briefs should be filed using ACCESS.[11] Executive summaries should be limited to five pages total, including footnotes. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[12]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[13] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: September 30, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2022–21850 Filed 10–6–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

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

DATES: Applicable October 7, 2022.

FOR FURTHER INFORMATION CONTACT: John Hoffner, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3315.

SUPPLEMENTARY INFORMATION: On August 1, 2022, the U.S. Department of Commerce (Commerce), pursuant to section 702(h) of the Trade Agreements Act of 1979 (as amended) (the Act), published the quarterly update to the annual listing of foreign government subsidies on articles of cheese subject to an in-quota rate of duty covering the period January 1, 2022, through March 31, 2022.[1] In the *First Quarter 2022 Update,* we requested that any party that has information on foreign government subsidy programs that benefit articles of cheese subject to an in-quota rate of duty submit such information to Commerce.[2] We received no comments, information, or requests for consultation from any party.

Pursuant to section 702(h) of the Act, we hereby provide Commerce's update of subsidies on articles of cheese that were imported during the period April 1, 2022, through June 30, 2022. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available.

Commerce will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed. Commerce encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing through the Federal eRulemaking Portal at *https://www.regulations.gov,* Docket No. ITA–2020–0005, ''Quarterly Update to Cheese Subject to an In-Quota Rate of Duty.'' The materials in the docket will not be edited to remove identifying or contact information, and Commerce cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only. All comments should be addressed to the Assistant Secretary for Enforcement and Compliance, U.S.

[7] *See Order.*

[8] *See* 19 CFR 351.224(b).

[9] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

[10] *See* 19 CFR 351.309(c)(2) and (d)(2).

[11] *See generally* 19 CFR 351.303.

[12] *See Temporary Rule.*

[13] *See* 19 CFR 351.310(d).

[1] *See Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty,* 87 FR 46941 (August 1, 2022) (*First Quarter 2022 Update*).

[2] *Id.*

Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

This determination and notice are in accordance with section 702(a) of the Act.

Dated: October 3, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross[3] subsidy ($/lb)	Net[4] subsidy ($/lb)
27 European Union Member States[5]	European Union Restitution Payments	$0.00	$0.00
Canada	Export Assistance on Certain Types of Cheese	0.45	0.45
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
	Total	0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

[FR Doc. 2022–21872 Filed 10–6–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–820]

Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes From Mexico; Preliminary Results of 2020–2021 Administrative Review

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that the respondents selected for individual examination, International Greenhouse Produce, S.A. de C.V. (IGP) and Negocio Agricola San Enrique, S.A. de C.V. and its affiliates (NASE), as a whole complied with the Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes from Mexico (2019 Agreement), for the period of review (POR) September 1, 2020, through August 31, 2021, except for certain instances of inconsequential or inadvertent noncompliance. We preliminarily determine that such noncompliance does not materially frustrate the purposes of the 2019 Agreement; however, we intend to address such noncompliance of the respondent IGP by engaging in Operations Consultations pursuant to Section VII.G the 2019 Agreement. Commerce also preliminarily determines that the 2019 Agreement continued to meet the statutory requirements under sections 734(c) and (d) of the Tariff Act of 1930, as amended (the Act) during the POR.

DATES: Applicable October 7, 2022.

FOR FURTHER INFORMATION CONTACT: Sally C. Gannon or David Cordell, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–0162 or (202) 482–0408, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 19, 2019, Commerce signed a suspension agreement [1] under section 734(c) of the Act, with representatives of Mexican fresh tomato producers/exporters accounting for substantially all imports of fresh tomatoes from Mexico, suspending the antidumping duty (AD) investigation on fresh tomatoes from Mexico.[2]

On September 17, 2021, the Florida Tomato Exchange (FTE),[3] a member of the U.S. petitioning industry, filed a request for an administrative review of the 2019 Agreement.[4] Commerce initiated the review of the 2019 Agreement on November 5, 2021.[5] On February 3, 2022, Commerce selected mandatory respondents and issued its questionnaire to two respondents, listed here in alphabetical order: International Greenhouse Produce and Negocio Agricola San Enrique, S.A.[6]

Scope of the 2019 Agreement

Merchandise covered by the 2019 Agreement is typically classified under the following subheading of the Harmonized Tariff Schedules of the United States (HTSUS), according to the season of importation: 0702. The tariff classification is provided for convenience and customs purposes; however, the written description of the scope of this 2019 Agreement is dispositive.[7]

Methodology and Preliminary Results

Commerce has conducted this review in accordance with section 751(a)(1)(C) of the Act, which specifies that Commerce shall ''review the current

[3] Defined in 19 U.S.C. 1677(5).

[4] Defined in 19 U.S.C. 1677(6).

[5] The 27 member states of the European Union are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

[1] *See Fresh Tomatoes from Mexico: Suspension of Antidumping Duty Investigation,* 84 FR 49987 (September 24, 2019) (*2019 Agreement*).

[2] The Mexican signatories are predominately represented by the following associations: Asociacion Mexicana de Horticultura Protegida, A.C., Asociacion de Productores de Hortalizas del Yaqui y Mayo, Confederacion de Asociaciones Agricolas del Estado de Sinaloa, A.C., Consejo Agricola de Baja California, A.C., and Sistema Producto Tomate.

[3] The members of the FTE are as follows: Ag-Mart Produce, Inc. dba Santa Sweets, Inc., Classie Produce, DiMare Homestead, Inc., DiMare Ruskin, Inc., Gargiulo, Inc., Kern Carpenter Farms, Lipman Family Farms, Mecca Family Farms, Inc., Michael Borek Farms, Pacific Tomato Growers, Ltd., Taylor & Fulton Packing, LLC, Tomatoes of Ruskin, Inc., TomPak, LLC, and West Coast Tomato, LLC.

[4] *See* FTE's Letter, ''Request for Administrative Review,'' dated September 17, 2021.

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 61121 (November 5, 2021).

[6] *See* Memorandum, ''Respondent Selection and Corrected Period of Review,'' dated February 3, 2022.

[7] For a complete description of the Scope of the 2019 Agreement, *see* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2020–2021 Administrative Review: Fresh Tomatoes from Mexico,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

status of, and compliance with, any agreement by reason of which an investigation was suspended.'' In this case, Commerce and representatives of the Mexican tomato producers/exporters accounting for substantially all imports of fresh tomatoes from Mexico signed the 2019 Agreement, which suspended the underlying antidumping duty investigation, on September 19, 2019. Pursuant to the 2019 Agreement, the Mexican signatories agreed to sell subject merchandise at or above certain minimum reference prices, and that their pricing would eliminate at least 85 percent of the dumping determined in the antidumping duty investigation.[8] The Mexican signatories also agreed to other conditions, including quarterly audits,[9] near-the-border inspections by the U.S. Department of Agriculture on all Round and Roma tomatoes and certain other types of tomatoes beginning on April 4, 2020,[10] and limits to adjustments to the sales price due to certain changes in condition and quality after shipment.[11]

After reviewing the information received to date from the respondent companies in their questionnaire and supplemental questionnaire responses, we preliminarily determine that the respondents have adhered to the terms of the 2019 Agreement, except for certain instances of inconsequential or inadvertent noncompliance that does not materially frustrate the purposes of the 2019 Agreement. We intend to address such noncompliance of the respondent IGP by engaging in Operations Consultations pursuant to Section VII.G of the 2019 Agreement. We also preliminarily determine that the 2019 Agreement is functioning as intended and that the 2019 Agreement continues to meet the statutory requirements under sections 734(c) and (d) of the Act.

For a full description of the analysis underlying our conclusions, *see* the Preliminary Decision Memorandum. Commerce examines issues involving the discussion of proprietary information concerning each of the respondents in separate memoranda which we incorporate into the Preliminary Decision Memorandum.[12] A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Verification

As provided in section 782(i) of the Act, Commerce may verify the information relied upon in making its final results. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. While we consider the possibility of conducting an on-site verification for some of the information submitted by the respondents, we may also need to verify the information relied upon in making the final results through alternative means in lieu of an on-site verification. Commerce intends to notify parties of its verification procedures, as applicable.

Public Comment

Case briefs are due 30 days from the publication of these preliminary results in the **Federal Register**. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[13] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[14] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the established deadline. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[15]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice.[16] Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act, unless extended.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 30, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2022–21868 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC444]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

[8] *See 2019 Agreement,* 84 FR at 49990, at Price Undertaking.

[9] *Id.,* 84 FR at 49991, at Compliance Monitoring.

[10] *Id.* at Inspection of Subject Merchandise; *see also* Memorandum, ''Frequently Asked Questions Regarding Inspections,'' dated March 17, 2020.

[11] *See 2019 Agreement,* 84 FR 49996, at Appendix D.

[12] *See* Memoranda, ''Preliminary Analysis of Proprietary Information and Argument Regarding International Greenhouse Produce,'' dated concurrently with this notice; and ''Preliminary Analysis of Proprietary Information and Argument Regarding Negocio Agricola San Enrique S.A. and its Affiliates,'' dated concurrently with this notice.

[13] *See* 19 CFR 351.309(d)(1).

[14] *See* 19 CFR 351.309(c)(2) and (d)(2).

[15] *See Temporary Rule.*

[16] *See* 19 CFR 351.310(c).

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scallop Advisory Panel to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). This meeting will be held in-person with a webinar option. Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This hybrid meeting will be held on Wednesday, October 26, 2022, at 9 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/2364779457565430287.*

ADDRESSES: This meeting will be held at the Hotel Providence, 139 Matthewson St., Providence, RI 02903; telephone: (401) 861–8000.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Advisory Panel plans to discuss Framework 36: Receive an update and provide input on a range of potential access area and days-at-sea (DAS) allocations for the 2023 and 2024 fishing years. Framework 36 will set specifications including ABC/ACLs, DAS, access area allocations, total allowable landings for the Northern Gulf of Maine (NGOM) management area, targets for General Category incidental catch, General Category access area trips, and set-asides for the observer and research programs for fishing year 2023 and default specifications for fishing year 2024. The panel also plans to develop recommendations for possible 2023 scallop work priorities. They will also consider recommending a control date that could be used to limit the movement of LAGC permits into the NGOM fishery. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: October 4, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–21917 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC438]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Ecosystem-Based Fishery Management Committee (EBFM) and Advisory Panel Chairs to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Friday, October 28, 2022, at 9:30 a.m.

ADDRESSES:

Meeting address: The meeting will be held at SMAST, 836 South Rodney French Boulevard, New Bedford, MA 02744; phone: (508) 999–1292.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Ecosystem-Based Fishery Management (EBFM) Committee and Advisory Panel Chairs will receive a preliminary progress report on the ongoing public information workshops. They will continue development of the Prototype Management Strategy Evaluation of EBFM strategies for Georges Bank, using Advisory Panel chairs and Committee members as stakeholders. They will also develop final committee recommendations for 2023 management priorities. Other business may be discussed as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: October 4, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–21916 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC427]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 82 South Atlantic Gray Triggerfish Post-Data Workshop Webinar II.

SUMMARY: The SEDAR 82 assessment of the South Atlantic stock of Gray Triggerfish will consist of a data workshop, a series of assessment

webinars, and a review workshop. See **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR 82 South Atlantic Gray Triggerfish Post data workshop webinar has been scheduled for October 28, 2022, from 10 a.m. until 1 p.m., Eastern. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Registration for the webinar is available by contacting the SEDAR coordinator via email at *Kathleen.Howington@safmc.net.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: *Kathleen.Howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 82 South Atlantic Gray Triggerfish Post-Data Workshop Webinar II are as follows: finalize any data decisions and discuss writing requirements.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business 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: October 4, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–21915 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC441]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Electronic Monitoring Policy Advisory and Technical Advisory Committees (GEMPAC/TAC) will hold an online meeting, which is open to the public.

DATES: The meeting will be held Monday, October 24, 2022, from 9 a.m. to 4 p.m. and Friday, October 28, 2022, from 9 a.m. to 12 p.m., Pacific Time, or until business for each day is completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Brett Wiedoff, Staff Officer, Pacific Council; telephone: (503) 820–2424.

SUPPLEMENTARY INFORMATION: The primary purpose of this meeting is for the GEMPAC/TAC to review materials and prepare recommendations for the November 2022 Pacific Council meeting regarding potential changes to the Pacific Council's electronic monitoring program.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*; (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: October 3, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–21810 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC445]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Scallop Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). This meeting will be held in-person with a webinar option. Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, October 27, 2022, at 9 a.m.

Webinar registration URL information: https://attendee.gotowebinar.com/register/3152605927146051085.

ADDRESSES: This meeting will be held at the Hotel Providence, 139 Matthewson St., Providence, RI 02903; telephone: (401) 861–8000.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will discuss Framework 36: Receive an update and provide input on a range of potential access area and days-at-sea (DAS) allocations for the 2023 and 2024 fishing years. Framework 36 will set specifications including ABC/ACLs, DAS, access area allocations, total allowable landings for the Northern Gulf of Maine (NGOM) management area, targets for General Category incidental catch, General Category access area trips, and set-asides for the observer and research programs for fishing year 2023 and default specifications for fishing year 2024. The Committee also plans to develop recommendations for possible 2023 scallop work priorities. They will also consider recommending a control date that could be used to limit the movement of LAGC permits into the NGOM fishery. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: October 4, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–21918 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC107]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S. Navy Construction at Naval Station Norfolk in Norfolk, Virginia

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

ACTION: Notice; receipt of application for letter of authorization; request for comments and information.

SUMMARY: NMFS has received a request from the U.S. Navy for authorization to take small numbers of marine mammals incidental to construction activities associated with the replacement of Pier 3 at Naval Station Norfolk over the course of 5 years from the date of issuance. Pursuant to regulations implementing the Marine Mammal Protection Act (MMPA), NMFS is announcing receipt of the Navy's request for the development and implementation of regulations governing the incidental taking of marine mammals. NMFS invites the public to provide information, suggestions, and comments on the Navy's application and request.

DATES: Comments and information must be received no later than November 7, 2022.

ADDRESSES: Comments on the applications should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.Corcoran@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Kim Corcoran, Office of Protected Resources, NMFS, (301) 427–8401. An electronic copy of the Navy's application may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a

proposed authorization is provided to the public for review.

An incidental take authorization shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On April 8, 2022, NMFS received an application from the Navy requesting authorization for take of marine mammals incidental to construction activities related to demolition and construction activities associated with the replacement of Pier 3 at Naval Station Norfolk. Following NMFS' review of the application, the Navy provided responses to our questions on June 3, 2022 and August 29, 2022. A revised version of the application was submitted on September 22, 2022 and the application was deemed adequate and complete on September 26, 2022. The requested regulations would be valid for 5 years, from April 1, 2023 through March 31, 2028. The Navy plans to conduct necessary work, including vibratory pile driving and removal, impact pile driving, and drilling, to demolish the existing Pier 3 and Pier 3T, replace a portion of the fender system at Pier 4, and construct the new Pier 3, two new wharfs/relieving platforms and a new portion of a bulkhead fender system. The proposed action may incidentally expose marine mammals occurring in the vicinity to elevated levels of underwater sound, potentially resulting in incidental take, by Level A and Level B harassment. Therefore, the Navy requests authorization to incidentally take marine mammals.

Specified Activities

The Navy is proposing to construct a new Pier 3 immediately north of the existing Pier 3 and align it with new bulkhead of CEP–176 wharf, providing a continuous berthing structure along the north side of a new submarine pier/wharf structure. The entire project scope includes construction of the new Pier 3, construction of a new wharf at CEP–176, construction of new wharf/relieving platform at CEP–102, demolition of Pier 3T, replacement of a portion of fender system at Pier 4, and construction of a new portion of fender system at CEP–175 bulkhead. The Navy expects construction will require approximately 513 in-water workdays over the 5 year period. Five species of marine mammals are known to occur in the area and have the potential to be taken by the Navy's activities.

Information Solicited

Interested persons may submit information, suggestions, and comments concerning the Navy's request (see **ADDRESSES**). NMFS will consider all information, suggestions, and comments related to the request during the development of proposed regulations governing the incidental taking of marine mammals by the Navy, if appropriate.

Dated: October 4, 2022.

Catherine G. Marzin,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–21894 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC443]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meetings.

SUMMARY: The New England Fishery Management Council's is convening several workshops to hear and discuss Ecosystem-Based Fishery Management (EBFM) for Georges Bank framework. Workshop summaries will be presented at a future Council Meeting.

DATES: These workshops will be held between the dates of Tuesday, October 25, 2022 and Thursday, November 10, 2022. See **SUPPLEMENTARY INFORMATION** for more details on specific dates and times.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** for specific dates and locations.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

1. *Tuesday, October 25, 2022,* 3–6 p.m., Maritime Gloucester, 23 Harbor Loop, Gloucester, MA 01930;

2. *Wednesday, October 26, 2022,* 3–6 p.m., DoubleTree Hotel, 363 Maine Mall Road, Portland, ME 04106;

3. *Tuesday, November 1, 2022,* 3–6 p.m., Chatham Community Center, 702 Main Street, Chatham, MA 02633;

4. *Wednesday, November 2, 2022,* 3–6 p.m. New Bedford Whaling Museum, 18 Johnny Cake Hill, New Bedford, MA 02740;

5. *Tuesday, November 8, 2022,* 3–6 p.m., Superior Trawl Conference Room, 55 State Street, Narragansett, RI 02882;

6. *Wednesday, November 9, 2022,* 3–6 p.m., Montauk Playhouse, 240 Edgemere Street, Montauk, NY 11954; and

7. *Thursday, November 10, 2022,* 3–6 p.m., Holiday Inn, 151 Route 72 West, Manahawkin, NJ 08050.

Agenda

The public is invited to participate in workshops to hear and discuss the potential for the New England Fishery Management Council to regulate fisheries on Georges Bank using what is known as Ecosystem-Based Fishery Management or EBFM. The Council developed an example Fishery Ecosystem Plan (eFEP) that describes a general framework to account for trophic interactions and managed groups of stocks as a stock complex to reduce fishing costs and bycatch technical interactions. It also discusses management options that need to be considered to implement EBFM policies. EBFM Public Outreach Materials are available on the Council's website and include a short introductory video, infographics, stakeholder brochures, presentations, and interactive tools.

The public also should be aware that the meeting will be recorded. Consistent

with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: October 3, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–21808 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC440]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Advisory Subpanel (GAP) will hold an online meeting, which is open to the public.

DATES: The meeting will be held Wednesday, October 26, 2022, from 9 a.m. to 4 p.m., Pacific Time, or until business for the day is completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Brett Wiedoff, Staff Officer, Pacific Council; telephone: (503) 820–2424.

SUPPLEMENTARY INFORMATION: The primary purpose of the meeting is for the GAP to begin reviewing materials and preparing recommendations on groundfish matters for the November 2022 Pacific Council meeting. The GAP may also discuss other items on the Pacific Council's November agenda, particularly Pacific halibut and administrative matters.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: October 3, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–21812 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC439]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Highly Migratory Species Advisory Subpanel (HMSAS) will hold an online meeting, which is open to the public.

DATES: The online meeting will be held Monday, October 24, 2022, from 1 p.m. to 4:30 p.m. Pacific Time, or until the business of the meeting is completed.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Kit Dahl, Staff Officer, Pacific Council; telephone: (503) 820–2422.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is for the HMSAS to familiarize its members with relevant topics to be taken up at the November 2022 Pacific Council meeting and begin considering the contents of reports the HMSAS may wish to submit to the Pacific Council. An agenda for the HMSAS meeting will be posted on the Pacific Council's website one week prior to the meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*); (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: October 3, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–21813 Filed 10–6–22; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* November 06, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 8/5/2022, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the service(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product(s) and service(s) to the Government.

2. The action will result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service(s) are added to the Procurement List:

Service(s)

Service Type: Janitorial Service
Mandatory for: FAA, Charlotte Air Traffic Control Tower, TRACON and Base Building, Charlotte, NC
Mandatory Source of Supply: OE Enterprises, Inc., Hillsborough, NC
Contracting Activity: FEDERAL AVIATION ADMINISTRATION, 697DCK REGIONAL ACQUISITIONS SVCS

The Committee finds good cause to dispense with the 30-day delay in the effective date normally required by the Administrative Procedure Act. See 5 U.S.C. 553(d). This addition to the Committee's Procurement List is effectuated because of the expiration of the Federal Aviation Administration, Janitorial Service, Air Traffic Control Center Charlotte, NC contract. The Federal customer contacted and has worked diligently with the AbilityOne Program to fulfill this service need under the AbilityOne Program. To avoid performance disruption, and the possibility that the Federal Aviation Administration will refer its business elsewhere, this addition must be effective on October 30, 2022, ensuring timely execution for a November 1, 2022, start date while still allowing 23 days for comment. The Committee also published a notice of proposed Procurement List addition in the **Federal Register** on August 5, 2022 and did not receive any comments from any interested persons. This addition will not create a public hardship and has limited effect on the public at large, but, rather, will create new jobs for other affected parties—people with significant disabilities in the AbilityOne program who otherwise face challenges locating employment. Moreover, this addition will enable Federal customer operations to continue without interruption.

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2022–21863 Filed 10–6–22; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete product(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: November 06, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
8415–00–NSH–0336—Trousers, Fleece,
8415–00–NSH–0365—Trousers, Fleece,
8415–00–NSH–0367—Trousers, Fleece,
8415–00–NSH–0366—Trousers, Fleece
Designated Source of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: W6QK ACC–APG NATICK, NATICK, MA

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2022–21866 Filed 10–6–22; 8:45 am]

BILLING CODE 6353–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Sunshine Act Meetings

The Board of Directors of the Corporation for National and Community Service (operating as AmeriCorps) gives notice of the following meeting:

TIME AND DATE: Wednesday, October 19, 2022, 4:00 p.m.–5:00 p.m. (ET)

PLACE: AmeriCorps, 250 E Street SW, Washington, DC 20525. For health and safety reasons, this will be a virtual meeting.

- To register for the meeting, please use this link: *https://americorps.zoomgov.com/webinar/register/WN_9b6kYQJjSbCTprosHUlPoQ*
- To participate by phone, call toll free: (833) 568–8864.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

I. Opening Remarks by the Chair
II. CEO Report
III. Oversight, Governance, and Audit Committee Report
IV. Approval of Grant Plan
V. Spotlight: Virtual Tour Around the Country of AmeriCorps' Role in Education
VI. Public Comment
VII. Chair's Closing Remarks and Adjournment

Members of the public who would like to comment on the business of the

Board may do so in writing or virtually. Submit written comments to *board@cns.gov* with the subject line: ''Comments for October 19, 2022, AmeriCorps Board Meeting'' no later than 5:00 p.m. (ET) October 14, 2022. Individuals who would like to comment during the meeting will be given instructions for signing up when they join the meeting. Comments are requested to be limited to two minutes.

AmeriCorps provides reasonable accommodation to individuals with disabilities, where needed.

CONTACT PERSON FOR MORE INFORMATION: Henry Hicks, by telephone: (202) 606–6864 or by email: *hhicks@cns.gov.*

Fernando Laguarda,

General Counsel.

[FR Doc. 2022–22062 Filed 10–5–22; 4:15 pm]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Army

Record of Decision Regarding Implementation of Area Development Plan at Davison Army Airfield, Fort Belvoir, Virginia

AGENCY: Department of the Army, Department of Defense.

ACTION: Notice of availability.

SUMMARY: The Department of the Army (Army) announces the availability of a Record of Decision (ROD) regarding the proposed implementation of an Area Development Plan (ADP) for Davison Army Airfield (DAAF). DAAF is located at U.S. Army Garrison—Fort Belvoir, Virginia. In accordance with the National Environmental Policy Act (NEPA), the ROD identifies the Army's selected alternative, the basis for its selection, the environmentally preferred alternative, and the mitigation and protective measures the Army commits to implement with the selected alternative. The ROD is based on the results of the Army's Final Environmental Impact Statement (EIS), which analyzed the potential environmental impacts associated with the proposed construction, modernization, infrastructure, and demolition projects at DAAF. The Proposed Action (*i.e.,* ADP implementation) consists of all these projects. The Proposed Action will improve the airfield's functional layout, demolish and replace aging facilities and infrastructure, and address multiple operational safety concerns along the runway. The ADP is specific to DAAF and all projects will occur entirely within its boundaries. The Proposed Action does not involve substantial changes in missions, air operations, the number of aircraft, or the workforce population at DAAF. The Army will implement the Proposed Action over approximately 30 years to provide the facilities and infrastructure necessary to support the ongoing and future missions of DAAF tenants.

FOR FURTHER INFORMATION CONTACT: Please contact the Fort Belvoir Directorate of Public Works—Environmental Division (DPW–ED), Ms. Wilamena Harback, via phone at (703) 806–3193 or (703) 806–0020, from Monday through Friday, 8 a.m. to 4 p.m. Further information may also be requested via email: *FortBelvoirNOI@usace.army.mil.* The ROD, Final EIS, and associated materials are available at the following website: *https://home.army.mil/belvoir/index.php/about/Garrison/directorate-public-works/environmental-division.*

SUPPLEMENTARY INFORMATION: DAAF has operated since 1951. It is a logistically and operationally valuable location for Department of Defense (DoD) units providing aviation support for federal activities in the national capital region. Many facilities at DAAF date to the 1950s, 1960s, and 1970s. More than 40 percent of buildings at the airfield are at least 50 years old, and an additional 25 percent are between 30 and 49 years old. As a result, multiple DAAF facilities are past their intended life cycle and are obsolete, undersized, and/or inefficient. Their age results in unnecessarily high maintenance costs. Several facilities at DAAF are located within safety zones associated with the airfield's runway and require temporary safety waivers to operate. Thus, they represent a danger to personnel that must be eliminated. Given the above factors, the Army proposed to implement the DAAF ADP over the next 30 years.

The Final EIS—published on 6 August 2021 and prepared in parallel with federal consultation processes (*e.g.,* section 106 of the National Historic Preservation Act and section 7 of the Endangered Species Act)—analyzed the potential environmental impacts associated with the Proposed Action, including direct, indirect, and cumulative effects. The Final EIS addressed comments received regarding the Draft EIS. The Final EIS also identified mitigation measures the Army and Fort Belvoir will implement to reduce potential adverse impacts.

The Army evaluated two alternatives that would meet the Proposed Action's purpose and need:

1. *Full Implementation Alternative (Preferred Alternative):* This alternative would implement the complete suite of 24 projects recommended in the DAAF ADP. The Full Implementation Alternative would accommodate the spatial and functional needs of all DAAF tenants consistent with applicable DoD requirements. It would also fulfill DAAF's vision to create a safe, secure, sustainable, and consolidated aviation complex.

2. *Partial Implementation Alternative:* This alternative would implement a modified, reduced set of 15 ADP projects at DAAF. The Partial Implementation Alternative would not address DAAF tenants' requirements in full, but would substantially improve conditions.

Under the No-Action Alternative, the DAAF ADP would not be implemented. While the No-Action Alternative would not satisfy the Proposed Action's purpose and need, in accordance with the Council on Environmental Quality's NEPA regulations, the No-Action Alternative provides a comparative baseline for gauging the Action Alternatives' potential effects.

The Final EIS determined the Full Implementation Alternative and Partial Implementation Alternative would have potentially significant adverse impacts on wetlands. The Army prepared a Finding of No Practicable Alternative (FONPA) addressing potential impacts on wetlands and floodplains. The approved FONPA is included as an appendix to the Final EIS. The Final EIS concluded the adverse impacts on all analyzed resources other than wetlands would be less than significant under either action alternative.

Based on the analysis presented in the Final EIS, the No-Action Alternative is the environmentally preferred alternative. The Full Implementation Alternative is the Army's selected alternative because it provides the facility and infrastructure upgrades necessary to support DoD requirements and DAAF tenant missions.

The ROD adopts multiple mitigation and protective measures to prevent or minimize the potential adverse environmental impacts of the Full Implementation Alternative. The Army is using all practicable means to avoid or minimize environmental harm caused by the selected alternative. Fort Belvoir DPW–ED will review the planning documents for each of the proposed ADP projects prior to initiation to ensure compatibility with applicable regulatory requirements, best management practices, and minimization measures. Additional

surveys, sampling, or testing may be required.

An electronic copy of the ROD is available for review and download at: *https://home.army.mil/belvoir/index.php/about/Garrison/directorate-public-works/environmental-division.* A printed copy may be requested from Fort Belvoir DPW–ED at the phone number or email address listed above.

Publication of the ROD formally concludes the NEPA process for this Proposed Action. The Army will proceed with the Full Implementation Alternative described in the Final EIS and will execute the mitigation and protective measures identified in the ROD.

James W. Satterwhite Jr.,

Army Federal Register Liaison Officer.

[FR Doc. 2022–21858 Filed 10–6–22; 8:45 am]

BILLING CODE 3711–02–P

DEPARTMENT OF DEFENSE

Department of the Army, Army Corps of Engineers

Notice of Intent To Prepare a Draft Supplemental Environmental Impact Statement/Subsequent Environmental Impact Report XIV [XIV] for the 2016 American River Watershed Common Features Project, Sacramento, CA

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The U.S. Army Corps of Engineers (USACE) intends to prepare a draft Supplemental Environmental Impact Statement (SEIS)/Subsequent Environmental Impact Report (SEIR) to the 2016 American River Watershed Common Features (ARCF) General Reevaluation Report (GRR), Final Environmental Impact Statement/Environmental Impact Report (FEIS/FEIR). USACE will serve as the lead National Environmental Policy Act (NEPA) agency and the Central Valley Flood Protection Board (CVFPB) will serve as the lead California Environmental Quality Act (CEQA) agency, with support from the California Department of Water Resources (DWR). The construction of cutoff walls and seepage berms to decrease the likelihood of levee failure, and installation of bank armoring to protect levees from erosion, are project actions authorized by WRDA 2016 to reduce flood risk to metropolitan Sacramento. The elements of the project will be organized and discussed in the SEIS in a manner to avoid restating discussions and findings that remain current and accurate in the 2016 ARCF EIS/EIR. This would allow the reader of the ARCF SEIS/SEIR to focus on the document's analysis of impacts of design changes to project features, while the relevant sections of the 2016 ARCF GRR FEIS/FEIR would be referenced where no design changes are planned. Mitigation will be considered as required for any additional impacts addressed in the ARCF SEIS/SEIR.

A description of the current proposed plans for the project is set forth below.

DATES: Written comments regarding the scope of the environmental analysis should be received by November 31, 2022.

ADDRESSES: Written comments and suggestions concerning ARCF Project and requests to be included on the Project mailing list may be submitted to Guy Romine, U.S. Army Corps of Engineers, Sacramento District, Attn: Environmental Analysis Section (CESPK–PDR–A), 1325 J Street, Sacramento, CA 95814.

FOR FURTHER INFORMATION CONTACT: Mr. Guy Romine, telephone at (916) 557–5100, email at *ARCF_SEIS@usace.army.mil.* Additional information will also be posted on the internet at: *www.sacleveeupgrades.com.*

SUPPLEMENTARY INFORMATION:

1. Purpose and Need

The Purpose of the ARCF SEIS/SEIR project is to reduce the overall flood risk within the study area. An unacceptably high risk of flooding from levee failure threatens the public safety of the City of Sacramento, as well as property and critical infrastructure throughout the study area. The Sacramento metropolitan area is one of the most at-risk areas for flooding in the United States. There is a high probability that flood flows in the American and Sacramento Rivers will stress the network of levees protecting the system to the point that levees could fail. Previous segments of the authorized project have been or will be constructed as authorized, but there are remaining segments that must still be implemented to reduce flood risk associated with erosion, seepage, and levee stability within the study area.

USACE has determined that the levee system along the Sacramento and American Rivers do not meet the current Federal standards for flood risk reduction due to seepage, slope stability, and erosion. The proposed project is needed to reduce risk of levee failure.

2. Proposed Action

USACE is preparing to draft a SEIS/SEIR to analyze changes made during final preliminary design of multiple contract actions within the ARCF project that could result in potentially significant environmental effects. This supplemental document will centralize where the public and agencies can look for the most current project information and will bring environmental considerations up to date. The SEIS/SEIR will focus on new or different features of project designs that have evolved since the original ARCF GRR FEIS/FEIR was completed, while analyzing the potential environmental impacts of these changes. Accordingly, the Proposed Action for this SEIS/SEIR consists of project features where the final design is sufficiently different from the original design. Environmental impacts are likely to be different than those analyzed in the 2016 FEIS/FEIR, with these project features are outlined below.

Lower American River Design Refinements

Using updated modeling and data, USACE completed a semi-quantitative risk assessment (SQRA), which identified several areas on the Lower American River requiring design refinements that were not specifically addressed in the ARCF GRR FEIS/FEIR. Different erosion protection methods than those discussed in the ARCF GRR FEIS/FEIR are now indicated to provide better onsite mitigation, fisheries habitat, and to decrease impacts to heritage oak trees. Specifically, launchable toe protection and tie backs may be required in many areas. A launchable rock toe and tie backs are placed at the waterside edge of a constructed planting bench, lower on the levee/riverbank, to allow riparian vegetation to grow next to the water's edge. If erosion and scour occur below the launchable toe, the revetment placed in the launchable toe would launch and cover the eroded area, preventing further erosion and providing bank slope stability. Additionally, haul routes and staging areas to implement these erosion control areas will be needed. Erosion protection work may also be implemented around trees in certain areas, to minimize a risk for scour caused by trees.

Lower American River—State Route 160 Bridge Area Design Refinements

The SQRA also determined that the area under the State Route 160 Bridge contributes to flood risk, and will need supplementary measures to properly

address this risk. The Proposed Action will require additional bank protection work in this area, including evaluation of staging areas, the addition of haul routes outside the original project footprint, and an extended nighttime work schedule not evaluated in the 2016 ARCF GRR FEIS/FEIR.

Sacramento River Erosion Design Refinements and Construction Requirements

The 2016 ARCF GRR FEIS/FEIR did not analyze staging areas for erosion protection work since it was assumed all work would be done by barge. Land side staging areas and haul routes to the staging areas have been added to the Proposed Action to ensure revised construction needs are met. Erosion protection features are now designed to include more rock than was originally estimated in the 2016 ARCF GRR FEIS/FEIR and will be further considered in the ARCF SEIS/SEIR.

Magpie Creek Area

The Proposed Action would require realignment of the levee and canal at Magpie Creek, increase localized storage and water conveyance, and an increased height of the levee at that site. Night work would be considered in the Proposed Action as a method to reduce daytime noise impacts and reduce the daytime closures of Raley Boulevard. In the Preferred Alternative of the ARCF GRR FEIS/FEIR, Raley Boulevard was presumed to be partially closed with the possibility of the loss of the northern right-hand turn lane, but under the Proposed Action the road would be fully closed during a portion of the construction season.

Mitigation Sites

The Proposed Action includes a comprehensive mitigation proposal to cover all remaining impacts of the ARCF project. The ARCF GRR FEIS/FEIR cited the need for additional mitigation and restoration planning once the designs of the ARCF Project were closer to completion. Project planners have now determined that on-site mitigation commitments set forth in the ARCF GRR FEIS/FEIR will be inadequate if the revised Proposed Action is implemented. The Proposed Action may include purchase of mitigation bank credits, or construction of dedicated mitigation facilities, or both, to meet additional mitigation requirements.

3. Alternatives

The Alternatives to the Proposed Action that may be considered in the SEIS/SEIR include: (1) Construction of mitigation sites and purchase of mitigation bank credits, as well as design refinements and construction requirements discussed above; and (2) the required No Action Alternative. The No Action Alternative would be defined as construction of the ARCF 2016 Project exactly as described in Alternative 2 of the ARCF GRR FEIS/FEIR, (the Preferred Alternative).

4. Scoping Process

a. A public scoping meeting will be held in the form of a teleconference and/or webinar to present an overview of the Proposed Action, its project features, and the ARCF SEIS/SEIR Process. Scoping will afford all interested parties an opportunity to provide comment on the proposed scope of analysis in the draft document and to identify alternatives measures. Comments on scoping, including potential alternatives, pertinent information, studies, and/or analyses, relevant to this Proposed Action may be submitted to the contacts listed below. If any reasonable alternatives are identified during the scoping period, USACE will evaluate those alternatives in the draft SEIS/SEIR, along with a no action alternative. The public scoping meeting is anticipated to be held on 2 November 2022. Exact time, registration details, additional information, and any schedule changes will be announced online at: *www.sacleveeupgrades.com.*

b. The Proposed Action is anticipated to affect the following resources, which the SEIS/SEIR will fully consider, including visual resources, vegetation and wildlife, fisheries, special status species, cultural resources, air quality, transportation, climate change, recreation, hydrology and water quality, noise, geological resources, environmental justice, and public utilities. Those resources expected to be unaffected by the design changes encompassed by the Proposed Action will not be discussed in the ARCF SEIS/SEIR.

c. USACE will consult with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (NMFS) to ensure that the Proposed Action complies with the Endangered Species Act and the Fish and Wildlife Coordination Act. The NMFS anticipates receipt of one or more requests for authorization to take incidental to activities related to the project under the Magnuson-Stevens Fishery Conservation and Management Act (MSA). USACE will also consult with the State Historic Preservation Officer and Native American Tribes to ensure compliance with the National Historic Preservation Act, and with the National Parks Service to seek a Wild and Scenic Rivers Act consistency determination for the Proposed Action. Additional State consultations may be required under CEQA or other California State Regulations. These consultations will be coordinated by CVFPB or DWR.

USACE intends to consult with CRWQCB support its decision on any permits and permissions requested under sections 10 and 14 of the Rivers and Harbors Act, section 401 and 404 of the Clean Water Act.

d. This NOI commences the public scoping process to identify issues and potential alternatives for consideration in the ARCF SEIS/SEIR. Throughout the scoping process, Federal agencies; Tribal, State, and local governments; and the general public have the opportunity to help USACE determine significant resources and issues, impact-producing factors, reasonable alternatives (*e.g.,* size, geographic, seasonal, or other restrictions on construction and siting of facilities and activities), and potential mitigation measures to be analyzed in the SEIS/SEIR, as well as to provide additional information. In the interests of efficiency, completeness, and facilitating public involvement, the SEIS/SEIR will use the NEPA process to fulfill public involvement requirements established in *36 CFR 800.2(d).*

USACE anticipates it will hold a virtual public scoping meeting for the SEIS/SEIR on 2 November 2022. Registration details, additional information, and any schedule changes will be announced online at: *www.sacleveeupgrades.com.*

After completion of the Draft ARCF SEIS/SEIR a 45-day public review period will be provided for interested parties and agencies to review and comment on the draft document. All interested parties are encouraged to respond to this notice and provide a current address if they wish to be notified of the ARCF SEIS/SEIR circulation.

4. Availability

After the draft ESIS/SEIR is completed, USACE will publish a notice of availability (NOA) and request public comments on the draft SEIS/SEIR. USACE expects to issue the NOA in August 2023. After the public comment period ends, the Army will review and respond to comments received and will develop the final SEIS/SEIR. USACE expects to make the final SEIS/SEIR available to the public in May 2024. A ROD will be completed no sooner than

30 days after the final EIS is released, in accordance with *40 CFR 1506.11.*

Antoinette R. Gant,

COL (P), EN, Commanding.

[FR Doc. 2022–21870 Filed 10–6–22; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0081]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Consolidated State Performance Report Renewal (Part 1 and Part 2)

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before November 7, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sarah Newman, 202–453–6956.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed ICR that is described below. The Department is especially interested in public comments addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public record.

Title of Collection: Consolidated State Performance Report Renewal (Part 1 and Part 2).

OMB Control Number: 1810–0724.

Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 14,653.

Total Estimated Number of Annual Burden Hours: 16,481.

Abstract: The Consolidated State Performance Report (CSPR) is the required annual reporting tool for each State, the Bureau of Indian Education, District of Columbia, and Puerto Rico as authorized under Section 8303 of the Elementary and Secondary Education Act (ESEA), as amended by the Every Student Succeeds Act (ESSA). The CSPR collects data on programs authorized by: Title I, Part A; Title I, Part C; Title I, Part D; Title II, Part A; Title III, Part A; Title IV Part A; Title V, Part A; Title V, Part B, Subparts 1 and 2; and The McKinney-Vento Act. The information in this collection relate to the performance and monitoring activities of the aforementioned programs under ESSA and the McKinney-Vento Act. These data are needed for reporting on Government Performance and Results Act (GPRA) as well as other reporting requirements under ESSA. This submission is a request to update the currently-approved CSPR collection (OMB 1810–0724) for school years 2022–23, 2023–24, and 2024–25. There are three substantive changes to the collection since it was last approved. First, we propose revising the structure and standardizing the language of the CSPR across sections to create consistent language, remove duplication or redundancies in the guidance, and to reduce text that will be added to technical assistance documents. Second, we propose reducing the number of tables containing Title I, Part A, Title I, Part C, and McKinney-Vento Act data. Third, we propose moving the State Report Cards section from CSPR Part I to CSPR Part II.

Dated: October 4, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–21926 Filed 10–6–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0124]

Agency Information Collection Activities; Comment Request; Educational Opportunity Centers Program (EOC) Annual Performance Report

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement without change of a previously approved collection.

DATES: Interested persons are invited to submit comments on or before December 6, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0124. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance

Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Emory Morrison, 202–453–6963.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Educational Opportunity Centers Program (EOC) Annual Performance Report.

OMB Control Number: 1840–0830.

Type of Review: A reinstatement without change of a previously approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 170.

Total Estimated Number of Annual Burden Hours: 1,360.

Abstract: The Department of Education (ED) collects Annual Performance Reports (APRs) from Educational Opportunity Centers (EOC) grantees under the authority of Title IV, part A, subpart 2, division 1, sections 402A and 402B of the Higher Education Act of 1965, as amended, the program regulations in 34 CFR 644, and the Education Department General Administrative Regulations (EDGAR), in 34 CFR 74.51, 75.720, and 75.732. The information that grantees submit in their APRs allows ED to annually assess each grantee's progress in meeting their project's approved goals and objectives. The APR data that grantees submit are compared with the projects' approved objectives to determine the projects' accomplishments, to make decisions regarding whether funding should be continued, and to award ''prior experience'' points. The regulations for this program provide for awarding up to 15 points for prior experience (34 CR 644.22).

During a competition for new grant awards, the prior experience points are added to the average of the field reader scores to arrive at a total score for each application. Funding recommendations and decisions are primarily based on the rank order of applications on the slate; therefore, assessment of prior experience points, based on data in the annual performance report, is a crucial part of the overall application process.

Further, this performance report form is the main source of data for the Department's response to the requirements of the Government Performance and Results Act (GPRA) for this program. In addition, the Department uses the annual performance reports to produce program level data for annual reporting, budget submissions to OMB, Congressional hearings and inquiries, and responding to inquiries from higher education interest groups and the general public.

EOC APRs are prepared and submitted by EOC grant projects. For each EOC grant project, the grant project director of record completes, or supervises the completion of the data submission process. The grant project director supervises the administration of an EOC grant. An EOC grant provides counseling and information on college admissions to qualified adults who want to enter or continue a program of postsecondary education.

The program also provides services to improve the financial and economic literacy of participants. An important objective of the program is to counsel participants on financial aid options, including basic financial planning skills, and to assist in the application process. The goal of the EOC program is to increase the number of adult participants who enroll in postsecondary education institutions.

Dated: October 4, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development

[FR Doc. 2022–21903 Filed 10–6–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0123]

Agency Information Collection Activities; Comment Request; Liquidation Extension Request Template

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is requesting the Office of Management and Budget (OMB) to conduct an emergency review of a new information collection.

DATES: The Department requested emergency approval for this information collection request; and therefore, the regular clearance process is hereby being initiated to provide the public with the opportunity to comment under the full comment period. Interested persons are invited to submit comments on or before December 6, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0123. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW,

LBJ, Room 6W208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Jennifer Timmons, (202)-987–1295.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Liquidation Extension Request Template.

OMB Control Number: 1810–0771.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments *Total Estimated Number of Annual Responses:* 104.

Total Estimated Number of Annual Burden Hours: 2,080.

Abstract: This is a request for approval for an extension of the OMB approved 1810–0771 collection by the Office of State and Grantee Relations (SGR) in the Office of Elementary and Secondary Education (OESE) at the U.S. Department of Education (ED) for the Elementary and Secondary School Education Relief (ESSER) fund and the Governor's Emergency Education Relief (GEER) fund authorized by the Coronavirus Aid, Relief and Economic Security Act of 2020, Public Law 116–136, Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The CARES–ESSER (ALN 84.425D) program is a $13 billion formula grant program allocated to State educational agencies (SEA) for use in responding to and recovering from the COVID–19 pandemic. The CARES–GEER (ALN 84.425C) program is a $2.9 billion formula grant program allocated to Governors for the purpose of providing local educational agencies (LEAs), institutions of higher education (IHEs), and other education related entities with emergency assistance to address the impact of the coronavirus pandemic. A liquidation extension request will be required in order for an SEA or Governor's office to receive approval to liquidate funds beyond the 120-day liquidation period following the period of availability of September 30, 2022. The Department will use the grantee's request to review and recommend approval for a liquidation extension request.

Dated: October 4, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–21897 Filed 10–6–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Department of Energy.

ACTION: Notice of request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection request with the Office of Management and Budget (OMB). The collections in this package are applicable to contract management in DOE, collected by DOE to monitor and manage the safety performance of its contractors and to fulfill federal reporting requirements. The information obtained from DOE contractors is used by Department management at the appropriate levels to manage the work pertaining to environment, safety and health throughout DOE and will include automated reporting of information into the following systems: Computerized Accident/Incident Reporting System (CAIRS); Occurrence Reporting and Processing System (ORPS); Radiation Exposure Monitoring System (REMS); Annual Fire Protection Summary Application; Safety Basis Information System; and DOE OPEXShare Lessons Learned System.

DATES: Comments regarding this proposed information collection must be received on or before December 6, 2022. If you anticipate any difficulty in submitting comments within that period, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

ADDRESSES: Written comments may be sent to Baldev Dhillon, EHSS–74, Germantown Building, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585–1290, or by email at *Baldev.Dhillon@hq.doe.gov,* or information about the collection instruments may be obtained at *https://energy.gov/ehss/information-collection.*

FOR FURTHER INFORMATION CONTACT: Baldev Dhillon, EHSS–74, (301) 903–0990, *Baldev.Dhillon@hq.doe.gov.*

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

This information collection request contains:

(1) *OMB No.:* 1910–0300.

(2) *Information Collection Request Titled:* Environment, Safety and Health.

(3) *Type of Review:* Renewal.

(4) *Purpose:* The collections are used by DOE to exercise management oversight and control over its contractors in the ways in which the DOE contractors provide goods and services for DOE organizations and activities in accordance with the terms of their contract(s); the applicable statutory, regulatory and mission support requirements of the Department.

(5) *Annual Estimated Number of Respondents:* 775.

(6) *Annual Estimated Number of Total Responses:* 73,040.

(7) *Annual Estimated Number of Burden Hours:* 33,771.

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $151,448.

Statutory Authority: Section 641 of the Department of Energy Organization

Act, codified at 42 U.S.C. 7251, and the following additional authorities:

Computerized Accident/Incident Reporting System (CAIRS): DOE Order 231.1B (November 28, 2012).

Occurrence Reporting and Processing System (ORPS): DOE Order 232.2A (October 4, 2019).

Radiation Exposure Monitoring System (REMS): 10 CFR part 835; DOE Order 231.1B (November 28, 2012).

Annual Fire Protection Summary Application: DOE Order 231.1B (November 28, 2012).

Safety Basis Information System: 10 CFR part 830; DOE Order 231.1B (November 28, 2012).

DOE OPEXShare Lessons Learned System: DOE Order 210.2A (April 8, 2011).

Signing Authority

This document of the Department of Energy was signed on September 29, 2022, by Todd N. Lapointe, Acting Director, The Office of Environment, Health, Safety and Security 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 October 4, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–21881 Filed 10–6–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Capabilities of Universities and Private-Sector Firms for Providing Technical Assistance to States, U.S. Territories, Indian Tribes, and Other Eligible Entities To Enhance the Resilience of Electricity Delivery Systems

AGENCY: Grid Deployment Office (GDO), U.S. Department of Energy (DOE).

ACTION: Request for information.

SUMMARY: The U.S Department of Energy (DOE) is seeking information from universities and private-sector firms, including non-profit organizations, on their capabilities for providing assistance to States, U.S. Territories, Indian Tribes, and other eligible entities to enhance their ability to plan and implement strategies for improving the resilience of systems that deliver electric power. Towards that aim, DOE requests that interested parties provide responses to the set of questions presented within this notice. DOE intends to use this information to ascertain the best available resources and approach for carrying out a technical assistance program under the Infrastructure Improvement and Jobs Act of 2021 (IIJA).

DATES: Responses to the RFI must be received by no later than 5:00 p.m. EDT on November 21, 2022.

ADDRESSES: Interested parties are to submit responses to the following email address: *40101TA@hq.doe.gov.* Include ''40101 TA RFI'' in the subject line of the email. Responses must be provided as a Microsoft Word (.docx) or PDF attachment to the email, and no more than 10 pages in length, 12-point font, 1-inch margins. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.,* zipped) to ensure message delivery. Only electronic responses will be accepted. For ease of replying and to aid categorization of your responses, please copy and paste the RFI questions, including the question numbering, and use them as a template for your response. Respondents may answer as many or as few questions as they wish. Respondents are requested to provide the following information at the start of their response to this RFI:

- Company/institution name.
- Company/institution contact.
- Contact's address, phone number, and email address.

FOR FURTHER INFORMATION CONTACT: Joe Paladino, (202) 586–0020, *40101TA@hq.doe.gov.* Submitting inquiries to the email address is preferred.

SUPPLEMENTARY INFORMATION: The purpose of the IIJA section 40101, Preventing Outages and Enhancing the Resilience of the Electric Grid, is to help States, U.S. Territories, Indian Tribes, and other entities eligible to receive funding deploy a variety of measures to improve the resilience of the electric grid against disruptive events in which the operations of the electric grid are disrupted, preventively shut off, or cannot operate safely due to extreme weather, wildfire, natural disasters, or cyber-attacks.[1] These measures may range from hardening assets to deploying more advanced practices and grid technologies, including energy storage systems and microgrids, for improving resilience.

Under this program, DOE is interested in helping entities better understand the implication of threats to their electricity delivery system and determine strategies for improving its resilience. This may include the formulation of planning guidelines that set priorities for mitigating impacts to critical facilities and services, as well as for investments that will lead to measurable enhancements in the resilience of infrastructure intended to provide reliable electric power. In addition, DOE will encourage the application of energy justice principles in efforts to determine and implement resilience measures so that the benefits derived from them are realized in an equitable manner by all.[2]

The technical assistance envisioned would apply expert capabilities in several areas including, for example:

1. Forecasting methods and tools to determine customer electricity demand, the adoption of distributed energy resources, and weather/climate parameters (*e.g.,* temperature, rainfall, windspeed, flooding/inundation) at national, regional, and local levels.

2. Risk assessment methods, tools, and processes to examine risks and their impacts on energy infrastructure, essential human services (*e.g.,* water supply and emergency services), and vulnerable populations to prioritize resilience investments.

3. Modeling and simulation methods and tools to determine the severity and impact of threats on energy and electricity infrastructure at national, regional, and local levels.

4. Methods and tools for multi-objective decision analysis to enable the prioritization of electric infrastructure investment options across a range of policy objectives.

5. Methods and tools for addressing energy equity (*e.g.,* relating to procedural, distributive, and restorative energy justice principles) in the determination of resilience measures.[3]

6. Cost-effectiveness methods and tools to ascertain the appropriateness and benefit of infrastructure investments to aid decision-making.

[1] The entirety of the Infrastructure Investment and Jobs Act (IIJA), Public Law 117–58, is available at: *https://www.congress.gov/bill/117th-congress/house-bill/3684/tex*t. IIJA Section 40101 defines an eligible entity as being (a) an electric grid operator, (b) an electricity storage operator, (c) an electricity generator, (d) a transmission owner or operator, (e) a distribution provider, (f) a fuel supplier, and (g) any other relevant entity, as determined by DOE.

[2] Information on DOE's Justice40 Initiative is available at: *https://www.energy.gov/diversity/justice40-initiative.*

[3] Ibid.

Where it may pertain to their specific capabilities, areas of expertise, or business interests, DOE would like interested parties to provide responses to the following questions:

1. What methods, tools, and datasets would you recommend for undertaking efforts associated with any of the areas of expertise listed previously? What methods, tools, and datasets are you developing, have developed, and/or applied for undertaking any of these areas of expertise? What additional advancements (*e.g.,* spatial or temporal resolution) are needed to improve these methods, tools, and datasets?

2. What approaches (*e.g.,* partnerships and business models) would you recommend for providing services and technical assistance in the areas of expertise listed above? What successful approaches have you observed and/or have undertaken in providing such services and technical assistance in ways that have specifically benefited States, U.S. Territories, Indian Tribes, and/or other eligible entities?

3. What are the current limitations in planning frameworks for improving the resilience of electricity delivery systems and how would you address them?

Interested parties may also provide reference documents and website links to support their responses.

Proprietary Information: Because information received in response to this RFI may be used to structure future programs and/or otherwise be made available to the public, respondents are strongly advised NOT to include any information in their responses that might be considered business sensitive, proprietary, or otherwise confidential. If, however, a respondent chooses to submit business sensitive, proprietary, or otherwise confidential information, it must be clearly and conspicuously marked as such in the response. Responses containing confidential, proprietary, or privileged information must be conspicuously marked as described below. Failure to comply with these marking requirements may result in the disclosure of the unmarked information under the Freedom of Information Act or otherwise. The U.S. Federal Government is not liable for the disclosure or use of unmarked information and may use or disclose such information for any purpose.

Confidential, Commercial, and Financial Information: Consistent with 10 CFR 1004.11, DOE requires that 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 Commercial and Financial Information'' 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. The copy containing confidential commercial and financial information must include a cover sheet marked as follows identifying the specific pages containing confidential, proprietary, or privileged information: ''Notice of Restriction on Disclosure and Use of Data: Pages [list applicable pages] of this response may contain confidential, commercial, or financial information that is exempt from public disclosure.'' The Government may use or disclose any information that is not appropriately marked or otherwise restricted, regardless of source. In addition, (1) the header and footer of every page that contains confidential, proprietary, or privileged information must be marked as follows: ''Contains Confidential, Commercial, or Financial Information Exempt from Public Disclosure'' and (2) every line and paragraph containing proprietary, privileged, or trade secret information must be clearly marked with [[double brackets]] or highlighting.

Signing Authority

This document of the Department of Energy was signed on September 30, 2022, by Maria D. Robinson, Director of the Grid Deployment Office, 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 on publication in the **Federal Register**.

Signed in Washington, DC, on October 4, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–21892 Filed 10–6–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Notice.

SUMMARY: EIA submitted an information collection request for extension as required by the Paperwork Reduction Act of 1995. The information collection requests a three-year extension with changes to the Petroleum Supply Reporting System (PSRS), OMB Control Number; 1905–0165. The PSRS consists of seven weekly surveys that make up the Weekly Petroleum Supply Reporting System (WPSRS), eight monthly surveys that make up the Monthly Petroleum Supply Reporting System (MPSRS), and one annual survey. EIA uses WPSRS surveys to collect data from a sample of operators on input, production, imports, and inventory levels of crude oil, hydrocarbon gas liquids, petroleum products, and biofuels. EIA uses MPSRS surveys to collect data from all in-scope operators on input, production, imports, biofuel feedstocks consumed, refinery capacity, biofuel plant production capacity, fuels consumed in plant operations, and annual storage capacity of crude oil, hydrocarbon gas liquids petroleum products, and biofuels. EIA uses annual Form EIA–820 to collect data on refinery capacity, refinery fuels and feedstocks consumed, and the quantity of crude oil received by method of transportation.

DATES: Comments on this information collection must be received no later than November 7, 2022. 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: If you need additional information, contact Michael Conner, U.S. Energy Information Administration, telephone (202) 586–1795, or by email at *PetroleumSupplyForms@eia.gov.* The forms and instructions are available on EIA's website at *www.eia.gov/survey/.*

SUPPLEMENTARY INFORMATION: This information collection request contains

(1) *OMB No.:* 1905–0165;

(2) *Information Collection Request Title:* Petroleum Supply Reporting System (PSRS);

(3) *Type of Request:* Three-year extension with changes;

(4) *Purpose:* The surveys included in the PSRS collect information, that is largely unavailable from other sources, on production, input, inventory levels, imports, inter-regional movements, and fuels and feedstocks consumed for plant operation, for crude oil, hydrocarbon gas liquids, petroleum products, and biofuels. PSRS surveys also collect storage capacities for crude oil, hydrocarbon gas liquids, petroleum products, and biofuels, refinery capacities, biofuel production capacities, and biofuel feedstocks consumed.

EIA requires data from PSRS surveys to meet requirements of energy data users for credible, reliable, and timely energy information. EIA uses PSRS survey data in statistical reports including, but not limited to, the Weekly Petroleum Status Report (WPSR), Petroleum Supply Monthly (PSM), and the Monthly Energy Review (MER). EIA uses PSRS survey data to support analysis and projection work with results reported in the Short Term Energy Outlook (STEO), Annual Energy Outlook (AEO), and other reports. EIA makes reports available at *https://www.eia.gov/.* EIA also uses PSRS data to complete monthly and annual reports of U.S. petroleum and biofuel supplies to the International Energy Agency to support U.S. participation as an IEA member county. In some cases, agencies outside of EIA publish data sourced from PSRS surveys in their own reports. For example Bioenergy Statistics reported by the U.S. Department of Agriculture.

Data from PSRS surveys provide data to inform policy and business decisions, the data promote efficient markets by providing transparency to petroleum and biofuel supplies. Use of PSRS data by academic researchers, educators, news media, and the general public promotes understanding of energy and its interaction with the economy and the environment.

(4a) Proposed Changes to Information Collection

All Petroleum Supply Reporting System Surveys

• EIA conducted two web surveys in 2022 to determine how much time respondents took to complete EIA reports. Based on the observations of this study it was determined that respondents take substantially less time than the approved burden times. Given this key finding that technology has substantially reduced reporting burden for respondents on these four surveys, EIA decided to reduce the burden to respond (annual hours) by 10 percent.

Pretesting Interviews

• EIA would like to conduct up to 50 pretesting interviews each year for testing purposes. These methodologies will test or evaluate new terminology, unclear questions in surveys, unclear instructions, or questions that may be added to the Petroleum Supply Reporting System surveys. This will help improve ongoing surveys and reduce errors due to respondent confusion.

Form EIA–800 Weekly Refinery Report

• Change survey instructions to require reporting production of propane and propylene fractionated from still gas whether fractionation takes place at the refinery or at a facility downstream of the refinery. This change is needed to more completely account for the quantity of propane and propylene supplied, particularly as petrochemical feedstock. The current practice of reporting still gas shipped from refineries as still gas (not reported weekly on Form EIA–800) when the still gas will ultimately be fractionated into product components overstates supply of still gas (implying use as plant fuel) and understates supply of propane and propylene.

• Change the ''Who Must Submit'' part of survey instructions to include reporting by non-refinery operators of distillation, reforming, cracking, coking, hydrotreating, and similar processes. This change is needed in order for EIA to capture complete data on operations of process units commonly associated with oil refineries but operated at non-refinery facilities such as natural gas liquids fractionation plants.

• Discontinue collecting propane production, propane stocks, and total natural gas liquids (NGL) stocks at NGL fractionators. NGL fractionators that hold stocks will report on the new Form EIA–806 *Weekly Natural Gas Liquids Report.* Rename Form EIA–800 from *Weekly Refinery and Fractionator Report* to *Weekly Refinery Report.*

Form EIA–805 Weekly Bulk Terminal Report

• Add a product line for bulk terminal operators to report stocks of propane that have been fractionated and are ready for sale (product code 626). The added product detail for fractionated propane will add transparency to propane supplies by showing separate stock levels of propane readily available for consumption and propane held as a component of product mixes where the propane requires processing through a fractionator or other unit before being consumed as propane. At present, EIA stock levels for propane do not differentiate between fractionated propane and propane contained as a component of a product mix.

• Change the label for product code 246 from *Propane* to *Propane, total including fractionated and unfractionated products.*

Form EIA–806 Weekly Natural Gas Liquids Report

• EIA is adding Form EIA–806 *Weekly Natural Gas Liquids Report* to the WPSRS. Form EIA–806 will be the weekly counterpart to Form EIA–816 *Monthly Natural Gas Liquids Report.* When implemented, EIA will use data from Form EIA–806 to report weekly total production of natural gas liquids (NGL), propane production from natural gas processing, and propane and NGL stocks held by operators of natural gas processing plants and NGL fractionators.

• Current EIA weekly reporting practice is to use Form EIA–800 to collect production of propane from natural gas processing equal to barrels of propane fractionated from mixed NGL by operators of NGL fractionators. Operators of NGL fractionators also report ending stocks of total NGL and propane on Form EIA–800. EIA intends to replace current reporting by NGL fractionators on NGL fractionators on Form EIA–800 with reports submitted by operators of natural gas processing plants that produce and/or hold stocks, and operators of NGL fractionation plants that hold stocks. With Form EIA–806, EIA will collect the total quantity of natural gas liquids produced weekly by operators of natural gas processing plants. Weekly total NGL production is unavailable from current data collected on Form EIA–800. In addition, collecting weekly data from operators of natural gas processing plants allows EIA to improve consistency of weekly and monthly regional propane production by reporting weekly propane production in the region of the producing natural gas processing plant as is done in monthly data, rather than in the region where a fractionator operator separated propane from mixed NGL.

• EIA will collect total NGL stocks held by operators of natural gas processing plants and NGL fractionators. EIA will use plant-level NGL product composition data reported on Form EIA–816 to allocate total production and stocks reported weekly

on Form EIA–806 to propane and other NGL products. EIA will allocate total NGL production and stocks reported weekly on Form EIA–806 to propane and other NGL current composition data, since this data is likely to be unavailable to plant operators in time to report weekly (*i.e.* weekly reports due to EIA by 5:00 p.m. eastern time on Monday with data for the week ended at 7:00 a.m. eastern time the previous Friday).

Form EIA–810 Monthly Refinery Report

• Change the ''Who Must Submit'' part of survey instructions to include reporting by non-refinery operators of distillation, reforming, cracking, coking, hydrotreating, and similar processes. This change is needed in order for EIA to capture complete data on operations of process units commonly associated with oil refineries but operated at non-refinery facilities such as natural gas liquids fractionation plants.

• Change the label for product code 207 from the current ''Other renewable fuels and intermediate products'' to ''Other Biofuels and Biointermediates'' not elsewhere specified or indicated. This change is to make the Form EIA–810 product label consistent with terminology used in EIA, other government agencies, and the biofuel industry.

• Change survey instructions to require reporting production of natural gas liquids (ethane, propane, normal butane, and isobutane) and refinery olefins (ethylene, propylene, normal butylene, isobutylene) on a product basis when the products are fractionated from still gas whether fractionation takes place at the refinery or at a facility downstream of the refinery. This change is needed to more completely account for quantities supplied of natural gas liquids and refinery olefins on a product basis, particularly for use as petrochemical feedstock. The current practice of reporting still gas shipped from refineries as still gas when the still gas will ultimately be fractionated into product components overstates supply of still gas (implying use as plant fuel) and understates supply of natural gas liquids and refinery olefin products.

Form EIA–814 Monthly Import Report

Change the product label of ''Other renewable fuels and intermediate products'' to ''Other biofuels and biointermediates'', not elsewhere specified or indicated. This change is to make product labels on Form EIA–814 consistent with terminology used in EIA, other government agencies, and the biofuel industry.

Form EIA–815 Monthly Bulk Terminal Report

• Change the label for product code 207 from the current ''Other renewable fuels and intermediate products'' to ''Other Biofuels and Biointermediates not elsewhere specified or indicated. This change is to make the Form EIA–815 product label consistent with terminology used in EIA, other government agencies, and the biofuel industry.

• Add a product line for bulk terminal operators to report stocks of propane that have been fractionated and are ready for sale (product code 626). The added product detail for fractionated propane will add transparency to propane supplies by showing separate stock levels of propane readily available for consumption and propane held as a component of product mixes where the propane requires processing through a fractionator or other unit before being consumed as propane. At present, EIA stock levels for propane do not differentiate between fractionated propane and propane contained as a component of a product mix. Change the label for product code 246 from *Propane* to *Propane, total including fractionated and unfractionated products.*

• Change the product code and label for reporting storage capacity in part 4 from product code 246, *Propane (dedicated),* to product code 626, *Propane, fractionated and ready for sale.* This change makes part 4 consistent with stocks reported in part 3 of Form EIA–815.

Form EIA–816 Monthly Natural Gas Liquids Report

• Add a separate product line for operators of natural gas processing plants to report condensate and scrubber oil (product code 210) as a product separate from natural gasoline (product code 220). Condensate and scrubber oil are separate products from natural gasoline with different uses, but the current Form EIA–816 combines the products under the natural gasoline label. Natural gasoline is normally used either for blending into gasoline, as petrochemical feedstock, or exported. Condensate and scrubber oil are usually either blended into crude oil or exported. Reporting condensate and scrubber oil as separate products from natural gasoline will provide greater transparency to supplies of both NGL and crude oil. This change will also make reporting on Form EIA–816 consistent, in terms of the products reported, with Form EIA–64A *Annual Report of the Origin of Natural Gas Liquids.*

Form EIA–817 Monthly Tanker and Barge Movements Report

• Change the label for product code 207 from the current ''Other renewable fuels and intermediate products'' to ''Other Biofuels and Biointermediates'' not elsewhere specified or indicated. This change is to make the Form EIA–817 product label consistent with terminology used in EIA, other government agencies, and the biofuel industry.

Form EIA–819 Monthly Report of Biofuels, Fuel Oxygenates, Isooctane, and Isooctene

• Change the label for product code 183 in part 8 of Form EIA–819 from the current ''Other renewable fuels and intermediate products'' to ''Other Biofuels and Biointermediates'' not elsewhere specified or indicated. This change is to make the Form EIA–819 product label consistent with terminology used in EIA, other government agencies, and the biofuel industry.

Form EIA–820 Annual Refinery Report

Change the ''Who Must Submit'' part of survey instructions to include reporting by non-refinery operators of distillation, reforming, cracking, coking, hydrotreating, and similar processes. This change is needed in order for EIA to capture complete data on operations of process units commonly associated with oil refineries but operated at non-refinery facilities such as natural gas liquids fractionation plants.

(5) *Estimated Number of Respondents:* 4,674 total respondents;

EIA–800 consists of 104 respondents
EIA–802 consists of 46 respondents
EIA–803 consists of 86 respondents
EIA–804 consists of 102 respondents
EIA–805 consists of 764 respondents
EIA–806 consists of 200 respondents
EIA- 809 consists of 146 respondents
EIA–810 consists of 133 respondents
EIA–812 consists of 107 respondents
EIA–813 consists of 235 respondents
EIA–814 consists of 288 respondents
EIA–815 consists of 1,484 respondents
EIA–816 consists of 485 respondents
EIA–817 consists of 36 respondents
EIA- 819 consists of 275 respondents
EIA- 820 consists of 133 respondents
Pretest methodology consists of 50 respondents

(6) *Annual Estimated Number of Total Responses:* 112,275 total responses;

(7) *Annual Estimated Number of Burden Hours:* 182,983 total annual burden hours;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* 182,983 annual hours * $83.38/hour = $15,257,122.54. EIA estimates that respondents will have no additional costs associated with the surveys other than the burden hours and the maintenance of the information during the normal course of business.

Statutory Authority

15 U.S.C. 772(b) and 42 U.S.C. 7101 *et seq.*

Signed in Washington, DC, on September 30, 2022.

Samson A. Adeshiyan,

Director, Office of Statistical Methods and Research, U. S. Energy Information Administration.

[FR Doc. 2022–21883 Filed 10–6–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR22–6–000]

FP Wheeler Midstream LLC; Notice of Request for Temporary Waiver

Take notice that on September 29, 2022, FP Wheeler Midstream LLC filed a petition seeking a temporary waiver of the tariff filing and reporting requirements of sections 6 and 20 of the Interstate Commerce Act and Parts 341 and 357 of the Federal Energy Regulatory Commission's regulations (Commission), all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene, or protest must serve a copy of that document on the Petitioner.

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://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 FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically 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.

Comment Date: 5 p.m. Eastern time on October 31, 2022.

Dated: October 3, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–21878 Filed 10–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: RP21–1171–001.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: Compliance filing: Revised 2021 Annual Cash Out Filing to be effective N/A.
Filed Date: 9/30/22.
Accession Number: 20220930–5174.
Comment Date: 5 p.m. ET 10/12/22.

Docket Numbers: RP23–1–000.
Applicants: WBI Energy Transmission, Inc.
Description: Penalty Revenue Crediting Report of WBI Energy Transmission, Inc.
Filed Date: 10/3/22.
Accession Number: 20221003–5093.
Comment Date: 5 p.m. ET 10/17/22.

Docket Numbers: RP23–2–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements on 10–3–22 to be effective 10/1/2022.
Filed Date: 10/3/22.
Accession Number: 20221003–5127.
Comment Date: 5 p.m. ET 10/17/22.

Docket Numbers: RP23–3–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases 10–1–2022 to be effective 10/1/2022.
Filed Date: 10/3/22.
Accession Number: 20221003–5129.
Comment Date: 5 p.m. ET 10/17/22.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

Filings Instituting Proceedings

Docket Numbers: RP22–1284–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: 2022 Fuel Tracker Filing to be effective 11/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5155.
Comment Date: 5 p.m. ET 10/12/22.

Docket Numbers: RP22–1285–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Remove Expired Agreements effective October 1, 2022 to be effective 10/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5161.
Comment Date: 5 p.m. ET 10/12/22.

Docket Numbers: RP22–1286–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Aethon 52454, 53154 to Scona 55634, 55635) to be effective 10/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5162.
Comment Date: 5 p.m. ET 10/12/22.

Docket Numbers: RP22–1287–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Oct 2022 to be effective 10/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5178.
Comment Date: 5 p.m. ET 10/12/22.

Docket Numbers: RP22–1288–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (SoCal Nov–Mar 2022) to be effective 11/1/2022.

Filed Date: 9/30/22.
Accession Number: 20220930–5195.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1289–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20220930 Negotiated Rate to be effective 10/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5200.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1290–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Mercuria Energy America to be effective 10/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5218.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1291–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Sabine Pass Liquefaction to be effective 10/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5219.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1292–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing-Spotlight Energy, LLC to be effective 10/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5223.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1293–000.
Applicants: BBT AlaTenn, LLC.
Description: § 4(d) Rate Filing: BBT Ala-Tenn NRA Filing to be effective 11/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5269.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1294–000.
Applicants: Roaring Fork Interstate Gas Transmission, LLC.
Description: Annual FL&U Reimbursement Percentage Filing for 2022 of Roaring Fork Interstate Gas Transmission, LLC.
Filed Date: 9/30/22.
Accession Number: 20220930–5278.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1295–000.
Applicants: Midwestern Gas Transmission Company.
Description: § 4(d) Rate Filing: Permenant Release Partial Capacity to Tenaska Marketing FA1542 to be effective 11/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5293.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1296–000.
Applicants: Columbia Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Non-Conforming—Columbia Gas Virginia—50473–11 to be effective 11/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5309.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1297–000.
Applicants: Leaf River Energy Center LLC.
Description: § 4(d) Rate Filing: Leaf River Low Pressure Tender filing (9–30–2022) to be effective 11/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5373.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1298–000.
Applicants: Maritimes & Northeast Pipeline, L.L.C.
Description: § 4(d) Rate Filing: MNUS FRQ 2022 Filing to be effective 11/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5397.
Comment Date: 5 p.m. ET 10/12/22.
Docket Numbers: RP22–1299–000.
Applicants: ANR Pipeline Company.
Description: § 4(d) Rate Filing: Dynegy—137273—Non-Conforming Agreement to be effective 11/1/2022.
Filed Date: 9/30/22.
Accession Number: 20220930–5399.
Comment Date: 5 p.m. ET 10/12/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 3, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–21876 Filed 10–6–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–2924–000.
Applicants: RWE Supply & Trading Americas, LLC.
Description: Supplement to September 23, 2022, RWE Supply & Trading Americas, LLC Application for Market-Based Rate Authorization.
Filed Date: 9/30/22.
Accession Number: 20220930–5454.
Comment Date: 5 p.m. ET 10/14/22.
Docket Numbers: ER22–2986–000.
Applicants: Pacific Gas and Electric Company.
Description: § 205(d) Rate Filing: Balancing Accounts Update 2023 (TRBAA, RSBAA, ECRBAA) to be effective 1/1/2023.
Filed Date: 9/30/22.
Accession Number: 20220930–5401.
Comment Date: 5 p.m. ET 10/21/22.
Docket Numbers: ER22–2987–000.
Applicants: Entergy Services, LLC, Midcontinent Independent System Operator, Inc.
Description: Schedule 41 Refund Report of Entergy Services, LLC, et al.
Filed Date: 9/26/22.
Accession Number: 20220926–5228.
Comment Date: 5 p.m. ET 10/17/22.
Docket Numbers: ER23–1–000.
Applicants: ITC Midwest LLC, Interstate Power and Light Company.
Description: § 205(d) Rate Filing: ITC Midwest LLC submits tariff filing per 35.13(a)(2)(iii: Update to O&T Agreement Exhibits and Appendices (2022) to be effective 12/2/2021.
Filed Date: 10/3/22.
Accession Number: 20221003–5024.
Comment Date: 5 p.m. ET 10/24/22.
Docket Numbers: ER23–2–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original IISA, Service Agreement No. 6615; Queue No. AF2–205 to be effective 9/2/2022.
Filed Date: 10/3/22.
Accession Number: 20221003–5130.
Comment Date: 5 p.m. ET 10/24/22.
Docket Numbers: ER23–3–000.
Applicants: ITC Midwest LLC.
Description: § 205(d) Rate Filing: Concurrence IPL Amended Exhibits and Attachments (2022) to be effective 12/2/2022.
Filed Date: 10/3/22.
Accession Number: 20221003–5131.

Comment Date: 5 p.m. ET 10/24/22.

Docket Numbers: ER23–4–000.

Applicants: New Market Solar ProjectCo 2, LLC.

Description: § 205(d) Rate Filing: SFA Amendment Filing to be effective 10/4/2022.

Filed Date: 10/3/22.

Accession Number: 20221003–5225.

Comment Date: 5 p.m. ET 10/24/22.

Docket Numbers: ER23–5–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 311, Sierra Estrella LGIA to be effective 12/3/2022.

Filed Date: 10/3/22.

Accession Number: 20221003–5237.

Comment Date: 5 p.m. ET 10/24/22.

Docket Numbers: ER23–6–000.

Applicants: Top Hat Wind Energy Holdings LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 12/3/2022.

Filed Date: 10/3/22.

Accession Number: 20221003–5245.

Comment Date: 5 p.m. ET 10/24/22.

Docket Numbers: ER23–7–000.

Applicants: Top Hat Wind Energy LLC.

Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 12/3/2022.

Filed Date: 10/3/22.

Accession Number: 20221003–5246.

Comment Date: 5 p.m. ET 10/24/22.

Docket Numbers: ER23–8–000.

Applicants: Microgrid Networks LLC.

Description: Baseline eTariff Filing: Application for Market Based Rate Authority to be effective 10/31/2022.

Filed Date: 10/3/22.

Accession Number: 20221003–5268.

Comment Date: 5 p.m. ET 10/24/22.

Docket Numbers: ER23–9–000.

Applicants: Doc Brown LLC.

Description: Baseline eTariff Filing: Baseline new to be effective 10/4/2022.

Filed Date: 10/3/22.

Accession Number: 20221003–5274.

Comment Date: 5 p.m. ET 10/24/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date.

Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 3, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–21877 Filed 10–6–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10241–01–OMS]

Good Neighbor Environmental Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Under the Federal Advisory Committee Act, the Environmental Protection Agency (EPA) gives notice of a public meeting of the Good Neighbor Environmental Board (GNEB or Board). The purpose of this meeting is to discuss and approve the integrated text of the GNEB's advice letter to the President and Congress, focusing on water and wastewater infrastructure issues and challenges along the U.S.-Mexico border region.

DATES: November 7, 2022, from 2:00 p.m.–6:00 p.m. (EST). A copy of the agenda will be posted at *www.epa.gov/faca/gneb.*

The meeting will be conducted virtually and is open to the public with limited access available on a first-come, first-served basis. Members of the public wishing to participate in the video/teleconference, should contact Eugene Green at *green.eugene@epa.gov* by October 31st. Requests to make oral comments or submit written public comments to the Board, should also be directed to Eugene Green at least five business days prior to the video/teleconference. Requests for accessibility and/or accommodations for individuals with disabilities should be directed to Eugene Green at the email address or phone number listed above. To ensure adequate time for processing, please make requests for accommodations at least 10 days prior to the video/teleconference.

SUPPLEMENTARY INFORMATION: The GNEB is an independent federal advisory committee. Its mission is to advise the President and Congress of the United States on good neighbor practices along the U.S. border with Mexico. Its recommendations are focused on environmental infrastructure needs within the U.S. states contiguous to Mexico. The Board is a federal advisory committee chartered under the Federal Advisory Committee Act, Public Law 92–463.

FOR FURTHER INFORMATION CONTACT: Eugene Green in the Federal Advisory Committee Division in the Office of Mission Support (1601M), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–2432; email address: *green.eugene@epa.gov.*

Date: September 29, 2022.

Eugene Green,

Program Analyst.

[FR Doc. 2022–21908 Filed 10–6–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–038]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS), Filed September 26, 2022 10 a.m. EST Through October 3, 2022 10 a.m. EST, Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20220140, Draft, NRC, TN, Construction Permit for the Kairos Hermes Test Reactor, Comment Period Ends: 12/06/2022, Contact: Tamsen Dozier 301–415–2272.

EIS No. 20220141, Draft, USCG, WA, Expansion and Modernization of Base Seattle, Comment Period Ends: 12/02/2022, Contact: Dean Amundson 510–637–5541.

EIS No. 20220142, Draft, FERC, PA, Ohio Valley Connector Expansion Project, Comment Period Ends: 11/21/2022, Contact: Office of External Affairs 866–208–3372.

EIS No. 20220143, Draft, USACE, NY, Draft Integrated Feasibility Report and Tier 1 Environmental Impact Statement, New York-New Jersey Harbor and Tributaries Coastal Storm Risk Management Feasibility Study,

Comment Period Ends: 01/06/2023, Contact: Cheryl Alkemeyer 917–790–8723.

EIS No. 20220144, Draft Supplement, BOEM, Other, Gulf of Mexico OCS Oil and Gas Lease Sales 259 and 261: Draft Supplemental Environmental Impact Statement, Comment Period Ends: 11/21/2022, Contact: Helen Rucker 504–736–2421.

Dated: October 4, 2022.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2022–21880 Filed 10–6–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID 107763]

Privacy Act of 1974; Matching Program

AGENCY: Federal Communications Commission.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (''Privacy Act''), this document announces a new computer matching program the Federal Communications Commission (''FCC'' or ''Commission'' or ''Agency'') and the Universal Service Administrative Company (USAC) will conduct with the Department of Veterans Affairs. The purpose of this matching program is to verify the eligibility of applicants to and subscribers of Lifeline, and the Affordable Connectivity Program (ACP), both of which are administered by USAC under the direction of the FCC. More information about these programs is provided in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Written comments are due on or before November 7, 2022. This computer matching program will commence on November 7, 2022, and will conclude 18 months after the effective date.

ADDRESSES: Send comments to Elliot S. Tarloff, FCC, 45 L Street NE, Washington, DC 20554, or to *Privacy@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Elliot S. Tarloff at 202–418–0886 or *Privacy@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Lifeline program provides support for discounted broadband and voice services to low-income consumers. Lifeline is administered by the Universal Service Administrative Company (USAC) under FCC direction. Consumers qualify for Lifeline through proof of income or participation in a qualifying program, such as Medicaid, the Supplemental Nutritional Assistance Program (SNAP), Federal Public Housing Assistance, Supplemental Security Income (SSI), Veterans and Survivors Pension Benefit, or various Tribal-specific federal assistance programs.

In the Consolidated Appropriations Act, 2021, Public Law 116–260, 134 Stat. 1182, 2129–36 (2020), Congress created the Emergency Broadband Benefit Program, and directed use of the National Verifier to determine eligibility based on various criteria, including the qualifications for Lifeline (Medicaid, SNAP, etc.). EBBP provided $3.2 billion in monthly consumer discounts for broadband service and one-time provider reimbursement for a connected device (laptop, desktop computer or tablet). In the Infrastructure Investment and Jobs Act, Public Law 117–58, 135 Stat. 429, 1238–44 (2021) (codified at 47 U.S.C. 1751–52), Congress modified and extended EBBP, provided an additional $14.2 billion, and renamed it the Affordable Connectivity Program (ACP). A household may qualify for the ACP benefit under various criteria, including an individual qualifying for the FCC's Lifeline program.

In a Report and Order adopted on March 31, 2016, (81 FR 33026, May 24, 2016) (*2016 Lifeline Modernization Order*), the Commission ordered USAC to create a National Lifeline Eligibility Verifier (''National Verifier''), including the National Lifeline Eligibility Database (LED), that would match data about Lifeline applicants and subscribers with other data sources to verify the eligibility of an applicant or subscriber. The Commission found that the National Verifier would reduce compliance costs for Lifeline service providers, improve service for Lifeline subscribers, and reduce waste, fraud, and abuse in the program.

The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants' eligibility for ACP. The purpose of this matching program is to verify the eligibility of Lifeline and ACP applicants and subscribers by determining whether they receive Veterans Pension or Survivors Pension benefits administered by the Department of Veterans Affairs.

Participating Agencies

Department of Veterans Affairs

Authority for Conducting the Matching Program

The authority for the FCC's ACP is Infrastructure Investment and Jobs Act, Public Law 117–58, 135 Stat. 429, 1238–44 (2021) (codified at 47 U.S.C. 1751–52); 47 CFR part 54. The authority for the FCC's Lifeline program is 47 U.S.C. 254; 47 CFR 54.400 through 54.423; Lifeline and Link Up Reform and Modernization, *et al.,* Third Report and Order, Further Report and Order, and Order on Reconsideration, 31 FCC Rcd 3962, 4006–21, paras. 126–66 (2016) (*2016 Lifeline Modernization Order*).

Purpose(s)

The purpose of this modified matching agreement is to verify the eligibility of applicants and subscribers to Lifeline, as well as to ACP and other Federal programs that use qualification for Lifeline as an eligibility criterion. This new agreement will permit eligibility verification for the Lifeline program and ACP by checking an applicant's/subscriber's participation in Veterans Pension or Survivors Pension benefit under the Department of Veterans Affairs. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for ACP benefits.

Categories of Individuals

The categories of individuals whose information is involved in the matching program include, but are not limited to, those individuals who have applied for Lifeline and/or ACP benefits; are currently receiving Lifeline and/or ACP benefits; are individuals who enable another individual in their household to qualify for Lifeline and/or ACP benefits; are minors whose status qualifies a parent or guardian for Lifeline and/or ACP benefits; or are individuals who have received Lifeline and/or ACP benefits.

Categories of Records

The categories of records involved in the matching program include, but are not limited to, the applicant's address, date of birth, and first and last name. The National Verifier will transfer these data elements to the Department of Veterans Affairs, which will respond either ''yes'' or ''no'' that the individual is enrolled in a qualifying assistance program: Veterans Pension or Survivors Pension benefit administered by the Department of Veterans Affairs.

System(s) of Records

The records shared as part of this matching program reside in the Lifeline system of records, FCC/WCB–1, Lifeline, which was published in the

Federal Register at 86 FR 11526 (Feb. 25, 2021).

The records shared as part of this matching program reside in the ACP system of records, FCC/WCB–3, Affordable Connectivity Program, which was published in the **Federal Register** at 86 FR 71494 (Dec. 16, 2021).

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2022–21928 Filed 10–6–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 108154]

Privacy Act of 1974; Matching Program

AGENCY: Federal Communications Commission.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (''Privacy Act''), this document announces a new computer matching program the Federal Communications Commission (''FCC'' or ''Commission'' or ''Agency'') and the Universal Service Administrative Company (USAC) will conduct with the Nevada Department of Health and Human Services, Division of Welfare and Supportive Services. The purpose of this matching program is to verify the eligibility of applicants to and subscribers of Lifeline, and the Affordable Connectivity Program (ACP), both of which are administered by USAC under the direction of the FCC. More information about these programs is provided in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Written comments are due on or before November 7, 2022. This computer matching program will commence on November 7, 2022, and will conclude 18 months after the effective date.

ADDRESSES: Send comments to Elliot S. Tarloff, FCC, 45 L Street NE, Washington, DC 20554, or to *Privacy@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Elliot S. Tarloff at 202–418–0886 or *Privacy@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Lifeline program provides support for discounted broadband and voice services to low-income consumers. Lifeline is administered by the Universal Service Administrative Company (USAC) under FCC direction. Consumers qualify for Lifeline through proof of income or participation in a qualifying program, such as Medicaid, the Supplemental Nutritional Assistance Program (SNAP), Federal Public Housing Assistance, Supplemental Security Income (SSI), Veterans and Survivors Pension Benefit, or various Tribal-specific federal assistance programs.

In the Consolidated Appropriations Act, 2021, Public Law 116–260, 134 Stat. 1182, 2129–36 (2020), Congress created the Emergency Broadband Benefit Program, and directed use of the National Verifier to determine eligibility based on various criteria, including the qualifications for Lifeline (Medicaid, SNAP, etc.). EBBP provided $3.2 billion in monthly consumer discounts for broadband service and one-time provider reimbursement for a connected device (laptop, desktop computer or tablet). In the Infrastructure Investment and Jobs Act, Public Law 117–58, 135 Stat. 429, 1238–44 (2021) (codified at 47 U.S.C. 1751–52), Congress modified and extended EBBP, provided an additional $14.2 billion, and renamed it the Affordable Connectivity Program (ACP). A household may qualify for the ACP benefit under various criteria, including an individual qualifying for the FCC's Lifeline program.

In a Report and Order adopted on March 31, 2016, (81 FR 33026, May 24, 2016) (*2016 Lifeline Modernization Order*), the Commission ordered USAC to create a National Lifeline Eligibility Verifier (''National Verifier''), including the National Lifeline Eligibility Database (LED), that would match data about Lifeline applicants and subscribers with other data sources to verify the eligibility of an applicant or subscriber. The Commission found that the National Verifier would reduce compliance costs for Lifeline service providers, improve service for Lifeline subscribers, and reduce waste, fraud, and abuse in the program.

The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants' eligibility for ACP. The purpose of this matching program is to verify the eligibility of Lifeline and ACP applicants and subscribers by determining whether they receive SNAP or Medicaid benefits administered by the Nevada Department of Health and Human Services, Division of Welfare and Supportive Services.

Participating Agencies

Nevada Department of Health and Human Services, Division of Welfare and Supportive Services.

Authority for Conducting the Matching Program

The authority for the FCC's ACP is Infrastructure Investment and Jobs Act, Public Law 117–58, 135 Stat. 429, 1238–44 (2021) (codified at 47 U.S.C. 1751–52); 47 CFR part 54. The authority for the FCC's Lifeline program is 47 U.S.C. 254; 47 CFR 54.400 through 54.423; Lifeline and Link Up Reform and Modernization, *et al.,* Third Report and Order, Further Report and Order, and Order on Reconsideration, 31 FCC Rcd 3962, 4006–21, paras. 126–66 (2016) (*2016 Lifeline Modernization Order*).

Purpose(s)

The purpose of this modified matching agreement is to verify the eligibility of applicants and subscribers to Lifeline, as well as to ACP and other Federal programs that use qualification for Lifeline as an eligibility criterion. This new agreement will permit eligibility verification for the Lifeline program and ACP by checking an applicant's/subscriber's participation in SNAP or Medicaid in Nevada. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for ACP benefits.

Categories of Individuals

The categories of individuals whose information is involved in the matching program include, but are not limited to, those individuals who have applied for Lifeline and/or ACP benefits; are currently receiving Lifeline and/or ACP benefits; are individuals who enable another individual in their household to qualify for Lifeline and/or ACP benefits; are minors whose status qualifies a parent or guardian for Lifeline and/or ACP benefits; or are individuals who have received Lifeline and/or ACP benefits.

Categories of Records

The categories of records involved in the matching program include, but are not limited to, the last four digits of the applicant's Social Security Number, date of birth, and last name. The National Verifier will transfer these data elements to the Nevada Department of Health and Human Services, Division of Welfare and Supportive Services, which will respond either ''yes'' or ''no'' that the individual is enrolled in a qualifying assistance program: SNAP or Medicaid administered by the Nevada Department of Health and Human Services, Division of Welfare and Supportive Services.

System(s) of Records

The records shared as part of this matching program reside in the Lifeline system of records, FCC/WCB–1,

Lifeline, which was published in the **Federal Register** at 86 FR 11526 (Feb. 25, 2021).

The records shared as part of this matching program reside in the ACP system of records, FCC/WCB–3, Affordable Connectivity Program, which was published in the **Federal Register** at 86 FR 71494 (Dec. 16, 2021).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2022–21921 Filed 10–6–22; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–PBS–2022–05; Docket No. 2022–0002; Sequence No. 24]

Notice of Availability for the Final Environmental Assessment for the Calexico West Land Port of Entry Temporary Pedestrian Process Facility Calexico, California

AGENCY: Public Buildings Service (PBS), General Services Administration (GSA).

ACTION: Notice; public meeting.

SUMMARY: This notice announces the availability of the Final Environmental Assessment (EA) for the proposed construction of a temporary pedestrian processing facility adjacent to the Historic Customs House, and interior renovation of the Historic Customs House at 340 East 1st Street, Calexico, California. The Final EA describes the reason the Project is being proposed; the alternatives that were evaluated; the potential impacts of each of the alternatives on the existing environment; and the proposed avoidance, minimization, and/or mitigation measures related to those alternatives.

DATES: A virtual public meeting to solicit comments and provide information about the Final EA will be held on October 24th, 2022, at 4:30 p.m., Pacific Standard Time at: *https://teams.microsoft.com/l/meetup-join/19%3ameeting_NTNiNmE2MDktNTk5OC00OGYxLWFmZjYtZjdlZGRhMTkxNWNh%40thread.v2/0?context=%7b%22Tid%22%3a%228aec2bf0-04af-4841-bcf6-bac6a58dd4ef%22%2c%22Oid%22%3a%221894920d-2cd7-4a1a-aa78-0ebeddc5bdf6%22%7d.* The availability period for the Final EA ends on November 7th, 2022.

ADDRESSES: Further information, including an electronic copy of the Final EA may be found online on the following website: *https://www.gsa.gov/about-us/regions/welcome-to-the-pacific-rim-region-9/land-ports-of-entry/calexico-west-land-port-of-entry.*

Questions or comments concerning the Draft EA should be directed to Osmahn Kadri, EPA Program Manager, GSA, via email: *osmahn.kadri@gsa.gov* or Ms. Bianca Rivera, 355 South Euclid Avenue, Suite 107, Tucson, AZ 85719 via postal mail/commercial delivery.

FOR FURTHER INFORMATION CONTACT: Mr. Osmahn A. Kadri, NEPA Program Manager, GSA, Pacific Rim Region, at 415–522–3617 or email *osmahn.kadri@gsa.gov.* Please call this number if special assistance is needed to attend and participate in the public meeting.

SUPPLEMENTARY INFORMATION:

Background

The Project is located adjacent to the Historic Customs House at 340 East 1st Street, Calexico, California. The Project is proposed to provide a temporary pedestrian processing facility for use during the demolition of existing structures and construction of the new processing building while ensuring continued services to those utilizing the international crossing between the United States of American and Mexico. The temporary facility is anticipated to be constructed on Heffernan Road, south of East 1st Street, to the west of the Historic Customs House. The facility will require the acquisition of Heffernan Road, to the south of East 1st Street. The building will be approximately 8,804 square feet and include a fire lane to the west, pedestrian ramps leading to/from the building, and pedestrian pick-up and drop-off areas at the north side of the building. The interior building will include wait areas, administrative offices, property storage interview rooms, inspection areas, processing areas, and restrooms.

The EA considered one Action Alternative (the Proposed Action) and the No Action Alternative. The Action Alternative would consist of the construction of the temporary processing facility and associated infrastructure. The Project is proposed to provide a temporary pedestrian processing facility for use during the demolition of existing structures and construction of the new processing building while ensuring continued services to those utilizing the international crossing between the United States of American and Mexico. The temporary facility is anticipated to be constructed on Heffernan Road, south of East 1st Street, to the west of the Historic Customs House. Even though the facility is temporary, the project will require the permanent acquisition of Heffernan Road, to the south of East 1st Street, removing the parking/pick up area. The building will be approximately 8,804 square feet and include a fire lane to the west, pedestrian ramps leading to/from the building, and pedestrian pick-up and drop-off areas at the north side of the building. The interior building will include wait areas, administrative offices, property storage interview rooms, inspection areas, processing areas, and restrooms. Since the facility is temporary, there would be no change in personnel staffing at this port of entry. Construction is likely to impact parking and loading/unloading merchandise for the retail facility to the west of the proposed facility, as well as traffic flow along East 1st Street during construction.

Under the No Action Alternative the construction of the temporary facilities, construction of the ramp, and renovations within the existing Historic Customs House would not occur.

The Draft EA was made publicly available on August 19, 2022, for a 30-day period. The public review period closed on September 26, 2018. The Notice of Availability for the Draft EA was published in the **Federal Register** at 87 FR 51110 on August 19, 2022. A virtual public meeting took place on August 23, 2022. In preparing this Final EA, GSA considered public comments received regarding the Draft EA during the public review period.

After careful consideration of the environmental analysis and associated environmental effects of the Proposed Action Alternative and No Action Alternative, the purpose and need for the Project, and comments received on the Draft EA, GSA will be implementing the Proposed Action Alternative.

Finding: Pursuant to the provision of GSA Order ADM 1095.1F, the PBS NEPA Desk Guide, and the regulations issued by the Council on Environmental Quality (CEQ; 40 CFR parts 1500 to 1508), this notice advises the public of our finding that the Proposed Action will not significantly affect the quality of the human environment.

Basis for Finding: The environmental impacts of constructing the proposed structural enhancements were considered in the Final EA pursuant to the National Environmental Policy Act (NEPA) and the CEQ regulations implementing NEPA. No significant impacts on the environment would occur with implementation of best management practices and avoidance, minimization, and mitigation measures identified in the Final EA.

The Final EA can be viewed on the GSA website at *https://www.gsa.gov/about-us/regions/welcome-to-the-pacific-rim-region-9/land-ports-of-entry/calexico-west-land-port-of-entry.*

The Finding of No Significant Impact will be signed thirty (30) days after the publication of this notice, provided that no information leading to a contrary finding is received or comes to light during this period.

Russell Larson,

Director, Portfolio Management Division, Pacific Rim Region, Public Buildings Service.

[FR Doc. 2022–21886 Filed 10–6–22; 8:45 am]

BILLING CODE 6820–YF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–0058–NC]

RIN 0938–ZB72

Request for Information; National Directory of Healthcare Providers & Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: This request for information solicits public comments on establishing a National Directory of Healthcare Providers & Services (NDH) that could serve as a ''centralized data hub'' for healthcare provider, facility, and entity directory information nationwide.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 6, 2022.

ADDRESSES: In commenting, please refer to file code CMS–0058–NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0058–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0058–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Alexandra Mugge, (410) 786–4457. David Koppel, (303) 844–2883.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Introduction

Healthcare directories that contain aggregated information about healthcare providers, facilities, and other entities involved in patient care are crucial resources for consumers and the healthcare industry. Contemporary and comprehensive directories can support a variety of use cases, such as helping consumers choose a provider, comparing health plan networks, auditing network adequacy, and coordinating patients' care.[1] Today, consumers use provider directories and online searches more than any other resource (such as word-of-mouth or physician referrals) to research healthcare providers. In a 2020 consumer preference report, a majority of the consumers surveyed indicated that the online availability of accurate directory information (address, insurance, specialty, hours, etc.) has affected their decisions when choosing a doctor.[2]

Although these are important resources, the fragmentation of current provider directories requires inefficient, redundant reporting from providers.[3] Directories often contain inaccurate information, rarely support interoperable data exchange or public health reporting, and are overall costly to the healthcare industry. According to one estimate from a provider survey completed in 2019 by the Council for Affordable Quality Healthcare (CAQH), physician practices collectively spend $2.76 billion annually on directory maintenance, which is equivalent to approximately $998.84 per month per practice, or one staff member workday per week.[4]

The CAQH estimated that transitioning directory data collection to a single streamlined platform could save the average physician practice an estimated $4,746 annually, or an approximated $1.1 billion in collective annual savings across the nation. Directory maintenance costs for physician practices vary based on many factors including practice size, the number of payers with which they are contracted, number of practice locations, and importantly, how often and timely they verify or update their information in directories. Furthermore, providers reported that they must submit directory information in various ways, including by fax, credentialing software, provider management and enrollment software, phone, and physical mail. This disjointed system results in barriers to patient care, administrative burden on providers and their staff, and increased cost for the entire healthcare industry.[5]

One driver of inaccuracy is the varying frequencies and levels of detail at which different directories require information. Some track directory information at the practice level, and others include directory information for each physical location. Without processes or internal audits for data accuracy, different practice staff may provide inconsistent information across

[1] ONC Health IT. (2016, February). Strategic Implementation Guide: Provider Directories. See page 4. Retrieved from *https://www.healthit.gov/sites/default/files/statestrategicimplementationguide-providerdirectories-v1-final.pdf.*

[2] Doctor.com. (2020). Customer Experience Trends in Healthcare. Retrieved from *https://cms.doctor.com/wp-content/uploads/2020/03/cxtrends2020-report-final.pdf.*

[3] We use the term ''providers'' generally in this RFI to refer to healthcare facilities and practitioners and do not intend that to include or exclude any specific category of individuals or entities.

[4] CAQH. (2019). The Hidden Causes of Inaccurate Provider Directories. Retrieved from *https://www.caqh.org/sites/default/files/explorations/CAQH-hidden-causes-provider-directories-whitepaper.pdf.*

[5] Ibid.

directories. Administrative complexity and unclear accountability for data accuracy also contributes to data quality and accuracy challenges. Even when payers have legal obligations to maintain an accurate directory, as discussed in section II. of this document, they generally must rely on providers to update the information within their directories and are left with few options if a provider does not do so in a timely manner. This also puts a burden on provider staff, who must update their directory information for an average of 20 different payers per practice.[6]

We believe that CMS may have an opportunity to alleviate some of these burdens and improve the state of provider directories through a CMS-developed and maintained, Application Programming Interface (API)-enabled, national directory. A National Directory of Healthcare Providers & Services (NDH) could serve as a ''centralized data hub'' for directory and digital contact information containing the most accurate, up-to-date, and validated (that is, data that is verified by CMS against primary sources) data in a publicly accessible index.[7] An NDH could both streamline existing data across CMS systems and publish information in an easier-to-use format than is available today. More useful public data could help patients find providers, facilitate interoperable provider data exchange, and help payers improve the accuracy of their own directories. We use the term ''centralized data hub'' to describe the practice of aggregating data from many existing systems into a single location, which is a best practice within any industry, including healthcare. Establishing a ''centralized data hub'' breaks down technological barriers between various data sets and allows other databases to reference the source of the information without duplicating data. This aggregation and standardization of data could help avoid errors and inaccuracies in directories that reference data in an NDH. CMS could use an NDH as a mechanism to collect and maintain directory information in a standardized, interoperable, and sharable format that allows widespread access while maintaining privacy and security protocols to safeguard access to sensitive information.

To align with national standards for interoperability, an NDH could be built on the standards established by the Office of the National Coordinator for Health Information Technology (ONC) at 45 CFR part 170, subpart B. Specifically, an NDH could use HL7® Fast Healthcare Interoperability Resources (FHIR®) APIs, the latest standard for which is codified at 45 CFR 170.215(a)(1), to enable data exchange. FHIR is a standard for exchanging healthcare information electronically that enables rapid and efficient data transactions through an API.[8] [9] Systems with different data architecture can use FHIR APIs to exchange health data in a consistent manner, which gives providers, payers, and other relevant entities a fast and secure way to send and receive healthcare data. FHIR is a widely adopted standard that we already require for specific types of health data exchange.[10] We expect ONC to periodically update the standards at 45 CFR part 170, subpart B through notice and comment rulemaking, and an NDH could use the most up-to-date standards, as appropriate.

ONC and the Federal Health Architecture (FHA), a former federal agency collaboration created to enhance interoperability among federal health information technology (IT) systems,[11] developed the Validated Healthcare Directory (VHDir) FHIR Implementation Guide (IG), which describes the technical design considerations for collecting, validating, verifying, and exchanging data from a central source of provider data using FHIR standards. That IG is currently a ''standard for trial use,'' meaning it has been deemed ''ready to implement'' by the sponsoring work group, but there has not yet been significant implementation experience.[12] Testing and development processes are ongoing toward establishing the IG as a normative standard through the American National Standards Institute (ANSI)-approved process. CMS will continue to monitor and work with the appropriate standards development organizations on this effort.

Previous healthcare directory technical efforts, described in section II. of this document, have identified CMS as the appropriate owner of a validated directory, such as an NDH.[13] We agree that CMS, with collaborative input from industry and federal partners, is positioned to develop an NDH in a manner that serves all stakeholders, builds and maintains trust in the data, advances public health goals, improves data exchange, streamlines administrative processes, and promotes interoperability.

Through this RFI, we seek input on the current state of healthcare provider directories and steps that we could or should take if CMS concludes that adequate legal authority exists to establish an NDH and proceeds to do so.

We believe a modern healthcare provider directory should serve multiple purposes for end users. In addition to helping patients locate providers that meet their individual needs and preferences, a modern healthcare directory should enable healthcare providers, payers, and others involved in patient care to identify one another's digital contact information, also referred to as digital endpoints,[14] for interoperable electronic data exchange. We are collecting feedback from the public regarding the topics and questions in the discussion that follows. We pose questions throughout this document; a response to every question is not required in order to submit comments.

II. Background

Provider directories have long been a focus of federal healthcare improvement efforts. On several occasions, Congress has acted to address the challenges of directory data availability and accuracy. Federal executive branch departments and agencies have also taken considerable steps to implement regulatory requirements aimed at addressing these challenges.

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new Medicare Part C (now also known as Medicare Advantage) program, and under section

[6] CAQH. (2019). The Hidden Causes of Inaccurate Provider Directories, See page 2. Retrieved from *https://www.caqh.org/sites/default/files/explorations/CAQH-hidden-causes-provider-directories-whitepaper.pdf.*

[7] To address digital contact information, section 4003(c)(1) of the 21st Century Cures Act requires the Secretary of Health and Human Services to ''establish a provider digital contact information index to provide digital contact information for health professionals and health facilities.''

[8] HL7. (2022, May 28). Welcome to FHIR. Retrieved from *http://hl7.org/fhir/.*

[9] Health IT. (2021, June 16). FHIR Fact Sheets. Retrieved from *https://www.healthit.gov/topic/standards-technology/standards/fhir-fact-sheets#:~:text=What%20is%20HL7%C2%AE%20FHIR,be%20quickly%20and%20efficiently%20exchanged.*

[10] CMS. (2020, May 1). 85 FR 25510. See page 25521–22, 25530. Retrieved from *https://www.federalregister.gov/d/2020-05050.*

[11] Health IT. (2020, January 17). Federal Health Architecture (FHA). Retrieved from *https://www.healthit.gov/archive/topic/onc-hitech-programs/federal-health-architecture-fha.*

[12] McKenzie, L. & Peters, M. (2021, March 3). HL7 Balloting. Retrieved from *https://confluence.hl7.org/display/HL7/HL7+Balloting.*

[13] FAST. (2020, December 17). Proposed Solutions Working Document: Directory (V3). Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Directory%2C+Versions+and+Scale+Tiger+Team?preview=/46301216/183107855/FAST-PS-Directory%20V3_122320.docx.*

[14] CMS. (2022, February 11). OBRHI FAQs. Retrieved from *https://www.cms.gov/about-cms/obrhi/faqs.*

1852(c)(1)(C) of the Social Security Act (the Act) required that Medicare Advantage organizations (MA organizations) annually disclose in a clear, accurate, and standardized form to each MA plan enrollee, the number, mix, and distribution of plan providers, among other information.

This requirement was implemented in regulations at 42 CFR 422.111(b)(3), which requires MA organizations to disclose a description of the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services. CMS has issued updated guidance over several years regarding the responsibilities of MA organizations to have accurate provider directories, with guidance appearing in the Medicare Marketing Guidelines and Medicare Communications and Marketing Guidelines [15] [16] and section 110 of Chapter 4 of the Medicare Managed Care Manual.[17] [18]

Similarly, in section 4701 of the BBA, Congress added section 1932(a)(5)(B)(i) of the Act, which requires that the Medicaid managed care organizations that are specified in the statute make available, upon request, the identity, locations, qualifications, and availability of providers that participate with that entity. These same requirements were applied to Children's Health Insurance Program (CHIP) managed care entities via section 403 of the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3), at section 2103(f)(3) of the Act.

In 2015, in the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016'' final rule (80 FR 10829), we established a requirement, at 45 CFR 156.230(b), that Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges publish online an easily-accessible, up-to-date, accurate, and complete provider directory. Those directories must include information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations. CMS also requires issuers to make this information publicly available on their own websites in a machine-readable file and format to allow third parties to create resources that aggregate information on different plans.[19] [20] CMS conducts annual reviews to assess the accuracy of issuers' machine-readable provider data files, comparing the data files to the issuers' online provider directories and other data sources, such as the National Plan and Provider Enumeration System (NPPES) and the United States Postal Service (USPS) address verification database. Over five plan years beginning in plan year (PY) 2017 through PY2021, CMS found that no more than 47 percent of the provider entries we reviewed from the machine-readable provider data files included a complete set of accurate telephone numbers, addresses, specialties, plan affiliations, and whether the provider is accepting new patients.[21] Furthermore, only 73 percent of the providers reviewed could be fully matched to the published directories on the payer's website. Finally, when we compared provider information from the machine-readable data files to the NPPES National Provider Identifier (NPI) registry, only 28 percent of the provider names, addresses, and specialties matched.[22] In addition to accuracy issues, we note that a machine-readable file is a static data source that must be entirely recreated to provide a snapshot of the dataset at any point in time. Conversely, the APIs that we discuss here could allow data to be accessed in real-time and with the most up-to-date information at the moment the system is queried.

In the Contract Year 2016 Call Letter for Part C (Medicare Advantage) and Part D plans, CMS announced it was initiating a monitoring effort of the accuracy of online provider directories for plans offered by MA organizations.[23] Beginning in February 2016, CMS studied the accuracy of information in MA organizations' online directories. We released findings in July 2018 from three review rounds in which we identified at least one deficiency in 45 percent, 55 percent, and 49 percent of listed locations.[24] Significant types of identified inaccuracies included providers who did not practice at the listed location, providers who did not accept the plan at the listed location, incorrect phone numbers or addresses, and mistaken ''accepting new patients'' flags. In that report, we identified a centralized database as a possible long-term solution.[25]

On January 3, 2020, as a follow-up to the MA provider directory monitoring study conducted from 2016 to 2018, CMS issued a Health Plan Management System (HPMS) memo encouraging MA organizations to work with their contracted providers and to urge those providers to review and update their NPPES data. CMS announced that it would exercise enforcement discretion with regard to potential violations of § 422.111(b)(3) should CMS uncover errors in an MA organization's provider directory where the errors are consistent with NPPES data that were updated or certified between January 1 and April 30, 2020, provided the MA organization corrected any identified errors within 30 days.[26]

[15] CMS. (2022, February 9). Medicare Communications and Marketing Guidelines (MCMG). Retrieved from *https://www.cms.gov/files/document/medicare-communications-marketing-guidelines-2-9-2022.pdf.*

[16] Prior to 2020, CMS issued the Medicare Marketing Guidelines (historical versions are available through the HHS Guidance Portal, available online here: *https://www.hhs.gov/guidance/*) but replaced that document with the Medicare Communications and Marketing Guidelines when the applicable regulations were revised in a final rule that appeared in the **Federal Register** on April 16, 2018 (83 FR 16440, 16624 through 16633).

[17] CMS. (2015, April 22). Medicare Managed Care Manual Publication # 100–16: Chapter 4—Benefits and Beneficiary Protections. Retrieved from *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS019326.*

[18] CMS. (2016, April 22). Medicare Managed Care Manual: Benefits and Beneficiary Protections. Retrieved from *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

[19] CMS. (2022, January 7). 2023 Letter to Issuers in the Federally-facilitated Exchanges, Chapter 3, Section 1. Retrieved from *https://www.cms.gov/files/document/2023-draft-letter-issuers-508.pdf.*

[20] CMS. (2017, February 17). Addendum to 2018 Letter to Issuers in the Federally-facilitated Marketplaces. Retrieved from *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces-and-February-17-Addendum.pdf.*

[21] CMS selected a sample of 25 providers from 45 QHP and 5 SADP issuers, For each issuer, the target sample was selected to equally distribute primary care physician (PCP), obstetrics/gynecology (OB/GYN), pediatrics, and specialty providers for QHPs, and general dentists, pediatric dentists, and specialty dentists for SADPs. The provider's National Provider Identification number (NPI) was used to ensure providers were not chosen more than once during each plan year review. One SADP in the sample had only 15 unique NPIs from which a sample could be selected; this resulted in the final sample size of 1,235 unique NPIs.

[22] CMS. (2022, March 22). Machine-Readable Provider Directory Review Summary Report Plan Years 2017–2021. Retrieved from *https://www.cms.gov/files/document/2017-2021mrpdsummaryreportfinal508.pdf.*

[23] CMS. (2015, April 6). Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Retrieved from *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf.*

[24] CMS. (2018, November 28). Online Provider Directory Review Report. Retrieved from *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Round_3_11-28-2018.pdf.*

[25] Ibid.

[26] CMS. (2020, January). HPMS Memo. Retrieved from *https://www.cms.gov/httpseditcmsgov research-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-3.*

In 2016, Congress enacted the 21st Century Cures Act (Cures Act) (Pub. L. 114–255). Section 4003(c) of the Cures Act requires the Secretary of HHS (the Secretary), directly or through a partnership with a private entity, to establish a provider digital contact information index to provide digital contact information for health professionals and health facilities. To implement that requirement of section 4003(c) of the Cures Act, in June 2018 we updated NPPES,[27] a system authorized by section 1173(b) of the Act and that we administer, to be able to capture digital contact information, also referred to as digital endpoints,[28] for both healthcare professionals and facilities. NPPES currently supplies NPI numbers to healthcare providers (both individuals and facilities), maintains their NPI record, and publishes the records online. NPPES has been updated to include the capability to capture one or more fields of digital contact information that can be used to facilitate secure health information exchange. For instance, providers can submit a type of digital endpoint such as a Direct address, which functions similar to a regular email address, but includes additional security measures to ensure that messages are only accessible by the intended recipient in order to keep the information confidential and secure.[29] As NPPES is publicly searchable on CMS' website, many other entities use the data included in the NPPES Downloadable File for other business and research purposes (for example, the Kaiser Family Foundation completed a 2020 report on the availability of active critical care physicians and nurses in a state-by-state analysis, relating to COVID–19).[30]

Additionally, section 4003(b) of the Cures Act amended section 3001(c) of the Public Health Service Act (PHSA) to add a new paragraph (9)(A) that directed the National Coordinator to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' The overall goal of the Trusted Exchange Framework and Common Agreement (TEFCA) is to establish a universal floor for interoperability across the country. Paragraph (9)(D) of section 3001(c) of the PHSA requires the National Coordinator to create and publish on ONC's website, ''a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement.'' On January 18, 2022, ONC released the Common Agreement for Nationwide Health Information Interoperability Version 1 (Common Agreement).[31] The Common Agreement and the incorporated by reference Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF) [32] establish a technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other. The Common Agreement and the QTF do not require FHIR-based exchange because network enablement of FHIR is still maturing in key areas. However, the ONC Recognized Coordinating Entity (RCE),[33] a private-sector entity that implements the Common Agreement, released a 3-year FHIR Roadmap for TEFCA Exchange, which lays out a deliberate strategy to add FHIR-based exchange under TEFCA in the near future.[34] The Common Agreement also includes requirements for maintaining a directory of exchange participants' digital endpoints.

Section 5006 of the Cures Act requires Medicaid agencies to publish online a directory of certain physicians who participate in the state's fee-for-service (FFS) program. Medicaid agencies must update these directories at least annually and include providers' names, specialties, addresses, and telephone numbers. For physicians participating in a primary care case-management system, the directory must also indicate whether they are accepting Medicaid beneficiaries as new patients and the physician's cultural and linguistic capabilities. Other providers may be included at the state's option, as may certain additional information such as the physician's or provider's internet website.

In 2016, ONC and FHA hosted a provider directory workshop to convene public and private stakeholders, including health IT developers, organizations, and vendors involved in directory solutions, to discuss provider directory issues and challenges.[35] [36] The workshop highlighted widely held concerns about provider directory data quality, administrative burden, and consumer satisfaction. To address these concerns, ONC and FHA launched the Healthcare Directory initiative. This group developed the VHDir FHIR IG to define the underlying architecture for a proposed national directory of validated healthcare data and to provide technical specifications for the exchange of such information.[37] FHIR standards and IGs, including the VHDir IG, are developed through an industry-led, consensus-based public process. ONC, HHS, and CMS are all engaged in work to promote the adoption and use of the FHIR standards for interoperability beyond the provider directory domain.

Building on that work, in 2020, ONC, through the FHIR At Scale Taskforce (FAST),[38] identified numerous technical challenges associated with directories, particularly related to digital endpoints.[39] [40] Specifically, FAST

[27] CMS. NPPES NPI Registry. Retrieved from *https://npiregistry.cms.hhs.gov/.*

[28] CMS. (2022, February 11). OBRHI FAQs. Retrieved from *https://www.cms.gov/about-cms/obrhi/faqs.*

[29] Health IT. (2014, May). Direct Basics: Q&A for Providers. Retrieved from *https://www.healthit.gov/sites/default/files/directbasicsforprovidersqa_05092014.pdf.*

[30] Lopez, E. (2020, July 30). The Critical Care Workforce and COVID–19. Retrieved from *https://www.kff.org/report-section/the-critical-care-workforce-and-covid-19-a-state-by-state-analysis-data-note/.*

[31] ONC. (2022, January). Common Agreement for National Health Information Interoperability, Version 1. Retrieved from *https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.*

[32] ONC TEFCA Recognized Coordinating Entity. (2022, January). Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0. Retrieved from *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf.*

[33] In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to serve as the initial RCE. The RCE will operationalize and enforce the Common Agreement, oversee QHIN-facilitated network operations, and ensure compliance by participating QHINs. The RCE will also engage stakeholders to create a roadmap for expanding interoperability over time. *See* The Sequoia Project. (2019, September 4). ONC Awards The Sequoia Project a Cooperative Agreement for the Trusted Exchange Framework and Common Agreement to Support Advancing Nationwide Interoperability of Electronic Health Information. Retrieved from *https://sequoiaproject.org/onc-awards-the-sequoia-project-a-cooperative-agreement-for-the-trusted-exchange-framework-and-common-agreement-to-support-advancing-nationwide-interoperability-of-electronic-health-information.*

[34] ONC TEFCA Recognized Coordinating Entity. (2022, January). FHIR Roadmap for TEFCA Exchange, Version 1. Retrieved from *https://rce.sequoiaproject.org/wp-content/uploads/2022/01/FHIR-Roadmap-v1.0_updated.pdf.*

[35] ONC. (2016, June 24). ONC/FHA Provider Directory Workshop. Retrieved from *https://www.ca-hie.org/site-content/CAHIE-Knowledge-Network-2016-06-24-Healthcare-Directory.pdf.*

[36] *Health IT.gov.* (2020, January 17). Federal Health Architecture (FHA). Retrieved from *https://www.healthit.gov/archive/topic/onc-hitech-programs/federal-health-architecture-fha.*

[37] ONC Tech Lab Standards Coordination. (2019, June 25). Healthcare Directory. Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Healthcare+Directory.*

[38] FAST. (2022, March 16), FAST Home. Retrieved from *https://confluence.hl7.org/display/FAST/FHIR+at+Scale+Taskforce+%28FAST%29+Home.*

[39] FAST. (2020, December 17). Proposed Solutions Working Document: Directory (V3). Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Directory%2C+Versions+and+Scale+Tiger+Team?preview=/*

Continued

determined that there is neither an authoritative source for digital contact information nor a consistent method for locating such information. ONC conducted research, stakeholder engagement, and key technical development activities to establish the technical framework and capabilities for an adaptable and scalable NDH.[41] [42]

The FAST analysis concluded that a more robust directory is the needed long-term solution to overcome the technical barriers of using NPPES as a digital endpoint repository. The Taskforce noted that NPPES was not originally designed to hold, validate, and maintain digital contact information required to ''appropriately describe the endpoints for FHIR.'' [43] They described that NPPES cannot sufficiently capture the data complexity necessary to fully facilitate electronic data exchange. For instance, provider-organization relationship information may be necessary to determine which endpoints are relevant for particular use cases. The Taskforce noted that other organizations that are not currently included in NPPES, such as payers, are vital to capture in a directory to effectively utilize digital endpoint information.[44] These challenges to using NPPES as a digital endpoint directory are evidenced by the low rate of provider digital endpoint submission. In 2021, CMS determined that 2.9 million providers still had missing digital endpoints in NPPES.[45] Additionally, the Taskforce found that the majority of the Direct addresses and FHIR endpoints that providers had submitted were invalid, a strong indication of the issues associated with using NPPES as an endpoint repository. The Taskforce described that there has ''historically [been a] low rate of publication of valid Direct addresses in NPPES,'' and ''that only 4.3 percent of FHIR endpoints [46] were valid as of 8/20/2020.'' [47] The FAST report concluded that for a digital endpoint directory to be effective, the directory ''needs to be based on a broader set of validated healthcare participants and relationships.'' [48] This means that such a directory must be designed to adapt to industry or market demands for its use. FAST proposed a ''national repository for validated information related to healthcare endpoints,'' which described the development of a centralized directory as a critical next step in promoting digital contact information discovery, and therefore interoperability, across the healthcare system.[49] FAST described that ''one authoritative national source of truth'' is needed to help address the issues with current directory systems and identified CMS as the potential owner of this asset.[50] [51]

In May 2020, CMS published a final rule, ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Healthcare Providers'' (CMS Interoperability and Patient Access final rule),[52] in which we required that, by January 1, 2021, MA organizations, Medicaid [53] and CHIP FFS [54] programs, Medicaid managed care plans,[55] and CHIP managed care entities [56] make standardized information about their provider networks available through a Provider Directory API that is conformant with technical standards finalized by ONC.[57] [58] Those Provider Directory APIs are required to be accessible via a public-facing digital endpoint on the payer's website to ensure public discovery and access. Payers must make all directory information available to current and prospective enrollees and the public through the Provider Directory API within 30 calendar days of receiving new or updated provider directory data.

In the same final rule, CMS finalized a policy to publicly report the names and NPIs of those providers who do not have digital contact information included in NPPES.[59] In December 2021, CMS published a report of approximately 2.9 million NPIs associated with providers and clinicians without digital contact information in NPPES,[60] an initiative CMS has undertaken to improve provider engagement. CMS noted that the NPPES Missing Digital Contact Information Report will be updated quarterly. The most recent data for the second quarter of 2022, reported July 25, 2022, do not show any significant improvements in the number of providers with missing digital contact information compared to the December 2021 report.[61] These data underscore FAST's call for a more robust long-term digital endpoint directory solution.

In 2020, the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260), Division BB, section 116 added a new section 2799A–5 to the PHSA, section 720 to the Employee Retirement Income Security Act of 1974 (ERISA), and section 9820 to the Internal Revenue Code of 1986. These

46301216/183107855/FAST-PS-Directory%20V3_122320.docx.

[40] Endpoints provide a simple, secure, scalable, and standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the internet. *See* CMS. (2016). Health Information Exchange (HIE) Page. Retrieved from *https://nppes.cms.hhs.gov/webhelp/nppeshelp/HEALTH%20INFORMATION%20EXCHANGE.html.*

[41] ONC Tech Lab Standards Coordination. (2019, June 27). Healthcare Directory Workshop—2019. Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Provider+Directory+Workshop+-+2016.*

[42] ONC Tech Lab Standards Coordination. (2019, June 27). Day 1 Agenda Presentations. Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Day+1-+Agenda-Presentations.*

[43] FAST. (2020, December 17). Proposed Solutions Working Document: Directory (V3). Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Directory%2C+Versions+and+Scale+Tiger+Team?preview=/46301216/183107855/FAST-PS-Directory%20V3_122320.docx.*

[44] Ibid.

[45] CMS. (2021, December 11). Public Reporting of Missing Digital Contact Information. Retrieved from *https://data.cms.gov/provider-compliance/public-reporting-of-missing-digital-contact-information.*

[46] FHIR endpoints are just one type of endpoint collected in NPPES and refer to a FHIR-compatible endpoint such as a FHIR URL. Other types of endpoints used by providers are not necessarily FHIR-compatible, such as a Direct address.

[47] FAST. (2020, December 17). Proposed Solutions Working Document: Directory (V3). Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Directory%2C+Versions+and+Scale+Tiger+Team?preview=/46301216/183107855/FAST-PS-Directory%20V3_122320.docx.*

[48] Ibid.

[49] Ibid.

[50] Ibid.

[51] Note, the FAST Initiative will transition from an ONC-convened initiative into an official HL7 FHIR Accelerator in 2022.

[52] CMS. (2020, May 1). 85 FR 25510, See page 25513. Retrieved from *https://www.federalregister.gov/d/2020-05050.*

[53] We note 42 CFR 431.70 as the current regulation requiring provider directory APIs.

[54] We note 42 CFR 457.760 as the current regulation requiring provider directory APIs.

[55] We note 42 CFR 438.242(b)(6) as the current regulation requiring provider directory APIs.

[56] We note 42 CFR 457.1233(d), through cross-reference to § 438.242, as the current regulation requiring provider directory APIs.

[57] While other aspects of that rule applied to issuers of QHPs on the FFEs, this requirement did not.

[58] ONC. (2020, May 1). 45 CFR 170.215. Retrieved from *https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification.*

[59] CMS. (2020, May 1). 85 FR 25510. See page 25584. Retrieved from *https://www.federalregister.gov/d/2020-05050/p-767.*

[60] CMS. (2021, December 11). Public Reporting of Missing Digital Contact Information. Retrieved from *https://data.cms.gov/provider-compliance/public-reporting-of-missing-digital-contact-information.*

[61] CMS. (2021, July 25). Public Reporting of Missing Digital Contact Information. Retrieved from *https://data.cms.gov/provider-compliance/public-reporting-of-missing-digital-contact-information.*

provisions require group health plans and health insurance issuers offering group or individual health insurance coverage to publish a provider directory and to establish a process to verify data in the directory at least every 90 days, beginning with plan years that start on or after January 1, 2022. Those directories must include names, addresses, specialty, telephone numbers, and digital contact information for healthcare providers and healthcare facilities. In addition, the CAA added a new section 2799B–9 to the PHSA, which requires each healthcare provider and healthcare facility to have in place business processes to ensure the timely provision of provider directory information to those payers.

To address part of the issue of inaccurate directory information, the CAA established consumer protections for incorrect provider directory information identifying a provider or facility as in-network for an item or service. If a patient receives provider directory information identifying a provider or healthcare facility as in-network with regard to an item or service, and receives that item or service from that provider or healthcare facility, and that provider or healthcare facility is actually out-of-network, their plan or issuer must limit cost-sharing to in-network terms that would apply to items or services that were furnished by an in-network provider or facility, and apply the deductible or out-of-pocket maximums as if the provider or facility were in-network. We note that further rulemaking is forthcoming for the provider directory requirements of that law, as discussed in the ''Requirements Related to Surprise Billing; Part I'' interim final rule (86 FR 36872).[62] [63]

In addition to these efforts, industry stakeholders have stepped in to try and fill this directory gap by developing large commercial digital endpoint directories.[64] [65] Although industry-developed directories have helped facilitate communication among users, access to their data is often fee-based, which inherently creates barriers to use and inequity for healthcare entities that do not have the resources or funds to buy access to these privately-owned endpoint directories. A free and publicly available CMS-sponsored NDH could minimize and may even eliminate this cost barrier associated with private industry created digital endpoint directories, and ensure all stakeholders have equal access to the relevant digital contact information they may need to securely exchange health data. Additionally, competing directories can lead to fragmentation and still require providers to submit similar information to multiple directories if information is not shared among directories. The FAST team concluded there should be one directory that acts as a centralized data hub to build trust, improve accuracy, and reduce the administrative burden on providers that submit data to multiple directories.[66] As discussed in section III, industry stakeholders could utilize the data contained in an NDH to populate their own directories, supplementing it with additional data that could be beneficial for end users.

The efforts noted previously have continued to drive improvements to provider directories and lead the discussion on how to improve patient access to information about healthcare services. However, the effort required to update and maintain these numerous and varied directories presents a significant burden across the healthcare industry, and we continue to see challenges with data availability and accuracy. We believe that CMS could build upon the previous work in NPPES to help address some of these challenges by streamlining our own data and making that data available in an enhanced form for public use.[67]

III. National Directory of Healthcare Providers & Services Concept and Perceived Benefits

A. National Directory of Healthcare Providers & Services Concept and Perceived Benefits

A centralized, validated NDH could help to alleviate current directory challenges by acting as a ''centralized data hub'' for healthcare directory information. By consolidating data into one source and reducing the number of places directory information must be maintained, an NDH could reduce the overall burden of keeping healthcare directory data up-to-date and accurate. For example, currently, when a provider changes their office location, that provider must update at least two separate CMS systems, NPPES and the Medicare Provider Enrollment, Chain, and Ownership System (PECOS), as well as an average of 20 separate payers' directories per physician practice.[68] With the establishment of an NDH, that provider may be able to update their information one time, through a single point of entry in an NDH, which would make that data available not only to CMS, but also publicly available for other payers and developers to utilize in their own directories. We believe that providers and their staff would be more likely to keep a single NDH updated, and verify it more frequently, thus improving accuracy within an NDH, CMS systems, and in payers' directories.

A core requirement of an NDH would be the capability to validate and verify submitted information. In the context of an NDH, validation and verification can refer to separate but related processes. First, it is important to validate that the format of submitted data meets the required standards. This could be done, for example, by checking for the existence of required data elements, that those data elements are in the appropriate format, that references to existing resources are correct, and that any codes are from appropriate value sets. Second, it is important to verify the accuracy of data against a primary source. For example, a digital endpoint could be verified by sending a secure message to that endpoint asking the provider to complete verification through some action. We do not expect that all data elements would require the same level of validation and verification. As part of initial phases of NDH planning and development, CMS would assess possible verification methods and sources. Through this RFI, we hope to receive comments on this topic that could inform that assessment.

To support the ''centralized data hub'' concept, and improve directory function, CMS seeks feedback on potentially establishing an NDH that would overlay existing CMS systems that have directory-like functions,

[62] ''Requirements Related to Surprise Billing; Part I (86 FR 36872, 36876).

[63] Interim guidance can be found at p. 7–8 of ''FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49'' at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.*

[64] CAQH. (2022). CAQH Endpoint Directory. Retrieved from *https://www.caqh.org/solutions/caqh-endpoint-directory.*

[65] GlobeNewswire. (2022, March 10). CareMESH Launches Developer Portal and APIs for its National Provider Directory. Retrieved from *https://www.globenewswire.com/news-release/2022/03/10/2401103/0/en/careMESH-Launches-Developer-Portal-and-APIs-for-its-National-Provider-Directory.html.*

[66] FHIR at Scale Taskforce (FAST). (2020, June 1 & 15). SME Session Summary Report. Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/FAST+Proposed+Solutions+-+Subject+Matter+Expert+%28SME%29+Panel+Sessions?preview=/149848177/181174490/FAST-Directory%20SME%20Session%20Summary%20Report.pdf.*

[67] CMS. (2022, February 11). OBRHI FAQs. Retrieved from *https://www.cms.gov/about-cms/obrhi/faqs#:~:text=Digital%20contact%20information%2C%20also%20known,trusted%20recipients%20over%20the%20internet.*

[68] CAQH. (2019, November 13). CAQH Survey: Maintaining Provider Directories Costs US Physician Practices 2.76 Billion Annually. Retrieved from *https://www.caqh.org/about/press-release/caqh-survey-maintaining-provider-directories-costs-us-physician-practices-276.*

consolidate the data within them, and provide a single point of entry for providers to streamline workflows. We also believe that CMS could reduce the burden on providers and payers by building this directory using the most up-to-date technology, leveraging FHIR APIs. FHIR APIs would allow external stakeholders to pull data from an NDH to use as a data source for their own directories, thus avoiding duplicative data collection efforts. We note that in this use case example, the payers pulling provider data from an NDH would be responsible for verifying their own list of network providers.

Using a FHIR API, stakeholders could access and use NDH data to support a variety of use cases. Industry would be able to transform the data for purposes beyond what a public-facing CMS portal would be able to provide, and present it in a customized format for consumers, commercial, or operational use. We envision the following as other potential use cases for a FHIR API-enabled NDH:

- A patient or consumer could use an NDH directly, or through an app of their choosing that connects to an NDH via a FHIR API, to locate a provider.
- To support interoperability, a provider could connect to an NDH through the FHIR API to request the digital endpoint a particular payer uses to receive prior authorization requests. Once returned by an NDH, the provider's electronic health record (EHR) or practice management system could use that digital contact information to direct a prior authorization request to the appropriate payer.
- A payer (such as an MA organization, a private insurer, or state Medicaid agency) could use an NDH, via a FHIR API, to update its own provider directory with the latest information. This would allow the payer to present a provider directory without having to bear the burden of collecting data that is already available through an NDH from individual providers. The providers would also experience less burden because they would only need to update data in an NDH, and not multiple payer-specific directories. We note that payers would still be required to verify the accuracy of their network information to ensure that the provider directory is accurate.

We recognize that widespread adoption of, and trust in, an NDH would be necessary to fulfill this role as a ''centralized data hub'' for directory data. Without up-to-date, useful, and comprehensive directory data, an NDH would not be able to address existing healthcare directory challenges. We seek feedback on both positive and negative incentives that could be put into place to encourage widespread NDH use. These incentives may be for providers to update and maintain data and/or for payers to use the data from an NDH rather than requiring duplicative submissions from providers. We want to understand what incentives, programs, or policies might promote timely and accurate data reporting, as well as robust NDH usage by stakeholders.

We note that we previously requested comments, summarized in the 2020 CMS Interoperability and Patient Access final rule,[69] regarding policies that we could implement to encourage providers to update their digital contact information in NPPES. Several commenters suggested incorporating a requirement to have up-to-date digital contact information in NPPES into the Merit-based Incentive Payment System (MIPS) program. We acknowledge a logical relationship with the Promoting Interoperability category of MIPS and continue to explore that avenue. However, we also realize the limitations of that possibility, as only certain types of clinicians who see Medicare patients are eligible to participate in MIPS and many Medicare providers participate in alternative programs.

We understand that it would be critical to allow listed entities, particularly providers, to delegate or authorize other individuals, either in their organization or intermediary organizations, to submit directory data on their behalf to reduce burden and ensure that data submission is feasible, timely, and accurate. We are using the term ''listed entities'' to refer to individuals and groups whose data could be available in an NDH. We want to understand current industry best practices for delegating authority and aspects of this functionality that could be used with an NDH.

B. Interactions With Current CMS Data Systems and Impacts to Business Processes

Integrating an NDH with current CMS-maintained systems, such as NPPES, PECOS, and Care Compare, could streamline data collection by acting as the single entry-point for listed entities to update their data across multiple CMS systems. Such data interactions could address provider data accuracy and consistency issues among CMS systems.[70]

Examples of existing CMS data collection and reporting systems that an NDH could interface with to streamline data processes include:

- NPPES: Developed to assign NPIs to healthcare providers.[71] Once an NPI is assigned, CMS, through NPPES, publishes the parts of the NPI record that have public relevance, including the provider's name, location, phone number, gender, specialty (taxonomy), practice address, and other identifiers for public use.[72] Authorized under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (section 1173(b) of the Act and at 45 CFR 160.103, 162.402, and 162.408 of the regulations).
- PECOS: Supports the Medicare provider and supplier enrollment process. Registered providers and suppliers use PECOS to securely submit and manage their Medicare enrollment and revalidation processes. This system and its information attestation workflows are integral to program integrity prevention, investigation, and enforcement activities. We note that PECOS data are not publicly available. Rather, the system only contains information on Medicare providers and suppliers, and updates are limited by Medicare enrollment requirements. Authorized under sections 1102(a), 1128, 1814(a), 1815(a), 1833(e), 1871, and 1886(d)(5)(F) of the Act; 1842(r); section 1124(a)(1), and 1124A, section 4313, as amended, of the BBA of 1997; and section 31001(I) (31 U.S.C. 7701) of the Debt Collection Improvement Act of 1996 (DCIA) (Pub. L. 104–134), as amended.
- Medicare Care Compare: Public, consumer-facing directory containing contact and quality information on certain types of Medicare providers, suppliers, and provider organizations, including doctors, clinicians, hospitals, nursing homes, home health and hospice care, inpatient rehabilitation facilities, long-term care hospitals, and dialysis facilities. Care Compare data are populated from several data sources, including PECOS, NPPES and CMS quality reporting programs. Care Compare allows for comparison of Medicare providers and suppliers. We are authorized to collect and publicly report the following:

++ Certain physician quality data, in part, by section 10331(a)(1) of the Affordable Care Act, section 104(e) of the Medicare Access and CHIP

[69] CMS. (2020, May 1). 85 FR 25510. See pages 25581–84. Retrieved from *https://www.federalregister.gov/d/2020-05050.*

[70] Levinson, D. R. (2013, May). Improvements Needed to Ensure Provider Enumeration and Medicare Enrollment Data are Accurate, Complete, and Consistent. Retrieved from *https://oig.hhs.gov/oei/reports/oei-07-09-00440.pdf.*

[71] CMS. NPPES. Retrieved from *https://nppes.cms.hhs.gov/#/.*

[72] CMS. NPPES NPI Registry. Retrieved from *https://npiregistry.cms.hhs.gov/.*

Reauthorization Act of 2015 (MACRA) and section 1848 of the Act.

++ Certain hospital quality data under section 501(b) of MMA of 2003 and section 5001(a) of the Deficit Reduction Act of 2005 and section 1886 of the Act.

++ Certain hospice quality data under section 3004 of the Affordable Care Act and section 1814 of the Act.

++ Certain long-term care hospital quality data under section 3004 of the Affordable Care Act and section 1886(m)(5) of the Act.

++ Certain inpatient rehabilitation facility quality data under section 3004 of the Affordable Care Act and section 1886(j)(7) of the Act.

++ Certain home health quality data under section 1895(b)(3)(B)(v) of the Act.

++ Certain dialysis facility quality data under section 1881 of the Act and required by 42 CFR 405.2100 through 405.2171 (now at 42 CFR 414.330, 488.60, and 494.100 through 494.180).

++ Certain skilled nursing home quality data under section 1888(e)(6) of the Act, modified under the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014.

We note that we are not specifically requesting comment on replacing any of these or other CMS systems with an NDH. Rather, we believe that an NDH could be a tool that works in combination with these systems to streamline and improve the processes for collecting, maintaining, and presenting information in a more user-friendly manner. As discussed earlier, we envision that an NDH would create efficiencies by serving as a ''centralized data hub'' that would feed data to these other systems to use within their intended functions. An NDH built with modern data exchange capabilities, such as APIs, could share data with other CMS systems in real-time, improving data accuracy across CMS while eliminating the need for stakeholders to update information in multiple places.

Within these systems, CMS collects various demographic, contact, and healthcare practice data from or about many provider types and payer entities. These systems, in combination with other data systems that CMS maintains, have been established over time to perform their specific roles and in total contain a significant breadth of provider and payer data. By strengthening current efforts to streamline data processes, CMS could further improve the value and usability of its data. For example, linking provider contact information and quality data into one streamlined CMS resource could help consumers identify, compare, and locate providers who meet their specific needs and preferences. We also note that linking this information may be valuable for providers and payers participating in value-based payment models. We seek feedback on how we could combine these datasets into a single interface to be able to display more complex information, such as a clinician's relationship with hospitals or nursing facilities. This data aggregation may better support patients when choosing a healthcare facility or help providers locate one another for improved data exchange and care coordination.

We have increasingly emphasized improving the interoperability of data collected across our systems. As we have discussed, we believe existing directory-like information within CMS' systems could benefit from the operational efficiencies and streamlined effort of an NDH. We seek comment, prompted by the questions below, on various aspects that we should consider as we evaluate the feasibility, scope, and functionality of an NDH.

C. Comment Solicitation

We solicit comments on the following topics related to the establishment of an NDH:

- What benefits and challenges might arise while integrating data from CMS systems (such as NPPES, PECOS, and Medicare Care Compare) into an NDH? What data elements from each of these systems would be important to include in an NDH versus only being available directly from the system in question?
- Are there other CMS, HHS (for example, HPMS, Title X family planning clinic locator, ACL's Eldercare Resource Locator, SAMHSA's Behavioral Health Resource Locator, HRSA's National Practitioner Data Bank, or HRSA's Get Health Care), or federal systems with which an NDH could or should interface to exchange directory data?

++ What are these systems, how should an NDH interact with these systems, and for what purpose?

++ What data elements from each of these systems would be important to include in an NDH?

- Are there systems at the state or local level that would be beneficial for an NDH to interact with, such as those for licensing, credentialing, Medicaid provider enrollment, emergency response (for example, the Patient Unified Lookup System for Emergencies (PULSE) [73]) or public health?

++ What data elements would be beneficial to include in an NDH for interaction with state or local systems, including State-based Exchanges or existing state-level provider directories?

- Added by the Cures Act, Section 3001(c)(9)(D)(i) of the PHSA requires ONC to create, annually update, and publish on its website a ''list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement.'' Are there beneficial ways an NDH could interface with such a list or provide additional information that may be useful, such as a directory of services? Are there use cases for integrating such health information network data in an NDH?
- What types of data should be publicly accessible from an NDH (either from a consumer-facing CMS website or via an API) and what types of data would be helpful for CMS to collect for only internal use (such as for program integrity purposes or for provider privacy)?
- Are there particular data elements that CMS currently collects or should collect as part of an NDH that we should not make publicly available, regardless of usefulness to consumers, due to its proprietary nature? To the extent that an NDH might collect proprietary data from various entities, what privacy protections should be in place for these data?
- We want an NDH to support health equity goals throughout the healthcare system. What listed entities, data elements, or NDH functionalities would help underserved populations receive healthcare services? What considerations would be relevant to address equity issues during the planning, development, or implementation of an NDH?
- How could NDH use within the healthcare industry be incentivized? How could CMS incentivize other organizations, such as payers, health systems, and public health entities to engage with an NDH?
- How could CMS evaluate whether an NDH achieves the targeted outcomes for its end users (for example, that it saves providers time or that it simplifies patients' ability to find care)? We solicit comments on an NDH concept and high-level functionality:
- Would an NDH as described provide the benefits outlined previously?
- Would an NDH as described reduce the directory data submission burden on providers?

[73] ONC. (2022, March 4). Patient Unified Lookup System for Emergencies (PULSE). Retrieved from *https://www.healthit.gov/topic/health-it-health-care-settings/public-health/patient-unified-lookup-system-for-emergencies-pulse.*

• How could a centralized source for digital contact information benefit providers, payers, and other stakeholders?

• We have heard interest in including additional healthcare-related entities and provider types beyond physicians in an NDH-type directory beyond those providers included in current CMS systems or typical payers' directories? For example, should an NDH include allied health professionals, post-acute care providers, dentists, emergency medical services, nurse practitioners, physician assistants, certified nurse midwives, providers of dental, vision, and hearing care, behavioral health providers (psychiatrists, clinical psychologists, licensed professional counselors, licensed clinical social workers, etc.), suppliers, pharmacies, public health entities, community organizations, nursing facilities, suppliers of durable medical equipment or health information networks? We specifically request comment on entities that may not currently be included in CMS systems.

++ For what use cases should these various entities be included?

• Are there NDH use cases to address social drivers and/or determinants of health? If so, what are they? Are there other entities, relationships, or data elements that would be helpful to include in an NDH to help address the social drivers and/or determinants of health (for example, community-based organizations that provide housing-related services and supports, non-medical transportation, home-delivered meals, educational services, employment, community integration and social supports, or case management)? What types of entities or data elements relating to social drivers and/or determinants of health should not be included in an NDH?

• What provider or entity data elements would be helpful to include in an NDH for use cases relating to patient access and consumer choice (for example, finding providers or comparing networks)?

++ What data elements would be useful to include in an NDH to help patients locate providers who meet their specific needs and preferences?

++ Would it be helpful to include data elements such as provider languages spoken other than English, specific office accessibility features for patients with disabilities and/or limited mobility, accessible examination or medical diagnostic equipment, or a provider's cultural competencies, such as the National Committee for Quality Assurance's Health Equity accreditation (though we note that these data elements may be difficult to verify in some cases)?

• What provider or entity data elements would be helpful to include in an NDH for use cases relating to care coordination and essential business transactions (for example, prior authorization requests, referrals, public health reporting)?

++ What specific health information exchange or use cases would be important for an NDH to support?

++ Are there other types of data transactions or use cases beyond those already discussed that would be helpful for an NDH to support?

++ Are there additional data elements beyond those already discussed that would be useful for these use cases?

++ Beyond using FHIR APIs, what strategic approaches should be taken to ensure that directory data are interoperable?

• The COVID–19 pandemic has highlighted a need for public health systems to be better connected to providers and with each other. Would there be benefits to including public health entities in an NDH?

++ What public health use cases would it be helpful for an NDH to support (for example, facilitating digital contact endpoint discovery for public health reporting, or to provide additional data for public health entities' analytics)?

++ What data elements would be useful to collect from these entities to advance public health goals?

• Understanding that individuals often move between public and commercial health insurance coverage, what strategies could CMS pursue to ensure that an NDH is comprehensive both nationwide and market-wide?

++ Are there specific strategies, technical solutions, or policies CMS could pursue to encourage participation in an NDH by group health plans and health insurance issuers offering group or individual health insurance coverage for programs or product lines not currently under CMS' purview?

• Are there use cases for which it would be helpful for an NDH to support state and local governments? For example, are there specific types of providers, data elements, or technical requirements that would allow for infrastructure planning support, resource allocation, policy analysis, research, evaluation, emergency preparedness and response (such as PULSE), care coordination, planning, establishing partnerships, and determining service gaps?

++ How should CMS work with states to align federal and state policies to allow all parties to effectively use an NDH?

• Are there use cases for which an NDH could be used to help prevent fraud, waste, abuse, improper payments, or privacy breaches? Conversely, are there any concerns that an NDH, as described, could increase the possibility of those outcomes, and, if so, what actions could be taken to mitigate that risk?

• What specific functionality or use cases, including any not discussed here, would it be helpful for CMS to consider developing within an NDH? What types of data elements would need to be included (or excluded) to support these use cases (for example, licensing, certification, and credentialing)?

• Beyond identifying providers associated with specific organizations, and organizations that may be under the umbrella of a single health system, what other relationships would be important to capture and why?

• We have received feedback that individual providers may not use their individual digital endpoints in many cases where the communications involve patients receiving institutional care. How can we associate group- or practice-level digital contact information with appropriate providers to ensure that data get to the right place?

• What types of entities should be encouraged to use data from an NDH? For what purposes and why?

• What are some of the functions or features of current provider directories that work particularly well?

• What are some of the lessons learned or mistakes to avoid from current provider directories of which we should be aware?

We solicit comments on key considerations related to data submission and maintenance for potential NDH development:

• What policy or operational factors should be considered for new data collection interfaces as part of a single point of entry?

• How can data be collected, updated, verified, and maintained without creating or increasing burden on providers and others who could contribute data to an NDH, especially for under-resourced or understaffed facilities?

• What are barriers to updating directory data in current systems that could be addressed with an NDH?

• What are current and potential best practices regarding the frequency of directory data updates?

• What specific strategies, technical solutions, or policies could CMS implement to facilitate timely and accurate directory data updates? How

could consistent and accurate NDH data submission be incentivized within the healthcare industry?

- How should duplicate information or conflicting information reported from different sources be resolved to balance the reporting burden versus confidence in data accuracy?
- The Healthcare Directory initiative and FAST both identified validation and verification as important functions of a centralized directory. What data types or data sources are important to verify (for example, provider endpoint information, provider credentialing) versus relying on self-reported information? Are there specific recommendations for verifying specific data elements?
- What use cases would benefit from data being verified and what sort of assurances would be necessary for trust and reliance on those data?
- Are there use cases where an NDH could provide data that has already been verified to reduce that burden on payers or other entities and, if so, how could that be achieved?
- What concerns might listed entities have about submitting data to an NDH? We solicit comments on provider delegation of authority to submit data on a provider's behalf:
- Outside of CMS, what mechanisms, standards, or processes are currently used to enable provider delegation of authority to submit data?
- What challenges, if any, occur in the processes for delegating authority to submit data on behalf of providers or in the processes for submitting directory data on behalf of providers?
- What specific strategies, technical solutions, or policies could be implemented to enable delegation of authority to submit data to an NDH?
- Should CMS consider including role-based access management to submit provider data to an NDH, and, if so, what kind of role-based access management?
- Are there entities that currently exist that would be helpful to serve as intermediaries for bulk data verification and upload or submission to an NDH? If so, are there existing models that demonstrate how this can be done (for instance, the verifications performed through the Federal Data Services Hub)?
- How do intermediaries currently perform bulk data verification and upload or submission to provider directories?

IV. Technical Framework for an NDH

A. Overview

The technical approach to establishing an NDH could leverage the extensive work the federal government has already done, in collaboration with industry stakeholders and standards development organizations, to develop healthcare directory information exchange standards. CMS could build on existing work to develop FHIR-based standards for healthcare directories. For years, ONC has collaborated with HL7, an ANSI-accredited standards development organization, to support the scalability and industry adoption of FHIR standards for use in a healthcare directory.[74] [75] Through an industry-led and consensus-based workgroup process, HL7 publishes various technical architecture standards, known as Implementation Guides (IGs). In 2016, HL7, in cooperation with the ONC and FHA Healthcare Directory initiative, developed and published the Validated Healthcare Directory (VHDir) IG. The VHDir IG was developed to describe the technical design considerations for collecting, validating, verifying, and exchanging data from a healthcare directory. The IG also provides technical guidance for a FHIR API for accessing data from a validated healthcare directory and could be used, for example, for provider credentialing and privileging.[76] [77] Building on this initial work, FAST has collaborated with HL7's Patient Administration Work Group to develop and maintain new FHIR IGs to further describe data attestation and verification processes, as well as a standard API for local directories to make verified data available to stakeholders: the National Directory Endpoint Query IG, the National Directory Exchange IG, and the National Directory Attestation and Validation IG.[78]

Additionally, CMS could build on work done by FAST. FAST identified numerous technical challenges associated with directories, particularly related to digital contact information, and conducted research, stakeholder engagement, and key technical development activities to establish the framework and capabilities needed for a scalable NDH.[79] [80] In their proposed directory technical solutions document, FAST also identified CMS as the appropriate potential maintainer of an NDH.[81]

Given these existing efforts to establish FHIR-based standards for healthcare directory information exchange, CMS could leverage this work to serve as the technical foundation on which to develop a FHIR API-enabled NDH. Additionally, using FHIR standards would help align an NDH with the technical standards at 45 CFR 170.215 finalized by ONC in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (85 FR 25642).

B. Comment Solicitation

We are soliciting comments on technical considerations for a potential NDH:

- In addition to FHIR, what technical standards are currently used or show promise to exchange directory data?
- What technical standards should an NDH support?
- What work related to developing FHIR standards for an NDH, such as building and refining IGs, still needs to be completed?
- How could CMS and ONC ensure that an NDH improves interoperability by promoting the adoption of TEFCA and supporting participating health information networks and healthcare entities? What are key opportunities for an NDH and TEFCA to work together in a mutually beneficial fashion?
- Are there use cases for providers accessing an NDH through their EHRs and, if so, what are the technical requirements?
- Are there use cases for individuals accessing an NDH through a patient-facing health app and, if so, what are the technical requirements?
- What security standards should be used to support an NDH?
- How should authentication and access to an NDH be managed for data

[74] ONC. (2021, April). What is HL7 FHIR? Retrieved from *https://www.healthit.gov/topic/standards-technology/standards/fhir-fact-sheets.*

[75] Hadassah, G. & Marcelonis, D. (2022, May 20). National Healthcare Directory. Retrieved from *https://confluence.hl7.org/display/PA/National+Healthcare+Directory.*

[76] ONC Tech Lab Standards Coordination. (2019, June 25). Healthcare Directory. Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Healthcare+Directory.*

[77] HL7. (2022). Validated Healthcare Directory. Retrieved from *http://build.fhir.org/ig/HL7/VhDir/index.html.*

[78] Hadassah, G. & Marcelonis, D. (2022, May 20). National Healthcare Directory. Retrieved from *https://confluence.hl7.org/display/PA/National+Healthcare+Directory.*

[79] FAST. (2020, December 17). Proposed Solutions Working Document: Directory (V3). Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Directory%2C+Versions+and+Scale+Tiger+Team?preview=/46301216/183107855/FAST-PS-Directory%20V3_122320.docx.*

[80] ONC Tech Lab Standards Coordination. (2022, April 1). FHIR at Scale Taskforce (FAST). Retrieved from *https://oncprojectracking.healthit.gov/wiki/pages/viewpage.action?pageId=43614268.*

[81] FAST. (2020, December 17). Proposed Solutions Working Document: Directory (V3). Page 13. Retrieved from *https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Directory%2C+Versions+and+Scale+Tiger+Team?preview=/46301216/183107855/FAST-PS-Directory%20V3_122320.docx.*

submission? Should authentication and access processes vary based on the type of data being submitted, and if so, how?

- What other technical considerations should CMS be aware of?

V. Phased Approach to Implementation

A. Overview

The primary goal of an NDH would be to serve as a ''centralized data hub'' for accurate directory information in the healthcare market. To achieve that goal, CMS is seeking comments on a potential phased approach to establishing an NDH, in alignment with IT industry best practices. We would assess our statutory authorities to establish an NDH and take appropriate action. The initial phases of implementation would focus on consolidating and verifying existing data, building trust, and gaining industry buy-in. Subsequent phases would build on that foundation by incorporating additional data elements, listed entity types, and functionality while maintaining trust in the integrity of the system and data. This phased approach would allow CMS to gather consumer and industry input while focusing on scalability, data validity and governance, ethics, and equity for needed agency action or NDH development.

B. Comment Solicitation

We are soliciting comments on the feasibility of a phased approach to implementation and potential opportunities to build stakeholder trust and adoption along the way:

- What entities or stakeholders should participate in the development of an NDH, and what involvement should they have?
- What stakeholders could have valuable feedback in the scoping and early implementation processes to ensure viability of an NDH and sufficient uptake across the healthcare industry?
- What functionality would constitute a minimum viable product?
- What specific strategies, technical solutions, or policies could CMS employ to best engage stakeholders and build trust throughout the development process?
- What use cases should be prioritized in a phased development and implementation process for immediate impact and burden reduction?
- What types of entities and data categories should be prioritized in a phased development and implementation process for immediate impact and burden reduction?
- How could human-centered design, including equity-centered design, principles be used to optimize the usability of an NDH?
- What issues should CMS anticipate throughout an NDH system development life cycle?

++ Development (for example: timelines, technologies).

++ Implementation (for example: phased roll out, obtaining buy-in).

++ Operations (for example: updating content, access, and security).

++ Maintenance (for example: updating technologies, ensuring data accuracy).

VI. Prerequisites and CMS Actions To Address Challenges and Risks

A. Overview

We are aware of the many prerequisites, risks, and challenges associated with the implementation of such a directory and would consider these throughout the development process. As noted previously, the federal government has led numerous technical efforts that would help inform the planning and development of an NDH. Challenges associated with establishing an NDH include, but are not limited to, project planning and scoping, stakeholder and collaborator engagement, development risks, use of existing identifiers (for example, NPI or TIN), data publication, system maintenance, and stakeholder adoption.

B. Comment Solicitation

We are soliciting comments on risks, challenges, and prerequisites associated with implementing such a directory:

- What technical or policy prerequisites would need to be met prior to developing an NDH?
- What specific risks or challenges should be anticipated throughout the system development life cycle of an NDH? How can these risks and challenges be minimized?
- What are the most promising efforts that exist to date in resolving healthcare directory challenges? How could CMS best incorporate outputs from these efforts into the requirements for an NDH? Which gaps remain that are not being addressed by existing efforts?

VII. Information Collection Requirements

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 28, 2022.

Dated: October 3, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–21904 Filed 10–5–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Procedures for Clinical Laboratory Improvement Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 7, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0607. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988

OMB Control Number 0910–0607—Revision

This information collection helps support implementation of statutory provisions applicable to laboratories that conduct testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These requirements are codified in 42 U.S.C. 263a and implementing regulations are found in 42 CFR 493. Regulations in 42 CFR 493.17 set forth certain notice requirements and establish test categorization criteria with regard to laboratory tests and are implemented by FDA's Center for Devices and Radiological Health. The guidance document entitled ''Administrative Procedures for CLIA Categorization'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/administrative-procedures-clia-categorization*) describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or premarket approval application. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (*e.g.,* name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

We are revising the information collection to include provisions associated with certificates of waiver. On February 26, 2020, FDA revised the guidance document entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and FDA Staff'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-clinical-laboratory-improvement-amendments-1988-clia-waiver-applications*). This guidance describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it ''simple''; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results.

In the **Federal Register** of June 16, 2022 (87 FR 36330), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA categorization (see 42 CFR 493.17)	80	5	400	1	400	$2,000
CLIA Waiver Application Submissions	13	1	13	1,200	15,600	$350,000
Total						$352,000

[1] There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Information collection activity	Number of Record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CLIA Waiver Recordkeeping as discussed in FDA Guidance	13	1	13	2,800	36,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have revised the information collection to include coverage previously accounted for under OMB control number 0910–0598 and discussed in revised Agency guidance. We otherwise retain our estimates of the burden we attribute to the individual elements included in the information collection.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21843 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0514 and FDA–2005–D–0027]

Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff; and Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of the final guidance documents entitled ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' and ''Procedures for Handling Post-Approval Studies Imposed by PMA [Premarket Approval Application] Order.'' These guidance documents are intended to facilitate and set expectations for timely initiation and completion of certain studies fulfilling postmarket surveillance requirements and of Post-Approval Studies (PAS), respectively. Additionally, these guidance documents are intended to increase transparency to stakeholders on FDA's approach to the issuance and tracking of postmarket surveillance orders and of PAS requirements. The final guidance ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' is intended to update and replace the guidance issued in May 2016; the final guidance ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' is intended to update and replace the guidance issued in June 2009.

DATES: The announcement of the guidance is published in the **Federal Register** on October 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–2011–D–0514 for ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' or Docket No. FDA–2005–D–0027 for ''Procedures for Handling Post-Approval Studies Imposed by PMA Order.'' 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 § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Electronic copies of the guidance documents are available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' or ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Megha Reddy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 240–402–2980.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' is intended to assist manufacturers of devices subject to section 522 orders, by providing:

- an overview of section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l),
- information on how to fulfill section 522 obligations, and
- recommendations on the format, content, and review of postmarket surveillance plan and report submissions.

The guidance ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' is intended to assist stakeholders with understanding PAS requirements imposed as a condition of PMA approval by providing:

- procedural information,
- recommendations concerning the format, content, and review of PAS-related submissions,
- recommendations to help facilitate FDA's review of a PAS protocol in a timely manner,
- recommendations for study timelines including enrollment milestones and study completion,
- revised definitions to PAS status categories that we believe better reflect progress of the PAS, and
- revised FDA review time goals for PAS-related submissions.

The primary changes for the guidance ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' from the 2016 version of this guidance document include: (1) clarification on when postmarket surveillance is considered commenced, (2) recommendations for achieving an approved postmarket surveillance plan in a timely manner, (3) recommendations for postmarket surveillance completion timelines, (4) updated surveillance status categories to better reflect progress, (5) revised FDA's review times for postmarket surveillance related submissions, and (6) updated FDA points of contact and organizational structure.

A notice of availability of the draft guidance ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' appeared in the **Federal Register** of May 27, 2021 (86 FR 28602). FDA considered comments received and revised this guidance as appropriate in response to the comments, including (1) by providing additional clarification on information to be included in postmarket surveillance plans, enrollment reports, interim reports, and final reports; (2) additional clarification on how changes to an approved postmarket surveillance plan should be made by the companies and reviewed by the FDA; and (3) additional clarification on information to be posted on FDA's 522 web page.

A notice of availability of the draft guidance ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' appeared in the **Federal Register** of May 27, 2021 (86 FR 28630). FDA considered comments received and revised this guidance as appropriate in response to the comments, including: (1) by providing additional clarification on information to be included in PAS protocols, enrollment reports, interim PAS reports, and final PAS reports; (2) additional clarification on how changes to an approved PAS protocol should be made by the sponsors and reviewed by the FDA; (3) additional clarification on using alternative study designs such as Real-World Data; and (4) one revised definition of PAS status.

These guidance documents are being issued consistent with FDA's good guidance practices regulation (§ 10.115). These guidance documents represent the current thinking of FDA on ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act,'' and ''Procedures for Handling Post-Approval Studies Imposed by PMA Order,'' respectively. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* These guidance documents are also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of either ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act (document number 19042)'' or ''Procedures for Handling Post-Approval Studies Imposed by PMA Order (document number 1043)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidance documents contain no new collection of information, they do 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 these guidance documents. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
822	Postmarket Surveillance of Medical Devices	0910–0449
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Device; Humanitarian Device Exemption	0910–0332
860, subpart D	De Novo classification process	0910–0844
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program".	Q-submissions; Presubmissions	0910–0756

Dated: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21832 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0576]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational Device Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 7, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0078. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Investigational Device Exemptions—21 CFR Part 812

OMB Control Number 0910–0078—Extension

This information collection supports implementation of section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), which governs exemption for devices for investigational use. An investigational device exemption (IDE) allows a device to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. For more information regarding IDE, please visit our website at *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide.*

FDA has promulgated regulations in part 812 (21 CFR part 812) intended to encourage the discovery and development of useful devices intended for human use. The regulations set forth the scope and applicability of exemption requirements for devices for investigational use, as well as establish application procedures, corresponding instruction, and provisions for emergency research. The regulations also provide for requesting waivers from the requirements and explain sponsor responsibilities, including requirements for institutional review board (IRB) review and approval. Finally, the regulations in part 812, subpart G (21 CFR 812.140, 812.145, and 812.150) provide for required recordkeeping, the inspection of records, and the preparation and submission of reports to FDA and/or IRBs that oversee medical device investigations.

In the **Federal Register** of May 6, 2022 (87 FR 27168), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
812.10; waivers	1	1	1	1	1
812.20, 812.25, and 812.27; applications, investigational plans, and supplements	229	1	229	80	18,320
812.27(b)(4)(i); prior investigations within the United States	400	1	400	1	400
812.27(b)(4)(ii); prior investigations outside the United States	100	1	100	0.25 (15 minutes)	25
812.28; acceptance of data from clinical investigations conducted outside the United States, and supporting information	1,500	1	1,500	10.25	15,375
812.28(c); waivers	10	1	10	1	10
812.35 and 812.150; application supplements	654	5	3,270	6	19,620
812.36(c); treatment IDE applications	1	1	1	120	120

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
812.36(f); treatment IDE reports	1	1	1	20	20
812.150; non-significant risk study reports	1	1	1	6	6
Total			5,513		53,897

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate of the average reporting burden is based on our continued experience with the information collection. We have adjusted the currently approved burden to reflect an increase we attribute to Agency rulemaking that has become effective (OMB control number 0910–AG48) since our last evaluation. Regulations in part 812 were amended to provide for reporting associated with the acceptance of data from clinical investigations conducted outside the United States.

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
812.2(c)(3); records regarding leftover specimens not individually identifiable used in certain studies	700	1	700	4	2,800
812.28(d); records for clinical investigations conducted outside United States	1,500	1	1,500	1	1,500
812.140; retention of records	1,249	3.09	3,865	1.9937	7,706
Total					12,006

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the guidance document ''Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' (April 2006), available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-informed-consent-vitro-diagnostic-device-studies-using-leftover-human-specimens-are-not,* FDA communicates its enforcement policy with regard to the informed consent regulations (as required by section 520(g) of the FD&C Act and 21 CFR part 50) for in vitro diagnostic device studies that are conducted using leftover specimens and that meet the criteria for exemption from IDE regulation at 21 CFR 812.2(c)(3). We include burden that may be attributable to FDA recommendations that sponsors of studies document certain information, in table 2, row 1. We have otherwise adjusted our estimate upward of the average recordkeeping burden attributable to provisions in part 812 to reflect those requirements associated with clinical investigations conducted outside the United States, and in recognition of the required retention period for records.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21852 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2352]

Biosimilar User Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2023. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application. BsUFA III directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year. These fees apply to the period from October 1, 2022, through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD, 301–796–7223, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA III, authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 7 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial

BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, the sponsor discontinues participation in FDA's BPD program for the product, or the sponsor has been administratively removed from the BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program or has been administratively removed from the BPD program for a product and wants to reengage with FDA on development of the product, the sponsor must pay all annual BPD fees previously assessed for such product and still owed, and a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: (1) no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or (2) upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA III also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver from its first biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA III. For FY 2023, the base revenue amount is the FY 2022 total revenue amount minus the operating reserve adjustment, which equates to the amount of $43,376,922. The FY 2023 base revenue amount is to be adjusted by the inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment (CPA), operating reserve adjustment, and the additional dollar amount. Each of these adjustments will be discussed in the sections below.

This document provides fee rates for FY 2023 for the initial and annual BPD fee ($47,325), for the reactivation fee ($94,650), for an application requiring clinical data ($1,746,745), for an application not requiring clinical data ($873,373), and for the program fee ($304,162). These fees are effective on October 1, 2022, and will remain in effect through September 30, 2023. For applications that are submitted on or after October 1, 2023, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2023

The base revenue amount for FY 2023 is $43,376,922 prior to adjustments for inflation, strategic hiring and retention, capacity planning, operating reserves, and the additional dollar amount (see section 744H(b)–(c) of the FD&C Act).

A. FY 2023 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the $43,376,922 is to be adjusted for inflation increases for FY 2023 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744H(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) positions at FDA for the first 3 of the preceding 4 fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent changes from the previous fiscal years and the average percent changes over the first 3 of the 4 fiscal years preceding FY 2023. The 3-year average is 1.3918 percent.

Table 1.--FDA PC&B Each Year and Percent Changes

	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$2,620,052,000	$2,875,592,000	$3,039,513,000	
Total FTE	$17,144	$17,535	$18,501	
PC&B per FTE	$152,826	$163,992	$164,289	
Percent Change From Previous Year	-3.3120%	7.3063%	0.1811%	1.3918%

The statute specifies that this 1.3918 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of biosimilar biological product applications. Table 2 shows the PC&B and the total obligations for the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 fiscal years.

Table 2.--PC&B as a Percent of Total Cost of the Process for the Review of Biosimilar Biological Product Applications

	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$32,946,252	$25,445,175	$30,932,267	
Total Costs	$65,210,467	$56,798,694	$55,928,075	
PC&B Percent	50.5230%	44.7989%	55.3072%	50.2097%

The payroll adjustment is 1.3918 percent from table 1 multiplied by 50.2097 percent (or 0.6988 percent).

The statute specifies that the portion of the inflation adjustment for nonpayroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; not seasonally adjusted; all items; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of biosimilar biological product applications for the first 3 years of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.[1]

Table 3.--Annual and 3-Year Average Percent Change in CPI for Washington-Arlington-Alexandria Area

	2019	2020	2021	3-Year Average
Annual CPI	264.78	267.16	277.73	
Annual Percent Change	1.2745%	0.8989%	3.9568%	2.0434%

The statute specifies that this 2.0434 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of biosimilar biological product applications obligated. Since 50.2097 percent was obligated for PC&B (as shown in table 2), 49.7903 percent is the portion of costs other than PC&B (100 percent minus 50.2097 percent equals 49.7903 percent). The non-payroll adjustment is 2.0434 percent times 49.7903 percent, 1.0174 percent.

Next, we add the payroll adjustment (0.6988 percent) to the nonpayroll adjustment (1.0174 percent), for a total inflation adjustment of 1.7162 percent (rounded) for FY 2023.

We then multiply the base revenue amount for FY 2023 ($43,376,922) by the inflation adjustment percentage (1.7162 percent), yielding an inflation adjustment of $744,435. Adding this amount yields an inflation-adjusted amount of $44,121,357.

B. Strategic Hiring and Retention Adjustment

The statute specifies that for each fiscal year, after the annual base revenue is adjusted for inflation, FDA shall further increase the fee revenue and fees by the strategic hiring and retention adjustment, which is $150,000 for FY 2023 (see section 744H(c)(2) of the FD&C Act).

C. FY 2023 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that the fee revenue and fees shall be further adjusted to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications (see section 744H(c)(3) of the FD&C Act). Following a process required in statute, FDA established the capacity planning adjustment methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** at 85 FR 47220. This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time.

Beginning in FY 2023, updates were made to refine the time reporting categories included within the CPA. As such, time reporting data and baseline capacity have been revised to match the refinements; in the coming fiscal years, additional updates are anticipated to be made to account for additional activities that are also directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types and the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products.

The CPA methodology consists of four steps:

1. Forecast workload volumes: predictive models estimate the volume of workload for the upcoming fiscal year.

2. Forecast the resource needs: forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs[2] for direct review-related effort. This is then compared to current available resources for the direct review-related workload.

3. Assess the resource forecast in the context of additional internal factors: program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the fiscal year and those funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

4. Convert the FTE need to dollars: utilizing FDA's fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount.

The following section outlines the major components of the FY 2023 BsUFA III CPA. Table 4 summarizes the forecasted workload volumes for BsUFA III in FY 2023 based on predictive models, as well as historical actuals from FY 2021 for comparison.

[1] The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0, CUUSS35ASA0.*

[2] Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

Table 4.--BsUFA III Actual FY 2021 Workload Volumes & Predicted FY 2023 Workload Volumes

Workload Category	FY 2021 Actuals	FY 2023 Predictions
Supplements with Clinical Data	8	8
Labeling Supplements	14	10
Manufacturing Supplements	95	127
Biosimilar Biological Product Applications	9	8
BsUFA Industry Meetings (BIA, BPD Type 1-4)	113	127
Participating BPD Programs	117	122

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2023 were then converted into estimated FTE needs for FDA's BsUFA III direct review-related work. The resulting expected FY 2023 FTE need for BsUFA III was compared to current onboard capacity for BsUFA III direct review-related work to determine the FY 2023 resource delta, as summarized in table 5.

Table 5.--FY 2023 BsUFA III Resource Delta

Current Resource Capacity	FY 2023 Resource Forecast	Predicted FY 2023 FTE Delta
50	67	17

The projected 17 FTE delta was then assessed by FDA in the context of additional operational and internal factors to ensure that a fee adjustment is only made for resources which can be utilized in the fiscal year and for which funds are required to support additional review capacity. FDA recognizes that FY 2023 presents significant hiring commitments for the Agency, including the hiring goals set forth for FY 2023 per the BsUFA III Commitment Letter, as well as hiring commitments for other user fee programs. In addition, current labor market conditions may present continuing hiring and retention challenges. In light of these commitments and challenges, FDA determined that there is no need for an adjustment from the CPA to provide funds for the realistic estimated net FTE gains.

Table 6.--FY 2023 BsUFA III CPA

Additional FTEs for FY 2023	Cost for Each Additional FTE	FY 2023 BsUFA III CPA
0	$316,349	$0

Although an adjustment to the fee amounts for resource needs by the CPA will not be made in FY 2023, FDA will evaluate the need for a fee adjustment from the CPA in future fiscal years and will make adjustments as warranted.

D. FY 2023 Additional Dollar Amount

For FY 2023 and FY 2024, BsUFA III provides an additional dollar amount for additional FTE for the biosimilar biological product review program to support enhancements outlined in the BsUFA III Commitment Letter. For FY 2023, the statute directs FDA to further increase the fee revenue and fees by the additional dollar amount, which is $4,428,886 for FY 2023 (see section 744H(b)(1)(F) of the FD&C Act).

E. FY 2023 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA III sets forth an operating reserve adjustment to the fee revenue and fees. Specifically, for FY 2023, the statute directs FDA: (1) to increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications and (2) if FDA has carryover balances for such process in excess of 33 weeks of such operating reserves, to decrease such fee revenue and fees to provide for not more than 33 weeks of such operating reserves (see section 744H(c)(4) of the FD&C Act).

To determine whether the operating reserve adjustment will be applied, FDA uses an estimated adjusted revenue amount which estimates FDA's costs of operations for BsUFA for FY 2023. To calculate the estimated adjusted revenue amount, the FY 2023 annual base revenue is adjusted for inflation, strategic hiring and retention, capacity planning, and the additional dollar amount. The annual base revenue amount for FY 2023 is $43,376,922. This amount is then multiplied by 1.7162 percent yielding an inflation-adjusted revenue amount of $44,121,357. The next adjustment is the strategic hiring and retention adjustment of $150,000. Adding the strategic hiring and retention adjustment of $150,000 to the inflation-adjusted revenue amount results in $44,271,357. Next, adding the FY 2023 CPA of $0 results in the capacity planning-adjusted revenue amount of $44,271,357. Next, adding the additional dollar amount of $4,428,886 generates the estimated adjusted revenue amount. For FY 2023, the BsUFA estimated adjusted revenue amount is $48,700,243.

To calculate the 10-week and 33-week threshold amounts for the FY 2023 operating reserve adjustment, the estimated adjusted revenue amount is divided by 52, resulting in a $936,543 cost of operation for 1 week. The unrounded 1-week value is then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2023 of $9,365,431. The unrounded 1-week value is multiplied by 33 to generate the 33-week operating reserve threshold amount for FY 2023 of $30,905,923.

To calculate the estimated operating reserve of carryover user fees at the end of FY 2022, FDA estimated the operating reserves of carryover fees at the end of July 2022. The balance of operating reserves of carryover fees at the end of July 2022 is combined with the forecasted collections and obligations for the remainder of FY 2022 to generate a full year estimate for FY 2022. The estimated operating reserve of

carryover user fees at the end of FY 2022 is $38,005,821.

The estimated operating reserve of carryover user fees at the end of FY 2022 of $38,005,821 exceeds the 33-week threshold allowable operating reserve of carryover user fees for FY 2023 of $30,905,923. As such, FDA is applying a downward operating reserve adjustment of $7,099,898 (rounded to the nearest dollar), an amount equivalent to a reduction of approximately 8 weeks of operations, to bring the operating reserve of carryover user fees to $30,905,923 or 33 weeks of operations at the start of FY2023. With this Operating Reserve Adjustment, the estimated adjusted revenue amount of $48,700,243 will be lowered by $7,099,898, yielding the FY 2023 target revenue amount of $41,600,000 (rounded to the nearest thousand).

III. Fee Amounts for FY 2023

Under section 744H(b)(2)(A) of the FD&C Act, FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from: (1) initial and annual BPD fees, and reactivation fees; (2) biosimilar biological product application fees; and (3) biosimilar biological product program fees. As described above, a downward operating reserve adjustment is required for FY 2023. The operating reserve adjustment in subsequent years may not be as large. As such, the target revenue in FY 2023 may be lower than in prior or future years, and thereby the fee amounts may also be lower than in prior or future years.

A. Application Fees

In establishing the biosimilar biological product application fee amount for FY 2023, FDA utilized an average of the three most recently completed fiscal years (*i.e.,* FY 2019 to 2022) of biosimilar biological product application submissions. Based on the available information, FDA estimates it will receive eight biosimilar biological product applications requiring clinical data for approval in FY 2023 and zero applications that do not require clinical data.

For FY 2023, FDA will maintain the biosimilar biological product application fee at the same level as FY 2022, which is $1,746,745 for applications requiring clinical data. Applications not requiring clinical data pay half that fee, or $873,373. This is estimated to provide a total of $13,973,960 representing 34 percent (rounded to the nearest whole number) of the FY 2023 target revenue amount.

B. Biosimilar Biological Product Program Fee

Under BsUFA III, FDA assesses biosimilar biological product program fees (''program fees''). An applicant in a biosimilar biological product application shall not be assessed more than five program fees for a fiscal year for biosimilar biological products identified in a single biosimilar biological product application (see section 744H(a)(3)(D) of the FD&C Act). Applicants are assessed a program fee for a fiscal year for biosimilar biological products that are identified in a biosimilar biological product application approved as of October 1 of such fiscal year; that may be dispensed only under prescription pursuant to section 503(b) of the FD&C Act; and that, as of October 1 of such fiscal year, do not appear on a list developed and maintained by FDA of discontinued biosimilar biological products. An approved biosimilar biological product that appears on the list of discontinued biosimilar biological products as of October 1 of a fiscal year would also be assessed the program fee if it is removed from the discontinued list during the fiscal year and the other statutory criteria for fee assessment are satisfied (see section 744H(a)(3)(E)(ii) of the FD&C Act).

Based on available information, FDA estimates that 72 program fees will be invoiced for FY 2023. For products invoiced in the FY 2023 regular billing cycle, FDA anticipates that zero program fees will be refunded.

For FY 2023, the biosimilar biological product program fee is $304,162. This is estimated to provide a total of $21,899,664, representing 53 percent (rounded to the nearest whole number) of the FY 2023 target revenue amount.

C. Initial and Annual BPD Fees, and Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2023, FDA must consider the number of new BPD programs, the number of current BPD programs, and the number of BPD programs that will be reactivated. These estimates provide information that, when aggregated, allows FDA to set BPD fees (initial BPD fees, annual BPD fees, reactivation fees).

FDA analyzed available data to estimate the total number of BPD programs for FY 2023. In FY 2023, FDA estimates approximately 23.5 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and approximately 97.75 BPD programs to pay the annual BPD fee, yielding a rounded total estimated equivalent of 121 BPD fees to be collected in FY 2023. The remainder of the target revenue of $5,726,376 or 14 percent (rounded to the nearest whole number), is to be collected from the BPD fees. Dividing this amount by the estimated 121 BPD fees to be paid equals an initial BPD and annual BPD fee amount of $47,325. The reactivation fee is set at twice the initial/annual BPD amount at $94,650 (rounded to the nearest dollar).

IV. Fee Schedule for FY 2023

The fee rates for FY 2023 are displayed in table 7.

Table 7.--Fee Schedule for FY 2023

Fee Category	Fee Rates for FY 2023
Initial BPD	$47,325
Annual BPD	$47,325
Reactivation	$94,650
Applications	
Requiring clinical data	$1,746,745
Not requiring clinical data	$873,373
Program	$304,162

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2023, *i.e.,* the period from October 1, 2022, through September 30, 2023. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 7 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program for a product or have been administratively removed from the BPD program for a product, and seek to resume participation in such program must pay all annual biosimilar biological product development fees previously assessed for such product and still owed and the reactivation fee by the earlier of the following dates: no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's website (*https://www.fda.gov/bsufa)* and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to use *www.pay.gov,* a web-based payment application, for online electronic payment. The *www.pay.gov* feature is available on the FDA website after the user fee ID number is generated. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (Note: only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click ''Pay Now'' to be redirected to *www.pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: this U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979108) and ID number is written on the check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

B. Annual BPD and Program Fees

FDA will issue invoices with payment instructions for FY 2023 annual BPD and program fees under the new fee schedule in October 2022. Under sections 744H(a)(1)(B)(ii) and 744H(a)(3)(B) of the FD&C Act, annual BPD and program fees are generally due on October 3, 2022. However, given the late date of the BsUFA reauthorization, invoices should be paid within 30 days of invoice.

FDA will issue invoices in December 2023 for any products that qualify for the annual program fee after the October 2022 billing.

C. Waivers and Refunds

To qualify for consideration for a waiver under section 744H(d) of the FD&C Act, or the return of any fee paid under section 744H of the FD&C Act, including if the fee is claimed to have been paid in error, a person shall submit to FDA a written request justifying such waiver or return and, except as otherwise specified in section 744H of the FD&C Act, such written request shall be submitted to FDA not later than

180 days after such fee is due. Such written request shall include any legal authorities under which the request is made. See section 744H(h) of the FD&C Act.

Dated: October 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21965 Filed 10–5–22; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1981]

Facility Readiness: Goal Date Decisions Under Generic Drug User Fee Amendments; 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 ''Facility Readiness: Goal Date Decisions Under GDUFA.'' This draft guidance provides information to applicants on how FDA will use information related to a facility's readiness for inspection as certified on Form FDA 356h to set a goal date for an original abbreviated new drug application (ANDA) submitted under the Federal Food, Drug, and Cosmetic Act. This guidance incorporates a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to reauthorization of the Generic Drug User Fee Amendments (GDUFA) and as described in ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027'' (GDUFA III commitment letter).

DATES: Submit either electronic or written comments on the draft guidance by December 6, 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–1981 for ''Facility Readiness: Goal Date Decisions Under GDUFA.'' 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Karen Takahashi, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6686, Silver Spring, MD 20993–0002, 301–796–3191.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Facility Readiness: Goal Date Decisions Under GDUFA.'' This draft guidance provides information to applicants on how FDA intends to assign a goal date based on a facility's readiness for inspection as certified on Form FDA 356h submitted as part of an original ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). This guidance explains how FDA incorporates a performance enhancement in the

GDUFA III commitment letter as part of its goal date assignments.

Under the commitment letter related to the GDUFA authorization for fiscal years 2018 through 2022 (under the Generic Drug User Fee Amendments of 2017), a goal date was assigned without regard to facility readiness for inspection. In contrast, under the GDUFA III commitment letter, FDA agreed to assign a longer goal date if a facility is not ready for an inspection at the time of application submission. An application containing a facility not ready for inspection is more likely to require multiple assessment cycles, extending the time required for possible approval and potentially delaying patient access to quality generic drugs. This change in goal date assignment will help FDA to focus resources on applications with facilities ready for inspection.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Facility Readiness: Goal Date Decisions Under GDUFA.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. Currently, manufacturing establishment information is submitted as part of the existing application form, Form FDA 356h, and is approved by OMB under control number 0910–0338. The collections of information in 21 CFR parts 210 and 211 (current good manufacturing practice) and part 11 (electronic records and signatures) have been approved under OMB control numbers 0910–0139 and 0910–0303, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft 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: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21811 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0902]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medication Guides for Prescription Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 7, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0393. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medication Guide Requirements for Prescription Drug Product Labeling

OMB Control Number 0910–0393—Extension

This information collection supports FDA regulations pertaining to the distribution of patient labeling, called Medication Guides, for human prescription drug and biological products used primarily on an outpatient basis, and required for products that pose a serious and significant public health concern. Applicable regulations are codified at part 208 (21 CFR part 208): Medication Guides for Prescription Drug Products, and set forth general content and format requirements, as well as provide for exemptions and deferrals. Medication Guides provide patients with important written information about drug products, including the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, and are required in accordance with Agency regulations.

To assist consumers and industry with understanding applicable regulatory requirements in part 208 pertaining to developing, distributing, and submitting certain Medication Guides, we have developed the guidance document entitled ''Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)'' (available at *https://www.fda.gov/media/79776/download*). The guidance document includes: (1) a discussion of the applicable regulations; (2) FDA enforcement policy with regard to Medication Guides associated with products dispensed to healthcare professionals, or patient caregivers, instead of being dispensed directly to the patient for self-administration; and (3) Medication Guides required as part of a risk evaluation and mitigation strategy.

In the **Federal Register** of March 22, 2022 (87 FR 16199), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content and format of a Medication Guide; § 208.20	41	1	41	320	13,120
Exemptions and deferrals; § 208.26(a)	1	1	1	4	4
Total			42		13,124

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Upon evaluation of the information collection, we have removed burden we attributed to reporting associated with supplements and other changes to approved abbreviated new drug applications, new drug applications, and biologics license applications (21 CFR 314.70(b)(3)(ii) and 601.12(f)). We now account for burden associated with these regulatory provisions in OMB control numbers 0910–0001 and 0910–0338 and have decreased the burden associated with this collection accordingly.

TABLE 2—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 [2]	Total hours
Distribute Medication Guides to authorized dispensers; § 208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Distribute and Dispense Medication Guides to Patients; § 208.24(e)	88,000	5,705	502,040,000	0.05 (3 minutes)	25,102,000
Total			503,759,000		27,250,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers may not sum due to rounding.

We have decreased our estimated burden associated with disclosures to reflect a decrease in related submissions over the past 3 years.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21840 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2353]

Medical Device User Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2023. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2022 (MDUFA V), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2023, which apply from October 1, 2022, through September 30, 2023, and provides information on how the fees for FY 2023 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT: *For information on Medical Device User Fees: https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.*

For questions related to the MDUFA Small Business Program, please visit the Center for Devices and Radiological Health's website: https://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program.

For questions related to this notice: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd, Rm. 61075, Beltsville, MD 20705–4304, 301–796–7223, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, as amended by MDUFA V, authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for simplicity, this document refers to these collectively as ''submissions'' or ''applications''); for periodic reporting on class III devices; and for the registration of certain establishments.

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2023 through FY 2027; the base fee for a premarket application received by FDA during FY 2023 is $425,000. From this starting point, this document establishes FY 2023 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified

in the FD&C Act. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see 21 U.S.C. 379j(d) and (e)). For more information on fee waivers, please see Section IX. Small Business Fee Reductions and Fee Waivers.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2023 through FY 2027; the base fee for an establishment registration in FY 2023 is $6,250. Each establishment that is registered (or is required to register) with the Secretary of Health and Human Services under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

II. Total Revenue Amount for FY 2023

The total revenue amount for FY 2023 is $312,606,000, as set forth in the statute prior to the inflation adjustment (see 21 U.S.C. 379j(b)(3)). MDUFA V directs FDA to use the yearly total revenue amount as a starting point to set the standard fee rates for each fee type. The fee calculations for FY 2023 are described in this document.

Inflation Adjustment

MDUFA specifies that the $312,606,000 is to be adjusted for inflation increases for FY 2023 using two separate adjustments: one for payroll costs and one for non-payroll costs (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2023 is the sum of one plus the two separate adjustments and is compounded as specified in the statute (see 21 U.S.C. 379j(c)(2)(C) and 379j(c)(2)(B)).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 1 summarizes the actual cost and FTE data for the specified FYs, provides the percent change from the previous fiscal year, and provides the average percent change over the first 3 of the 4 fiscal years preceding FY 2023. The 3-year average is 1.3918 percent (rounded).

Table 1.--FDA PC&Bs Each Year and Percent Change

	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$ 2,620,052,000	$ 2,875,592,000	$ 3,039,513,000	
Total FTE	$ 17,144	$ 17,535	$ 18,501	
PC&B per FTE	$ 152,826	$ 163,992	$ 164,289	
Percent Change From Previous Year	-3.3120%	7.3063%	0.1811%	1.3918%

The payroll adjustment is 1.3918 percent multiplied by 60 percent, or 0.8351 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2023 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All Items; Annual Index) for the first 3 of the preceding 4 years of available data multiplied by 0.40, or 40 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the Washington-Arlington-Alexandria area. These data are published by the Bureau of Labor Statistics and can be found on their website under series Id CUURS35ASA0 at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

Table 2.--Annual and 3-Year Average Percent Change in Washington-Arlington-Alexandria Area CPI

	2019	2020	2021	3-Year Average
Annual CPI	264.78	267.16	277.73	
Annual Percent Change	1.2745%	0.8989%	3.9568%	2.0434%

The non-payroll adjustment is 2.0434 percent multiplied by 40 percent, or 0.8174 percent. Next, the payroll adjustment (0.8351 percent or 0.008351) is added to the non-payroll adjustment (0.8174 percent or 0.008174), for a total of 1.6525 percent (or 0.016525). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.016525 for FY 2023.

MDUFA V provides for this inflation adjustment to be compounded for FY 2023 and each subsequent fiscal year (see 21 U.S.C. 379j(c)(2)(B)(ii)). To complete the compounded inflation adjustment for FY 2023, the FY 2022 base adjustment (1.022046) is multiplied by the FY 2023 base inflation adjustment (1.016525) to reach the applicable inflation adjustment of 1.038935 (rounded) for FY 2023. We then multiply the total revenue amount for FY 2023 ($312,606,000) by 1.038935, yielding an inflation-adjusted total revenue amount of $324,777,000 (rounded to the nearest thousand dollar).

III. Adjustments to Base Fee Amounts for FY 2023

Under the FD&C Act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see 21 U.S.C. 379j(a)(2)(A)).

A. Inflation Adjustment

MDUFA specifies that the base fees of $425,000 (premarket application) and $6,250 (establishment registration) are to be adjusted for FY 2023 using the same methodology as that for the total revenue inflation adjustment in section

II (see 21 U.S.C. 379j(c)(2)(D)(i)). Multiplying the base fees by the compounded inflation adjustment of 1.038935 yields inflation-adjusted base fees of $441,547 (premarket application) and $6,493 (establishment registration).

B. Further Adjustments To Generate the Inflation-Adjusted Total Revenue Amount

After the applicable inflation adjustment to fees is done, FDA may increase, if necessary to achieve the inflation-adjusted total revenue amount, the base fee amounts on a uniform proportionate basis (see 21 U.S.C. 379j(c)(2)(D)(ii)). After this adjustment, if necessary, FDA may further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount (see 21 U.S.C. 379j(c)(3)).

C. MDUFA V Adjustments Solely to Registration Fees

MDUFA V has three new potential adjustments that will not change the total revenue amount but may impact collections by increasing or decreasing establishment registration base fees only. These adjustments are the performance improvement adjustment, the hiring adjustment, and the operating reserve adjustment. Only the operating reserve adjustment is potentially applicable in FY 2023.

1. Performance Improvement Adjustment

For FY 2023, there is no performance improvement adjustment. Beginning with FY 2025, this adjustment allows FDA to collect fees in addition to the total revenue amount in FYs 2025, 2026, and 2027, if the Agency meets certain performance goals in FYs 2023, 2024, and 2025. If applicable, this provision further increases base establishment registration fee amounts to achieve an increase in total fee collections equal to the applicable performance improvement adjustment, which is set forth in the statute (see 21 U.S.C. 379j(c)(4)).

2. Hiring Adjustment

For FY 2023, there is no hiring adjustment. Beginning with FY 2025, this adjustment provides for the reduction of base establishment registration fees in FYs 2025, 2026, and 2027, if specified hiring goals for FYs 2023, 2024, and 2025 are not met by a certain threshold. The hiring adjustment would serve to decrease the base establishment registration fee amounts as necessary to achieve a reduction in total fee collections equal to the hiring adjustment amount, which is set forth in the statute (see 21 U.S.C. 379j(c)(5)).

3. Operating Reserve Adjustment

For FYs 2023 to 2027, the operating reserve adjustment requires FDA to decrease base establishment registration fees if the amount of operating reserves of carryover user fees exceeds the ''designated amount'' and such reduction is necessary to provide for not more than such designated amount of operating reserves of carryover user fees (see 21 U.S.C. 379j(c)(6)). In making this calculation for FYs 2023 to 2026, a certain amount is excluded from the designated amount and is not subject to the decrease (see 21 U.S.C. 379j(c)(6)(C)). For FY 2023, this excluded amount is $118,000,000.

The designated amount is equal to the sum of 13 weeks of operating reserves of carryover user fees plus 1 month of operating reserves described in 21 U.S.C. 379j(c)(8) (see 21 U.S.C. 379j(c)(6)(B)).

To determine the 13-week operating reserves of carryover user fees amount, the FY 2023 inflation-adjusted total revenue amount, $324,777,000 is divided by 52, and then multiplied by 13. The 13-week operating reserve amount for FY 2023 is $81,194,250.

To determine the 1 month of operating reserves described in 21 U.S.C. 379j(c)(8), the FY 2023 inflation-adjusted total revenue amount of $324,777,000 is divided by 12. The 1 month of operating reserves for FY 2023 is $27,064,750.

For FY 2023, the designated amount is equal to the 13-week operating reserve of $81,194,250 plus the 1 month of operating reserves of $27,064,750, totaling $108,259,000.

To determine the FY 2022 end-of-year operating reserves of carryover user fees amount, FDA combined the actual collections and obligations at the end of the third quarter (June 2022) and added the forecasted collections and obligations for the fourth quarter of FY 2022 to generate a full year estimate for FY 2022. The estimated end-of-year FY 2022 operating reserves of carryover user fees is $40,290,467. (Note, this amount includes the 1-month reserve.)

Note that under MDUFA V, for the purposes of calculating the operating reserve adjustment, this amount does not include user fee funds considered unappropriated ($26,680,243) or unearned revenue ($57,171,986). In addition, as noted above, for purposes of the operating reserve adjustment, operating reserves of carryover user fees do not include the $118,000,000 intended to support the Total Product Life Cycle Advisory Program Pilot and Third-Party Review programs.

Because the estimated end-of-year FY 2022 MDUFA operating reserves of carryover user fees amount totaling $40,290,467 does not exceed the FY 2023 designated amount of $108,259,105, FDA will not decrease the base establishment registration fee amounts for FY 2023 to provide for not more than such designated amount.

IV. Calculation of Fee Rates

As noted in section II, the total revenue amount after the applicable inflation adjustment is $324,777,000 (rounded to the nearest thousand dollar). As noted in section III, there is no MDUFA V adjustment solely to registration fees for FY 2023.

Table 3 provides the last 3 years of fee-paying submission counts and the 3-year average. These numbers are used to project the fee-paying submission counts that FDA will receive in FY 2023.

Table 3.--Three-Year Average of Fee-Paying Submissions[1]

Application Type	FY 2019 Actual	FY 2020 Actual	FY 2021 Actual	3-Year Average
Full Fee Applications	32	29	25	29
Small Business	8	7	5	7
Panel-Track Supplement	15	23	31	23
Small Business	4	6	6	5
De Novo Classification Request	16	20	16	17
Small Business	39	47	42	43
180-Day Supplements	125	124	98	116
Small Business	24	20	34	26
Real-Time Supplements	209	175	150	178
Small Business	43	28	20	30
510(k)s	2,082	2,048	2,133	2,088
Small Business	1,573	1,667	1,846	1,695
30-Day Notice	924	870	843	879
Small Business	110	104	77	97
513(g) (21 U.S.C. 360c(g)) Request for Classification Information	78	96	83	86
Small Business	54	57	53	55
Annual Fee for Periodic Reporting	640	622	613	625
Small Business[2]	98	95	84	92
Establishment Registration	27,728	41,942	33,812	34,494

[1] Includes collection of quarter 4 billing for FYs 2019, 2020, and 2021 during FY 2021.

The information in table 3 is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Table 4 displays the FY 2023 base fees set in statute (column one) and the inflation-adjusted base fees (per calculations in section III.A.) (column two). Using the inflation-adjusted fees and the 3-year averages of fee-paying submissions, collections are projected to total $330,787,011, which is $6,010,011 higher than the inflation-adjusted total revenue amount (in section II). The fees in column two are those FDA is establishing in FY 2023. The fees in column two are the standard fees.

Table 4.--Fees Needed to Achieve New FY 2023 Revenue Target

Application Type	FY 2023 Statutory Fees (Base Fees)	FY 2023 Inflation Adjusted Statutory Base Fees (Standard Fees)	3-Year Average of Fee-Paying Submissions	FY 2023 Revenue from Adjusted Fees
Full Fee Applications	$425,000	$441,547	29	$12,804,863
Small Business	$106,250	$110,387	7	$772,709
Panel-Track Supplement	$340,000	$353,238	23	$8,124,474
Small Business	$85,000	$88,309	5	$441,545
De Novo Classification Request	$127,500	$132,464	17	$2,251,888
Small Business	$31,875	$33,116	43	$1,423,988
180-Day Supplements	$63,750	$66,232	116	$7,682,912
Small Business	$15,938	$16,558	26	$430,508
Real-Time Supplements	$29,750	$30,908	178	$5,501,624
Small Business	$7,438	$7,727	30	$231,810
510(k)s	$19,125	$19,870	2,088	$41,488,560
Small Business	$4,781	$4,967	1,695	$8,419,065
30-Day Notice	$6,800	$7,065	879	$6,210,135
Small Business	$3,400	$3,532	97	$342,604
513(g) Request for Classification Information	$5,738	$5,961	86	$512,646
Small Business	$2,869	$2,980	55	$163,900
Annual Fee for Periodic Reporting	$14,875	$15,454	625	$9,658,750
Small Business	$3,719	$3,864	92	$355,488
Establishment Registration	$6,250	$6,493	34,494	$223,969,542
Total				$330,787,011

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $441,547 for FY 2023. The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 80 percent of the standard fee;
- For a de novo classification request, 30 percent of the standard fee;
- For a 180-day supplement, 15 percent of the standard fee;
- For a real-time supplement, 7 percent of the standard fee;
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard fee;
- For a 510(k) premarket notification, 4.5 percent of the standard fee;
- For a 30-day notice, 1.6 percent of the standard fee; and
- For a 513(g) request for classification information, 1.35 percent of the standard fee.

For all submissions other than a 30-day notice and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee for the submission (see 21 U.S.C. 379j(d)(2)(C) and (e)(2)(C)). For a 30-day notice and a 513(g) request for classification information, the small business fee is 50 percent of the standard (full) fee for the submission (see 21 U.S.C. 379j(d)(2)(C)).

The annual fee for establishment registration, after adjustment, is set at $6,493 for FY 2023. For FY 2023, there is no small business waiver for the annual establishment registration fee; all establishments pay the same fee.

For more information on reduced fees and waivers for small businesses, please see Section IX. Small Business Fee Reductions and Fee Waivers.

Table 5 summarizes the FY 2023 rates for all medical device fees.

Table 5.--Medical Device Fees for FY 2023

Application Fee Type	Standard Fee (as a percent of the standard fee for a premarket application)	FY 2023 Standard Fee	FY 2023 Small Business Fee
Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act, or a BLA submitted under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262))	Base fee specified in statute	$441,547	$110,387
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	100%	$441,547	$110,387
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100%	$441,547	$110,387
Panel-track supplement	80%	$353,238	$88,309
De novo classification request	30%	$132,464	$33,116
180-day supplement	15%	$66,232	$16,558
Real-time supplement	7%	$30,908	$7,727
510(k) premarket notification submission	4.5%	$19,870	$4,967
30-day notice	1.60%	$7,065	$3,532
513(g) request for classification information	1.35%	$5,961	$2,980
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.50%	$15,454	$3,864
Annual establishment registration fee (to be paid by the establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, as defined by 21 U.S.C. 379i(14))	Base fee specified in statute	$6,493	$6,493

V. How To Qualify as a Small Business for Purposes of Medical Device Fees

If your business, including your affiliates, has gross receipts or sales of no more than $100 million for the most recent tax year, you may qualify for reduced small business fees. If your business, including your affiliates, has gross sales or receipts of no more than $30 million, you may also qualify for a waiver of the fee for your first premarket application (*i.e.,* PMA, PDP, or BLA) or premarket report. If you want to pay the small business fee rate for a submission or you want to receive a waiver of the fee for your first premarket application or premarket report, you should submit the materials showing you qualify as a small business at least 60 days before you send your submission to FDA. For more information on fee waivers or reductions, please see Section IX. Small Business Fee Reductions and Fee Waivers.

Please note that the establishment registration fee is not eligible for a reduced small business fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2023, you should not submit a Small Business Certification Request. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard (full) fee for that submission.

If your business qualified as a small business for FY 2022, your status as a small business will expire at the close of business on September 30, 2022. You must re-qualify for FY 2023 in order to pay small business fees during FY 2023.

A. Domestic (U.S.) Businesses

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2023, submit the following to FDA:

1. A completed MDUFA Small Business Certification Request For a Business Headquartered in the United States (Form FDA 3602). Form FDA 3602 is provided in the FDA Forms database: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573420.pdf.*

2. A signed copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2022, except:

If you submit your MDUFA Small Business Certification Request for FY 2023 before April 15, 2023, and you have not yet filed your return for 2022, you may use tax year 2021.

If you submit your MDUFA Small Business Certification Request for FY 2023 on or after April 15, 2023, and have not yet filed your 2022 return because you obtained an extension, you may submit your most recent return filed prior to the extension.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year, or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is

headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the business has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

4. Once you have completed your Form FDA 3602, print and sign the form. Mail the completed form and your supporting documentation (copies of the Federal (U.S.) income tax returns) to Medical Device User Fee Small Business Certification Request mailing address, which is available at the following website: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm.*

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

B. Foreign Businesses

If you are a foreign business, and wish to qualify as a small business for FY 2023, submit the following:

1. A completed MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States (Form FDA 3602A). Form FDA 3602A is provided in the FDA Forms database: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573423.pdf.*

2. A National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2021 or later), or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority, of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates for the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

4. Once you have completed your Form FDA 3602A, print and sign the form. Mail the completed form and your supporting documentation including the following to CDRH's Medical Device User Fee Small Business Certification Request address, which is available at the following website: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm.*

- A copy of the most recent Federal (U.S.) income tax return for each of your affiliates headquartered in the U.S. and
- A copy of an MDUFA Foreign Small Business Certification Request for each of your foreign affiliates.

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

VI. Procedures for Paying Application Fees

If your application or submission is subject to a fee and your payment is received by FDA between October 1, 2022, and September 30, 2023, you must pay the fee in effect for FY 2023. To avoid delay in the review of your application, you should pay the application fee at the time you submit your application to FDA. The later of the date that the application is received in the reviewing center's document room or the date the U.S. Treasury recognizes the payment determines whether the fee rates for FY 2022 or FY 2023 apply. FDA must receive the correct fee at the time that an application is submitted or the application will not be accepted for fling or review.

FDA requests that you follow the steps below before submitting a medical device application subject to a fee to ensure that FDA links the fee with the correct application. (*Note:* Do not send your user fee check to FDA with the application.)

A. Secure a Payment Identification Number (PIN) and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment

Log into the User Fee System at: *https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp.* Complete the Medical Device User Fee cover sheet. Be sure you choose the correct application submission date range. (Two choices will be offered until October 1, 2022. One choice is for applications and fees that will be received on or before September 30, 2022, which are subject to FY 2022 fee rates. A second choice is for applications and fees received on or after October 1, 2023, which are subject to FY 2023 fee rates.) After completing data entry, print a copy of the Medical Device User Fee cover sheet and note the unique PIN located in the upper right-hand corner of the printed cover sheet.

B. Electronically Transmit a Copy of the Printed Cover Sheet With the PIN

When you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Applicants are required to set up a user account and password to assure data security in the creation and electronic submission of cover sheets.

C. Submit Payment for the Completed Medical Device User Fee Cover Sheet

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov,* a web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay. Note:* Only full payments are accepted. No partial payments can be made online. Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

2. If paying with a paper check:

• All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.

• Please write your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) on your check.

• *Mail the paper check and a copy of the completed cover sheet to:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

If you prefer to send a check by a courier, the courier may deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

3. If paying with a wire transfer:

• Please include your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) in your wire transfer. Without the PIN, your payment may not be applied to your cover sheet and review of your application may be delayed.

• The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

FDA records the official application receipt date as the later of the following: (1) the date the application was received by the FDA Document Control Center for the reviewing Center or (2) the date the U.S. Treasury recognizes the payment.

D. Submit Your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee cover sheet to the address located at *https://www.fda.gov/cdrhsubmissionaddress.*

VII. Procedures for Paying the Annual Fee for Periodic Reporting

You will be invoiced at the end of the quarter in which your PMA Periodic Report is due. Invoices will be sent based on the details included on your PMA file. You are responsible for ensuring FDA has your current billing information, and you may update your contact information for the PMA by submitting an amendment to the pending PMA or a supplement to the approved PMA.

1. The preferred payment method is online using electronic check (ACH also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. *If paying with a paper check:* The check must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.

• Please write your invoice number on the check.

• *Mail the paper check and a copy of the invoice to:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

To send a check by a courier, the courier must deliver the check and printed copy of the cover sheet to U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

3. When paying by a wire transfer, it is required that the invoice number is included; without the invoice number, the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

VIII. Procedures for Paying Annual Establishment Registration Fees

To pay the annual establishment registration fee, firms must access the Device Facility User Fee (DFUF) website at *https://userfees.fda.gov/OA_HTML/furls.jsp.* (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website address after this document publishes in the **Federal Register**.) Create a DFUF order and you will be issued a PIN when you place your order. After payment has been processed, you will be issued a payment confirmation number (PCN). You will not be able to register your establishment if you do not have a PIN and a PCN. An establishment required to pay an annual establishment registration fee is not legally registered in FY 2023 until it has completed the steps below to register and pay any applicable fee (see 21 U.S.C. 379j(f)(2)).

Companies that do not manufacture any product other than a licensed biologic are required to register in the Blood Establishment Registration (BER) system. FDA's Center for Biologics Evaluation and Research (CBER) will send establishment registration fee invoices annually to these companies.

A. Submit a DFUF Order With a PIN From FDA Before Registering or Submitting Payment

To submit a DFUF order, you must create or have previously created a user account and password for the user fee website listed previously in this section. After creating a user name and password, log into the Establishment Registration User Fee FY 2023 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. When you are satisfied that the information in the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

B. Pay for Your DFUF Order

Unless paying by U.S. credit card, all payments must be in U. S. currency and drawn on a U.S. bank.

1. *If paying by credit card or electronic check (ACH or eCheck):* The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic check. Follow the instructions provided to make an electronic payment.

2. *If paying with a paper check:* The check must be in U.S. currency and drawn on a U.S. bank, and mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. (*Note:* This address is different from the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

Please make sure that both of the following are written on your check: (1) the FDA post office box number (P.O. Box 979108) and (2) the PIN that is printed on your order. Include a copy of your printed order when you mail your check.

3. *If paying with a wire transfer:* Wire transfers may also be used to pay annual establishment registration fees. To send a wire transfer, please read and comply with the following information:

Include your order's unique PIN (in the upper right-hand corner of your completed DFUF order) in your wire transfer. Without the PIN, your payment may not be applied to your facility and your registration may be delayed.

The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept. of the Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2023, or To Register a New Establishment for FY 2023

Go to the Center for Devices and Radiological Health's website at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing* and click the ''Access Electronic Registration'' link on the left side of the page. This opens a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the ''Access Electronic Registration'' link in the middle of the page. This link takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account, if your establishment did not create an account in FY 2022. Manufacturers of licensed biologics should register in the electronic Blood Establishment Registration (eBER) system at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-establishment-registration.*

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register and existing establishments will update their annual registration using choices on the DRLM menu. When you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (*Note:* This email address and this telephone number are for assistance with establishment registration only; they are not to be used for questions related to other aspects of medical device user fees.) Problems with the eBER system should be directed to *https://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm* or call 240–402–8360.

D. Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

IX. Small Business Fee Reductions and Fee Waivers

To qualify for reduced fees for small businesses or a small business fee waiver, please see the requirements for qualification provided in Section V. How To Qualify as a Small Business for Purposes of Medical Device Fees. The applicant should submit a Small Business Certification Request and the supporting materials showing you qualify as a small business at least 60 days before you send your submission to FDA. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard (full) fee for that submission.

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

A. Premarket Approval Fee Reduction or Waiver

A small business applicant may request to pay a reduced rate for premarket approval fees. An applicant may also request a fee waiver for their first premarket application or premarket report (see 21 U.S.C. 379j(d)).

B. Premarket Notification Submission Fee Reduction

A small business applicant may request to pay a reduced rate for a premarket notification submission.

C. Annual Establishment Registration Fee

There is no small business waiver for the annual establishment registration fee; all establishments pay the same fee.

X. Refunds

To qualify for consideration for a refund, a person shall submit to FDA a written request for a refund not later than 180 days after such fee is due. FDA has discretion to refund a fee or a portion of the fee. A determination by FDA concerning a refund shall not be reviewable. For more information on qualifying and submitting a refund, see 21 U.S.C. 379j(a)(2)(D).

Dated: October 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21967 Filed 10–5–22; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2392]

Fee Rate for Using a Priority Review Voucher in Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a priority review voucher for fiscal year (FY) 2023. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, authorizes FDA to determine and collect priority review user fees for certain applications for review of human drug or biological products when those applications use a tropical disease, rare pediatric disease, or material threat medical countermeasure (MCM) priority review voucher. These vouchers are awarded to the sponsors of tropical disease, rare pediatric disease, or material threat MCM product applications, respectively, that meet the requirements of the FD&C Act, upon FDA approval of such applications. The amount of the fee for using a priority review voucher is determined each fiscal year, based on the difference between the average cost incurred by FDA to review a human drug application designated as priority review in the previous fiscal year, and the average cost incurred in the review of an application that is not subject to priority review in the previous fiscal year. This notice establishes the FY 2023 priority review fee rate applicable to submission of eligible applications for review of human drug or biological products using a rare pediatric disease, material threat MCM, or tropical disease priority review voucher and outlines the payment procedures for such fees. This rate is effective on October 1, 2022, and will remain in effect through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 301–796–7223 and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Establishment of the Tropical Disease Priority Review Voucher

Section 1102 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) added section 524 to the FD&C Act (21 U.S.C. 360n). In section 524 of the FD&C Act, Congress encouraged development of new human drug and biological products for prevention and treatment of tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524 of the FD&C Act, the sponsor of an eligible human drug application for a tropical disease (as defined in section 524(a)(3) of the FD&C Act) shall receive a priority review voucher upon approval of the tropical disease product application (as defined in section 524(a)(4) of the FD&C Act).

B. Establishment of the Rare Pediatric Disease Priority Review Voucher

Section 908 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) added section 529 to the FD&C Act (21 U.S.C. 360ff). In section 529 of the FD&C Act, Congress encouraged development of new human drugs and biological products for prevention and treatment of certain rare pediatric diseases by offering additional incentives for obtaining FDA approval of such products. Under section 529 of the FD&C Act, the sponsor of an eligible human drug application for a rare pediatric disease (as defined in section 529(a)(3)) shall receive a priority review voucher upon approval of the rare pediatric disease product application (as defined in section 529(a)(4) of the FD&C Act).

C. Establishment of the Material Threat MCM Priority Voucher

Section 3086 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) added section 565A to the FD&C Act (21 U.S.C. 360bbb–4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the sponsor of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the material threat MCM application.

D. Transferability of the Priority Review Voucher

The recipient of a priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party. The voucher may be transferred repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. As further described below, a priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding review goals for FY 2023 is available at: *https://www.fda.gov/media/151712/download.*

The sponsor that uses a priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA published information on its website about how the priority review voucher program operates.[1] [2] [3]

This notice establishes the FY 2023 priority review fee rate for use of tropical disease, rare pediatric disease, and material threat MCM priority review vouchers at $1,524,039 and outlines FDA's process for implementing the collection of priority review user fees. This rate is effective on October 1, 2022, and will remain in effect through September 30, 2023.

II. Priority Review User Fee Rate for FY 2023

FDA interprets sections 524(c)(2) (tropical disease priority review user fee), 529(c)(2) (rare pediatric disease priority review user fee), and 565A(c)(2) (material threat MCM priority review user fee) of the FD&C Act as requiring that FDA determine the amount of each priority review user fee for each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the

[1] Information regarding the tropical disease priority review voucher program is available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tropical-disease-priority-review-vouchers.*

[2] Information regarding the rare pediatric disease priority review voucher program, visit: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm375479.htm.*

[3] Information regarding the material threat MCM priority review voucher program is available at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions.*

previous fiscal year, and the average cost incurred by FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year.

A priority review is a review conducted within a time frame prescribed in FDA commitments for such reviews made in connection with PDUFA VII. For the FYs 2023 through 2027, FDA has committed to a goal date to review and act on 90 percent of the applications granted priority review status within the expedited timeframe of 6 months after receipt or filing date (filing date for new molecular entity (NME) new drug application (NDA) and original biologics license applications (BLA) submissions; receipt date for priority non-NME original NDA submissions.) Normally, an application for a human drug or biological product will qualify for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. An application that does not receive a priority designation receives a standard review. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

FDA is setting a fee for FY 2023, which is to be based on standard cost data from the previous fiscal year, FY 2022. However, the FY 2022 submission cohort has not been closed out yet, thus the cost data for FY 2022 are not complete. The latest year for which FDA has complete cost data is FY 2021. Furthermore, because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked. The Agency expects all applications that received priority review would contain clinical data. The application categories with clinical data for which FDA tracks the cost of review are: (1) NDAs for an NME with clinical data and (2) BLAs.

The total cost for FDA to review NME NDAs with clinical data and BLAs in FY 2021 was $240,559,727. There was a total of 76 applications in these two categories (41 NME NDAs with clinical data and 35 BLAs). (*Note:* these numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) Of these applications 47 (27 NDAs and 20 BLAs) received priority review and the remaining 29 (14 NDAs and 15 BLAs) received standard reviews. Because a priority review compresses a review that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject, which supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). Using FY 2021 figures, the costs of a priority and standard review are estimated using the following formula:

$$(47\ \alpha \times 1.67) + (29\ \alpha) = \$240{,}559{,}727$$

where ''α'' is the cost of a standard review and ''α times 1.67'' is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be $2,237,973 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $3,737,415 (rounded to the nearest dollar). The difference between these two cost estimates, or $1,499,442, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2023 fee, FDA will need to adjust the FY 2021 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2022, to adjust the FY 2021amount for cost increases in FY 2022. That adjustment, published in the **Federal Register** setting the FY 2023 PDUFA fees, is 1.6404 percent for the most recent year, not compounded. Increasing the FY 2021 incremental priority review cost of $1,499,442 by 1.6404 percent (or 0.016404) results in an estimated cost of $1,524,039 (rounded to the nearest dollar). This is the priority review user fee amount for FY 2023 that must be submitted with a priority review voucher for a human drug application in FY 2023, in addition to any PDUFA fee that is required for such an application.

III. Fee Rate Schedule for FY 2023

The fee rate for FY 2023 is set in table 1:

TABLE 1—PRIORITY REVIEW FEE SCHEDULE FOR FY 2023

Fee category	Priority review fee rate for FY 2023
Application submitted with a tropical disease priority review voucher in addition to the normal PDUFA fee	$1,524,039
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	1,524,039
Application submitted with a material threat MCM priority review voucher in addition to the normal PDUFA fee	1,524,039

IV. Implementation of Priority Review User Fee

Sections 524(c)(4)(B), 529(c)(4)(B), and 565A(c)(4)(B) of the FD&C Act specify that the human drug application for which the sponsor requests the use of a priority review voucher will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under these sections of the FD&C Act (see sections 524(c)(4)(C), 529(c)(4)(C), and 565A(c)(4)(C)). FDA may not collect priority review voucher fees for any fiscal year ''except to the extent provided in advance in appropriation Acts.'' (Section 524(c)(5)(B), 529(c)(5)(B), and 565A(c)(6) of the FD&C Act.)

The priority review fee established in the new fee schedule must be paid for any application received on or after October 1, 2022, submitted with a priority review voucher. As noted in section II, this fee must be paid in addition to any PDUFA fee that is required for the application. The sponsor would need to follow normal requirements for timely payment of any PDUFA fee for the human drug application. For more information regarding timely payment of PDUFA user fees generally, please see section 736(a)(2)(A) of the FD&C Act.

A. Priority Review Voucher Notification of Intent Requirement

All three priority review vouchers have a notification requirement. To comply with this requirement, the sponsor must notify FDA not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the estimated

submission date. See sections 524(b)(4), 529(b)(4)(B), and 565A(b)(3)(A) of the FD&C Act.

B. Priority Review Voucher User Fee Due Date

Under sections 524(c)(4)(A) (tropical disease priority review user fee) and 565A(c)(4)(A) (material threat MCM priority review user fee) of the FD&C Act, the priority review user fee is due (*i.e.,* the obligation to pay the fee is incurred) upon submission of a human drug application for which the priority review voucher is used.[4]

Under section 529(c)(4)(A) (rare pediatric disease priority review user fee) of the FD&C Act, the priority review user fee is due (*i.e.,* the obligation to pay the fee is incurred) when a sponsor notifies FDA of its intent to use the voucher. Upon receipt of this notification, FDA will issue an invoice to the sponsor for the rare pediatric disease priority review voucher fee. The invoice will include instructions on how to pay the fee via wire transfer, check, or online payments.

V. Fee Payment Options and Procedures

Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, credit card, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after the user fee identification (ID) number is generated.

A. Paper Check Payment Process

If paying by paper check, the sponsor should include on the check the appropriate reference number and the type of review requested. For rare pediatric disease priority review, please use the invoice number issued by the FDA. The invoice number is issued by the FDA upon receipt of the rare pediatric priority review notification (see section IV.A). For tropical disease priority review and for material threat MCM priority review, please use the user fee ID number generated for the *Pay.gov* feature.

- Tropical disease priority review: A paper check for a tropical disease priority review fee should include the user fee ID number and the words: ''Tropical Disease Priority Review''.
- Rare pediatric disease priority review: A paper check for a rare pediatric disease priority review fee should include the invoice number followed by the words: ''Rare Pediatric Disease Priority Review''.
- Material threat MCM priority review: A paper check for a material threat MCM priority review fee should include the user fee ID number and the words: ''Material Threat Medical Countermeasure Priority Review'' (or ''MCMPRV'').

All paper checks should be in U.S. currency from a U.S. bank made payable and mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). The FDA post office box number (P.O. Box 979107) must be written on the check. If needed, FDA's tax identification number is 53–0196965.

B. Wire Transfer Payment Process

If paying by wire transfer, please reference your invoice number/unique user fee ID number when completing your transfer. (For rare pediatric priority review, please use your invoice number issued by the FDA upon receipt of notification. For all other priority reviews, please use the unique user fee ID number generated for the *Pay.gov* feature.) The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. The account information is as follows: U.S. Dept. of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33.

VI. Reference

The following reference is on display with the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852, 240–402–7500, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is not available electronically at *https://www.regulations.gov* as this reference is copyright protected. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Ridley, D.B., H.G. Grabowski, and J.L. Moe, ''Developing Drugs for Developing Countries,'' *Health Affairs,* vol. 25, no. 2, pp. 313–324, 2006, available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.25.2.313.*

Dated: October 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21969 Filed 10–5–22; 11:15 am]

BILLING CODE 4164–01–P

[4] In the case of ''rolling review'' of an application (as discussed in May 2014 ''expedited programs'' guidance) for which a tropical disease PRV or material threat MCM PRV is redeemed, the PRV fee is due upon submission of the final portion of the application, given that the Agency generally views ''submission of a human drug application'' (including as used in sections 524(c)(4)(A) and 565A(c)(4)(A)) to mean the submission of a complete application. Also see section 506(d) of the FD&C Act, relating to review of incomplete applications for approval of a fast track product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 7, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0800. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0800—Revision

This information collection helps support implementation of sections 503A (21 U.S.C. 353a) and 503B (21 U.S.C. 353b) of the Federal Food Drug and Cosmetic Act (FD&C Act), which govern requirements for pharmacy compounding and outsourcing facilities, respectively. For efficiency of Agency operations, we are revising the information collection to include related reporting activities currently approved under OMB control number 0910–0827. Specifically, upon electing and in order to become an outsourcing facility, respondents must register under section 503B of the FD&C Act and submit certain reports and updates to FDA. The information is required to be submitted by electronic means unless otherwise exempt, and prepared in such form and manner as the Secretary of the Department of Health and Human Services may prescribe through regulation or guidance.

In the guidance for industry entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (December 2016), available on our website at *https://www.fda.gov/media/90173/download,* we explain how facilities that elect to register with FDA as outsourcing facilities are to submit drug product reports, consistent with section 503B of the FD&C Act. The guidance document describes who must report and what information must be provided to FDA. The guidance document also explains that drug compounding reports must be submitted in structured product labeling (SPL) format using FDA's electronic submissions system and discusses the consequences of outsourcing facilities' failure to submit reports.

In the **Federal Register** of June 17, 2022 (87 FR 36507) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section 503B of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial product reports	3	53	159	0.0833 (5 minutes)	13.25
Waiver request from electronic submission of initial product reports.	1	1	1	1	1
June product reports	75	53	3,975	0.025 (1.5 minutes)	99.375
December product reports	75	53	3,975	0.025 (1.5 minutes)	99.375
Waiver request from electronic submission of product reports.	1	1	1	1	1
Total					214

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are outsourcing facilities. Based upon our evaluation of the information collection, we have adjusted our estimate downward by 16 hours (from 230 to 214) annually to reflect more recent Agency data. We estimate that each year three outsourcing facilities will submit a product report upon initial registration under section 503B of the FD&C Act. We estimate that twice each year 75 outsourcing facilities will submit a report identifying all human drugs compounded in the facility in the previous 6 months. For the purposes of this estimate, each product's SPL submission is considered a separate product response, and therefore each facility's product report will include multiple product responses. We estimate that each facility will average 53 product responses. We expect each product report will consist of multiple product responses per facility and estimate that preparing and submitting this information electronically may take up to 5 minutes for each initial product response.

Assuming an average of 53 product responses per facility, we estimate that, for semiannual reports, preparing and submitting this information electronically will take 1.5 minutes per product response. Our burden estimate for semiannual product report submissions is lower than for initial product reports because outsourcing facilities can save each product response once initially created and submitted. For subsequent reports, an outsourcing facility may resubmit the same file(s) after changing the RootID and version number (both SPL metadata), effective date (to identify the reporting period), and the number of units produced, along with other data as appropriate, to appropriate values for the reporting period. Furthermore, if a product was not compounded during a particular reporting period, no product response would be sent for that product during that reporting period.

We expect to receive no more than one waiver request from the electronic submission process for initial product reports and semiannual reports, and that each waiver request will take 60 minutes to prepare and submit.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21841 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2389]

Authorization of Emergency Use of a Biological Product in Response to an Outbreak of Monkeypox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of monkeypox. FDA has issued one Authorization for a biological product as requested by the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of the Department of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States (U.S.) citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on August 9, 2022, that circumstances exist justifying the authorization of emergency use of vaccines pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of August 9, 2022.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564 of the FD&C Act, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(5) of the FD&C Act.

III. The Authorization

The Authorization follows the August 9, 2022, determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on August 9, 2022, that circumstances exist justifying the authorization of emergency use of vaccines pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's determination and declaration was provided in the **Federal Register** on August 15, 2022 (87 FR 50090). Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has issued the authorization for the emergency use of a biological product during the monkeypox outbreak. On August 9, 2022, FDA issued an EUA to NIAID for the biological product JYNNEOS, subject to the terms of the Authorization.

The initial Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorization can be found on FDA's web page at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

August 9, 2022

John Beigel, M.D.
Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases (NIAID)

Dear Dr. Beigel:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for FDA-unapproved emergency use of Jynneos, an FDA-approved vaccine, for the prevention of monkeypox disease in individuals determined to be at high risk of monkeypox infection. In response to this request and our review of available data, we are authorizing certain unapproved uses of Jynneos as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3).

On August 9, 2022, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States (U.S.) citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of vaccines for use against the monkeypox virus, pursuant to Section 564 of the Act, subject to terms of any authorization issued under that section.[1]

Jynneos is a live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus. Each 0.5 mL single dose is formulated to contain 0.5×10^8 to 3.95×10^8 infectious units of MVA-BN live virus. Jynneos is licensed for active immunization to prevent smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. It is FDA-approved as a two-dose series, with each 0.5 mL dose given subcutaneously (SC) 4 weeks apart.

For the authorization of intradermal administration of two doses (0.1 mL each) of Jynneos to individuals 18 years of age and older, FDA reviewed immunogenicity and safety data from a completed phase 2 trial in which 191 subjects received two intradermal (ID) doses of Jynneos (0.1 mL each), and 167 subjects received two SC doses of Jynneos (0.5 mL each). Study vaccinations were administered 4 weeks apart to all subjects. FDA's review of the available safety data did not identify specific safety concerns that would preclude issuance of an EUA. Following vaccination with Jynneos SC and ID immunogenicity was evaluated using 4 different

[1] U.S. Department of Health and Human Services, Determination of Public Health Emergency or Significant Potential for a Public Health Emergency and Declaration that Circumstances Exist Justifying an Authorization Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b).

assays. Plaque reduction neutralizing antibody titers (PRNT) were obtained using assays performed at St. Louis University (SLU) and Bavarian-Nordic (BN) and enyzme linked immunosorbent assay (ELISA) values were obtained from assays conducted at SLU and BN. The development of the immune response to Jynneos over time following SC and ID administration was nearly identical, and the $\log_2$ transformed peak titers obtained following ID administration were non-inferior those obtained following SC administration. For the authorization of SC administration of two doses (0.5 mL each) of Jynneos to individuals younger than 18 years of age FDA has considered the available Jynneos safety and immunogenicity data in adults as well as the historical data with use of live vaccinia virus smallpox vaccine in pediatric populations. Based on these data, FDA concluded that it is reasonable to believe, based on the totality of scientific evidence available, that Jynneos may be effective and that the known and potential benefits of Jynneos outweigh the known and potential risks of the vaccine, for the prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk of monkeypox infection when two 0.5 mL doses are administered subcutaneously 4 weeks apart, and in individuals 18 years of age and older determined to be at high risk of monkeypox infection when two 0.1 mL doses are administered intradermally 4 weeks apart.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Jynneos for the prevention of monkeypox disease as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Jynneos for the prevention of monkeypox disease when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1) The monkeypox virus can cause a serious or life-threatening disease or condition to humans infected by this virus;

2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the use of Jynneos under this authorization may be effective in preventing monkeypox disease, and that, when used under the conditions described in this authorization, the known and potential benefits of this use when used to prevent monkeypox disease outweigh its known and potential risks; and

3) There is no adequate, approved, and available alternative[2] for the unapproved uses of Jynneos to prevent monkeypox disease.[3]

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[2] Although Jynneos is approved as a two-dose series (0.5 mL each) to prevent monkeypox disease in individuals 18 years of age and older determined to be at high risk of monkeypox infection, there is currently not sufficient quantities of this vaccine available for distribution to this population in its entirety using the approved route of administration. Additionally, Jynneos is not approved to provide vaccination in the pediatric population.

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Emergency uses of Jynneos covered by this authorization are supplied by the Administration for Strategic Preparedness & Response (ASPR) to emergency response stakeholders[4] consistent with the terms and conditions of this EUA;
- Use of Jynneos in accordance with this authorization will be administered by vaccination providers[5] and used only to prevent monkeypox disease in:
    1. individuals less than 18 years of age determined to be at high risk of monkeypox infection when two 0.5 mL doses are administered subcutaneously 4 weeks apart, and
    2. individuals 18 years of age and older determined to be at high risk of monkeypox infection when two 0.1 mL doses are administered intradermally 4 weeks apart.
- Jynneos may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

Product Description

Jynneos is supplied as a suspension and does not contain a preservative. Jynneos is approved for use in individuals 18 years of age and older. The FDA-approved dosing regimen is two doses (0.5 mL each) given subcutaneously 4 weeks apart. Under the license, Jynneos is supplied in a single dose vial.

Under this authorization, each vial contains a single dose (0.5 mL) for subcutaneous injection in individuals less than 18 years of age or up to 5 doses (0.1 mL each) for intradermal injection in individuals 18 years of age and older.

Jynneos is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

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[4] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's monkeypox vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers." In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[5] For purposes of this letter, "vaccination provider" refers to anyone who is licensed or otherwise authorized to administer or provide vaccination services (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) in accordance with the applicable emergency response stakeholder's official emergency response plan(s).

- Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization (EUA) of Jynneos (Smallpox and Monkeypox Vaccine, Live, Non-Replicating) for Prevention of Monkeypox Disease in Individuals Determined to be at High Risk for Monkeypox Infection

- Fact Sheet for Recipients and Caregivers About Jynneos (Smallpox and Monkeypox Vaccine, Live, Non-Replicating) to Prevent Monkeypox Disease in Individuals Determined to be at High Risk for Monkeypox Infection

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of use of Jynneos under this authorization, when used to prevent monkeypox disease and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that use of Jynneos under this authorization may be effective in preventing monkeypox disease when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that use of Jynneos (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The authorized emergency use of Jynneos under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), use of Jynneos is authorized to prevent monkeypox disease as described in the Scope of Authorization (Section II) under this EUA, despite the fact that such use does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

The Administration for Strategic Preparedness & Response (ASPR)

A. For distributions under this authorization, ASPR will distribute Jynneos under its direction to the extent such distributions are consistent with and do not exceed the terms of this letter, including distribution with the authorized labeling.

B. ASPR will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. ASPR will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders and vaccination providers) involved in distributing or receiving Jynneos under this authorization. ASPR will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. ASPR may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. ASPR will maintain records regarding release of Jynneos for distribution (i.e., lot numbers, quantity, release date).

F. ASPR will make available to FDA upon request any records maintained in connection with this EUA.

National Institute of Allergy and Infectious Diseases (NIAID)

G. NIAID may request changes to this authorization, including to the authorized Fact Sheets for Jynneos. Any request for changes to this EUA must be submitted to the Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[6]

Bavarian Nordic A/S

H. Bavarian Nordic A/S will submit to the STN 125678 file quarterly manufacturing reports that include a listing of all drug substance and drug product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report. The first report is due November

[6] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. All changes to the authorization require review and concurrence from OVRR. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is also required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

9, 2022. This EUA does not supersede requirements under the biologics license applicable to facilities, equipment, manufacturing, and lot release.

I. Bavarian Nordic A/S must submit reports to Vaccine Adverse Event Reporting System (VAERS) for the following:
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of cardiac events including myocarditis and pericarditis (regardless of seriousness or expectedness)
   - Cases of thromboembolic events and neurovascular events

   These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Bavarian Nordic A/S. All other adverse events must be submitted to VAERS as periodic (non-expedited) reports in compliance with 21 CFR 600.80.

J. Bavarian Nordic A/S must submit to STN 125678 periodic safety reports for Jynneos at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Pharmacovigilance (OBPV)/CBER, beginning after the first full calendar month after authorization. Each periodic safety report must contain consolidated aggregate analysis for all postmarketing and post-authorization spontaneous adverse event reports, and descriptive information which includes:
   - A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
   - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
   - Newly identified safety concerns in the interval; and
   - Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

Emergency Response Stakeholders

K. Emergency response stakeholders will identify vaccination sites to receive authorized Jynneos and ensure its distribution and administration, consistent with the terms of this letter.

L. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

M. Emergency response stakeholders receiving Jynneos will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

N. Vaccination providers will administer the vaccine in accordance with the authorization.

O. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

P. Vaccination providers administering Jynneos must report the following information associated with the administration of Jynneos of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
   - Vaccine administration errors whether or not associated with an adverse event
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of cardiac events including myocarditis and pericarditis
   - Cases of thromboembolic events and neurovascular events

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Jynneos" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. Please also provide a copy of the VAERS form to Bavarian Nordic at 1-800-675-9596.

Q. Vaccination providers will conduct any follow-up requested by the U.S. government, including ASPR, CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

R. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

S. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

T. All descriptive printed matter, advertising, and promotional material, relating to the use of Jynneos under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Page 8 –Dr. Beigel, NIAID

U. All descriptive printed matter, advertising, and promotional material relating to the use of Jynneos under this authorization clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA for use in individuals less than 18 years of age, or as two 0.1 mL doses administered intradermally 4 weeks apart in individuals 18 years of age and older determined to be at high risk of monkeypox infection but has been authorized for emergency use by FDA, under an EUA to prevent monkeypox disease; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of vaccines for use to prevent monkeypox disease is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

Peter W. Marks, M.D., Ph.D.
Director
Center of Biologics Evaluation and Research
Food and Drug Administration

Enclosures

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21834 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2355]

Prescription Drug User Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2023. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2023. These fees apply to the period from October 1, 2022, through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD, 301–796–7223; and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h) establish two different kinds of user fees. Fees are assessed as follows: (1) application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). The statute also includes conditions under which such fees may be waived or reduced (section 736(d) of the FD&C Act), or under which fee exceptions, refunds, or exemptions apply (sections 736(a)(1)(C) through (G), 736(a)(2)(B) through (C), and 736(k) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VII. The base revenue amount for FY 2023 is $1,151,522,958. The FY 2023 base revenue amount is adjusted for inflation, strategic hiring and retention, and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). This amount is further adjusted to include the additional dollar amount as specified in the statute (see section 736(b)(1)(F) of the FD&C Act) to provide for additional full-time equivalent (FTE) positions to support PDUFA VII initiatives. If applicable, an operating reserve adjustment is added to provide sufficient operating reserves of carryover user fees. The amount from the preceding adjustments is then

adjusted to provide for additional direct costs to fund PDUFA VII initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue (see section 736(b)(2) of the FD&C Act).

This document provides fee rates for FY 2023 for an application requiring covered clinical data [1] ($3,242,026), for an application not requiring covered clinical data ($1,621,013), and for the prescription drug program fee ($393,933). These fees are effective on October 1, 2022, and will remain in effect through September 30, 2023. For applications that are submitted on or after October 1, 2022, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2023

The base revenue amount for FY 2023 is $1,151,522,958 (see section 736(b)(1)(A) and (b)(3) of the FD&C Act). This amount is prior to any adjustments made for inflation, the strategic hiring and retention adjustment, CPA, additional dollar amount, operating reserve adjustment (if applicable), and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2023 Statutory Fee Revenue Adjustments for Inflation

PDUFA VII specifies that the $1,151,522,958 is to be adjusted for inflation increases for FY 2023 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all PC&B paid per FTE positions at FDA for the first 3 of the preceding 4 fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications for the first 3 of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(i) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, provides the percent changes from the previous fiscal years, and provides the average percent changes over the first 3 of the 4 fiscal years preceding FY 2023. The 3-year average is 1.3918 percent.

Table 1.--FDA Personnel Compensation and Benefits (PC&B) Each Year and Percent Changes

	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$2,620,052,000	$2,875,592,000	$3,039,513,000	
Total FTE	17,144	17,535	18,501	
PC&B per FTE	$152,826	$163,992	$164,289	
Percent Change From Previous Year	-3.3120%	7.3063%	0.1811%	1.3918%

The payroll adjustment is 1.3918 percent from table 1 multiplied by 61.8539 percent resulting in 0.8609 percent.

The statute specifies that this 1.3918 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of human drug applications. Table 2 shows the PC&B and the total obligations for the process for the review of human drug applications for the first 3 of the preceding 4 fiscal years.

Table 2.--PC&B as a Percent of Total Cost of the Process for the Review of Human Drug Applications

	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$872,087,636	$891,395,106	$959,387,333	
Total Costs	$1,430,338,888	$1,471,144,928	$1,499,064,056	
PC&B Percent	60.9707%	60.5919%	63.9991%	61.8539%

The payroll adjustment is 1.3918 percent from table 1 multiplied by 61.8539 percent resulting in 0.8609 percent.

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(ii)). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.[2]

[1] As used herein, ''covered clinical data'' is ''clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness [that] are required for approval'' (see section 736(a)(1)(A)) of the FD&C Act).

[2] The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0, CUUSS35ASA0.*

Table 3.--Annual and 3-Year Average Percent Change in CPI for Washington-Arlington-Alexandria Area

	2019	2020	2021	3-Year Average
Annual CPI	264.78	267.16	277.73	
Annual Percent Change	1.2745%	0.8989%	3.9568%	2.0434%

The statute specifies that this 2.0434 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of human drug applications obligated. Because 61.8539 percent was obligated for PC&B (as shown in table 2), 38.1461 percent is the portion of costs other than PC&B (100 percent minus 61.8539 percent equals 38.1461 percent). The non-payroll adjustment is 2.0434 percent times 38.1461 percent, or 0.7795 percent.

Next, we add the payroll adjustment (0.8609 percent) to the non-payroll adjustment (0.7795 percent), for a total inflation adjustment of 1.6404 percent (rounded) for FY 2023.

We then multiply the base revenue amount for FY 2023 ($1,151,522,958) by 1.6404 percent which produces an inflation adjustment amount of 18,889,582. Adding this amount to the base revenue amount yields an inflation-adjusted base revenue amount of $1,170,412,541.

B. FY 2023 Strategic Hiring and Retention Adjustment

For each fiscal year, after the annual base revenue established in section II is adjusted for inflation in accordance with section II.A above, the statute directs FDA to further increase the fee revenue and fees to support strategic hiring and retention. For FY 2023, this amount is $9,000,000 (see section 736(c)(2)(A) of the FD&C Act).

C. FY 2023 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2023 of $1,151,522,958 has been adjusted as described in sections II.A and II.B above, this amount shall be further adjusted to reflect changes in the resource capacity needs for the process of human drug application reviews (see section 736(c)(3) of the FD&C Act). Following a process required in statute, FDA established a new CPA methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** of August 3, 2020 (85 FR 46651). This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time.

For FY 2023, updates were made to refine the time reporting categories included within the CPA. As such, the time reporting data and baseline capacity have been revised to match the refinements. In the coming fiscal years, additional updates are anticipated to be made to account for additional activities that are also directly related to the direct review of applications and supplements, including additional formal meeting types and the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved prescription drug products.

The CPA methodology includes four steps:

1. Forecast workload volumes: predictive models estimate the volume of workload for the upcoming FY.

2. Forecast the resource needs: forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs [3] for direct review-related effort. This is then compared to current available resources for the direct review-related workload.

3. Assess the resource forecast in the context of additional internal factors: program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the FY, and the funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

4. Convert the FTE need to dollars: utilizing FDA's fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount.

To determine the FY 2023 CPA, FDA calculated a CPA for the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) individually. The final Center-level results were then combined to determine the total FY 2023 PDUFA CPA. The following section outlines the major components of each Center's FY 2023 PDUFA CPA.

Table 4 summarizes the forecasted workload volumes for CDER in FY 2023 based on predictive models, as well as historical actuals from FY 2021 for comparison.

[3] Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

Table 4.--CDER Actual FY 2021 Workload Volumes and Predicted FY 2023 Workload Volumes

Workload Category	FY 2021 Actuals	FY 2023 Predictions
Efficacy Supplements	260	227
Labeling Supplements	1,072	1,063
Manufacturing Supplements	2,371	2,272
NDA/BLA[1] Original	171	158
PDUFA Industry Meetings (including WROs[2])	3,773	4,594
Active Commercial INDs[3]	9,045	10,389

[1] New drug applications (NDA)/biological license applications (BLA).
[2] Written responses only (WRO).
[3] For purpose of the CPA, this is defined as an active commercial investigational new drug (IND) for which a document has been received in the past 18 months.</PHOTO>

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2023 were then converted into estimated FTE needs for CDER's PDUFA direct review-related work. The resulting expected FY 2023 FTE need for CDER was compared to current resource capacity for direct review related work to determine the FY 2023 resource delta, as summarized in table 5. Refinement of the time reporting categories included in the CPA resulted in a lowering of both the resource capacity and resource forecast compared to prior years.

Table 5.--CDER FY23 PDUFA Resource Delta

Center	Current Resource Capacity	FY 2023 Resource Forecast	Predicted FY 2023 FTE Delta
CDER	1,682	1,833	151

The projected 151 FTE delta was then assessed by FDA in the context of additional operational and internal factors to ensure that a fee adjustment is only made for resources that can be utilized in the fiscal year and for which funds are required to support additional review capacity. CDER recognizes that FY 2023 presents significant hiring commitments for the Center, including the hiring goals set forth for FY 2023 per the PDUFA VII Commitment Letter, as well as hiring commitments for other user fee programs. In addition, current labor market conditions may present continuing hiring and retention challenges. In light of these commitments and challenges, CDER is opting to take a conservative adjustment for FY 2023.

CDER emphasizes that the limiting factor on the FY 2023 adjustment is its ability to net gain additional hires above and beyond the existing committed hires across its user fee programs. If a significant resource gap persists in future years and the Agency's ability to net gain additional hires above existing commitments improves, larger CPA adjustments should be expected.

After assessing current hiring capacity and existing funded vacancies, CDER adjusted the 151 FTE delta to 27 FTEs. The FY 2023 PDUFA CPA for CDER is therefore $8,541,423, as summarized in table 6.

Table 6.--CDER FY 2023 PDUFA CPA

Center	Additional FTEs for FY 2023	Cost for Each Additional FTE	CDER FY 2023 PDUFA CPA
CDER	27	$316,349	$8,541,423

To calculate the FY 2023 PDUFA CPA for CBER, FDA followed the approach outlined above. Table 7 summarizes the forecasted workload volumes for CBER in FY 2023 as well as the corresponding historical actuals from FY 2021 for comparison.

Table 7.--CBER Actual FY 2021 Workload Volumes and Predicted FY 2023 Workload Volumes

Workload Category	FY 2021 Actuals	FY 2023 Predictions
Efficacy Supplements	17	12
Labeling Supplements	39	44
Manufacturing Supplements	778	645
NDA/BLA Original	10	8
PDUFA Industry Meetings (including WROs)	695	645
Active Commercial INDs[1]	1,572	1,857

[1] For purpose of the CPA, this is defined as an active commercial IND for which a document has been received in the past 18 months.

The forecasted CBER PDUFA workload for FY 2023 was then converted into expected FTE resources and compared to current resource capacity for PDUFA direct review work, as summarized in table 8.

Table 8.--CBER FY 2023 PDUFA Resource Delta

Center	Current Resource Capacity	FY 2023 Resource Forecast	Predicted FY 2023 FTE Delta
CBER	370	379	10[4]

The projected 10 FTE delta for CBER was also assessed in the context of other operational and financial factors that may impact the need and/or feasibility of obtaining the additional resources. After considering subject matter expert input on industry trends and ongoing workload impacts stemming from the COVID–19 pandemic, accounting for historical net FTE gains within CBER and the hiring necessary to meet the hiring commitments set forth for FY 2023 in the PDUFA VII commitment letter, subtracting previously funded PDUFA vacancies aligned with CPA-covered activities, CBER determined that an adjustment of 10 additional FTEs for FY 2023 is needed. The FY 2023 CPA for CBER is therefore $3,116,730, as summarized in table 9.

Table 9.--CBER FY 2023 PDUFA CPA

Center	Additional FTEs for FY 2023	Cost for Each Additional FTE	CBER FY 2023 CPA
CBER	10	$311,673	$3,116,730

The CDER and CBER CPA amounts were then added together to determine the PDUFA CPA for FY 2023 of $11,658,153, as outlined in table 10. FDA will track the utilization of the CPA funds to ensure they are supporting the organizational components engaged in PDUFA direct review work to enhance resources and expand staff capacity and capability. Should FDA be unable to utilize any amounts of the CPA funds during the fiscal year, it will not spend those funds and the unspent funds will be transferred to the carryover balance at the end of the fiscal year.

Table 10.--FY 2023 PDUFA CPA

Center	FY 2023 PDUFA CPA
CDER	$8,541,423
CBER	$3,116,730
Total	$11,658,153

D. FY 2023 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VII provides an additional dollar amount for each of the 5 fiscal years covered by PDUFA VII for additional FTE to support enhancements outlined in the PDUFA VII commitment letter. The additional dollar amount for FY 2023 as outlined in statute is $65,773,693 (see section 736(b)(1)(F) of the FD&C Act). This amount will be added to the total FY 2023 PDUFA VII revenue amount.

Table 11.--Base Revenue Amount and Section 736(c)(1) through (3) Adjustment Amounts

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,151,522,958
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	$18,889,583
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	$9,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	$11,658,153
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	$65,773,693
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	**$1,256,844,387**

E. FY 2023 Statutory Fee Revenue Adjustments for Operating Reserve

PDUFA VII provides for an operating reserve that may result in an increase or decrease in fee revenue and fees for a given FY (see section 736(c)(4) of the FD&C Act). For FY 2023, FDA is required to further increase fee revenue and fees if an adjustment is necessary to provide for at least 8 weeks of operating reserves of carryover user fees (see section 736(c)(4)(A)(i) of the FD&C Act). If FDA has carryover balances of user fees in excess of 14 weeks of operating reserves, FDA is required to decrease fee revenue and fees to provide for not more than 14 weeks of operating reserves of

carryover user fees (see section 736(c)(4)(B) of the FD&C Act).

To determine the dollar amounts for the 8-week and 14-week operating reserve thresholds, the adjustments (inflation, strategic hiring and retention, capacity planning, and additional dollar amount) discussed in sections II.A, II.B, II.C, and II.D are applied to the FY 2023 base revenue (see section 736(c)(4)(A) of the FD&C Act), resulting in $1,256,844,387. This amount is then divided by 52 to generate the 1-week operating amount of $24,170,084. The one-week operating amount is then multiplied by 8 and 14. This results in an 8-week threshold amount of $193,360,675 and a 14-week threshold amount of $338,381,181.

To determine the FY 2022 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of July 2022 and forecast collections and obligations in the fourth quarter of FY 2022 combined. This provides an estimated end-of-year FY 2022 operating reserve of carryover user fees, or $184,271,732, which equates to 7.6 weeks of operations.[5]

Because the estimated FY 2022 end-of-year operating reserves of carryover user fees does not exceed the 14-week threshold amount, FDA will not reduce the FY 2023 fees or fee revenue. However, because the estimated FY 2022 end-of-year operating reserves of carryover user fees of $184,271,732 is below the 8-week threshold amount of $193,360,675 by $9,088,943, FDA will apply an operating reserve adjustment of $9,088,943 to increase the fee revenue and fees for FY 2023.

With respect to target revenue for FY 2023, adding the operating reserve adjustment amount of $9,088,943 to the inflation, strategic hiring and retention, CPA, and additional dollar amount of $1,256,844,387 results in the cumulative revenue amount of $1,265,933,330.

Table 12.--Base Revenue Amount and Section 736(c)(1) through (4) Adjustment Amounts

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,151,522,958
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	$18,889,583
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	$9,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	$11,658,153
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	$65,773,693
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	$9,088,943
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	**$1,265,933,330**

F. FY 2023 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VII specifies that an additional direct cost of $44,386,150 is to be added to the total FY 2023 PDUFA revenue amount (see section 736(c)(5) of the FD&C Act). With respect to target revenue for FY 2023, adding the additional direct cost amount of $44,386,150 to the inflation, strategic hiring and retention, CPA, additional dollar amount, and operating reserve adjustment of $1,265,933,330 results in the total revenue amount of $1,310,319,000 (rounded to the nearest thousand dollars).

Table 12.--Total Estimated Adjusted Revenue Amount

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,151,522,958
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	$18,889,583
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	$9,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	$11,658,153
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	$65,773,693
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	$9,088,943
Additional Direct Cost (section 736(c)(5) of the FD&C Act)	$44,386,150
Total Revenue Amount (rounded to the nearest thousand dollars) (sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act	**$1,310,319,000**

[5] For purposes of the operating reserve adjustment under PDUFA VII, the operating reserve of carryover user fees includes only user fee funds that are available for obligation. FDA does not consider part of the operating reserve of carryover user fees certain user fee funds that were collected prior to 2010 and that are held by FDA, but which are considered unavailable for obligation due to lack of an appropriation ($78,850,995).

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate 20 percent of the total revenue amount, amounting to $262,063,800 in FY 2023.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

Historically, FDA has estimated the total number of fee-paying full application equivalents (FAEs) it expects to receive during the next fiscal year by averaging the number of fee-paying FAEs received in the three most recently completed fiscal years. For FY 2023 fee setting, the three relevant fiscal years are FYs 2019, 2020,[6] and 2021. Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.

In estimating the number of fee-paying FAEs, an application requiring covered clinical data[7] counts as one FAE. An application not requiring covered clinical data counts as one-half of an FAE. An application that is withdrawn before filing, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

As table 14 shows, the average number of fee-paying FAEs received annually in FY 2019 through FY 2021 is 80.8333. FDA will set fees for FY 2023 based on this estimate as the number of full application equivalents that will be subject to fees.

Table 14.--Fee-Paying FAEs

	FY 2019	FY 2020	FY 2021	3-Year Average
Fee-Paying FAEs	86.75	65.25	90.5	80.8333

Note: Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.

The FY 2023 application fee is estimated by dividing the average number of full applications that paid fees from FY 2019 through FY 2021, 80.8333, into the fee revenue amount to be derived from application fees in FY 2023, $262,063,800. The result is a fee of $3,242,026 per full application requiring clinical data, and $1,621,013 per application not requiring clinical data.

IV. Fee Calculation for Prescription Drug Fees

PDUFA VII assesses prescription drug program fees for certain prescription drug products. Program fees will be set to generate 80 percent of the total target revenue amount amounting to $1,048,255,200 in FY 2023.

An applicant will not be assessed more than five program fees for a FY for prescription drug products identified in a single approved NDA or BLA (see section 736(a)(2)(C) of the FD&C Act). Applicants are assessed a program fee for a fiscal year for user fee eligible prescription drug products identified in a human drug application approved as of October 1 of such fiscal year. Additionally, applicants are assessed a program fee for a product that is not a prescription drug product on October 1 because it is included in the discontinued section of the Orange Book or the CDER/CBER Biologics List on that date, if the product becomes a fee-eligible prescription drug product during the fiscal year.

FDA estimates 2,876 program fees will be invoiced in FY 2023 before factoring in waivers, refunds, and exemptions. FDA approximates that there will be 70 waivers and refunds granted. In addition, FDA approximates that another 43 program fees will be exempted in FY 2023 based on the orphan drug exemption in section 736(k) of the FD&C Act.

PDUFA VII changes the definition of the same product exception for program fees. FDA determined that 93 products may be eligible for the pharmaceutical equivalence same product exception. An additional exception for program fees for skin-test diagnostic products is included in the PDUFA VII. FDA has determined that there are nine skin-test diagnostic application products that may be eligible for the exception for skin diagnostic tests. FDA estimates 2,661 program fees in FY 2023, after allowing for an estimated 215 waivers and reductions, including the orphan drug exemptions, excepted and exempted fee-liable products. The FY 2023 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($1,048,255,200) by the estimated 2,661 program fees resulting in a FY 2023 program fee of $393,933 (rounded to the nearest dollar).

V. Fee Schedule for FY 2023

The fee rates for FY 2023 are displayed in table 15.

Table 15.--Fee Schedule for FY 2023

Fee Category	Fee Rates for FY 2023
Application	
Requiring clinical data	$3,242,026
Not requiring clinical data	$1,621,013
Program	$393,933

[6] FY 2020 data was omitted in FY 2022 methodology as FDA took into account the global COVID–19 pandemic situation at the time. However, after reviewing the data trend, FY 2020 data is included in this year's methodology given the higher FAE count for FY 2021. See table 13.

[7] As defined in section 736(a)(1)(A)(i) of the FD&C Act.

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application subject to fees under PDUFA VII that is submitted on or after October 1, 2022. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA website after completing the Prescription Drug User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (Note: only full payments are accepted. No partial payments can be made online). Once an invoice is located, ''Pay Now'' should be selected to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties.

Note: The originating financial institution may charge a wire transfer fee, especially for international wire transfers. Applicable wire transfer fees must be included with payment to ensure fees are paid in full. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2023 program fees under the new fee schedule in October 2022. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are generally due on October 3, 2022. However, given the late date of the PDUFA reauthorization, invoices should be paid within 30 days of invoice.

FDA will issue invoices in December 2023 for products that qualify for FY 2023 program fee assessments after the October 2022 billing.

C. Fee Waivers and Refunds

To qualify for consideration for a waiver or reduction under section 736(d) of the FD&C Act, an exemption under section 736(k) of the FD&C Act, or the return of an application or program fee paid under section 736 of the FD&C Act, including if the fee is claimed to have been paid in error, a person must submit to FDA a written request justifying such waiver, reduction, exemption or return not later than 180 days after such fee is due (section 736(i) of the FD&C Act). A request submitted under this paragraph must include any legal authorities under which the request is made.

Dated: October 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21968 Filed 10–5–22; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0242]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 7, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0667. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practices for Positron Emission Tomography Drugs—21 CFR Part 212

OMB Control Number 0910–0667—Revision

FDA current good manufacturing practice (CGMP) regulations in part 212 (21 CFR part 212) are intended to ensure that positron emission tomography (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 U.S. 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 one 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) (21 CFR 212.40(a) and (b)) contain requirements on SOPs regarding receiving, testing, and accepting components. We estimate that four corporate firms will expend approximately 8 hours each to create one procedure for acceptance of raw materials and components (a total of four 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) (21 CFR 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 four corporate firms will expend approximately 8 hours each to establish one procedure (a total of four procedures), which results in a total recordkeeping burden of approximately 32 hours.

Section 212.90(a) (21 CFR 212.90(a)) requires the establishment and maintenance of written procedures for the distribution of PET drug products. We estimate that four corporate firms will each expend approximately 8 hours to establish and maintain one written procedure regarding the distribution of PET drugs (a total of four records), which results in a total recordkeeping burden of approximately 32 hours.

Sections 212.20(e) and 212.100(a), (b), and (c) (21 CFR 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) (21 CFR 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 four corporate QA sites will expend approximately 2 hours to document and investigate one 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 a 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 (one 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 tests 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 seven PET drug producers will submit two reports to FDA and send one notification (a total of three 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.

In the **Federal Register** of April 7, 2022 (87 FR 20420), FDA published a 60-day notice requesting public comment on the proposed collection of information. Five comments were received and are summarized here.

The comments did not question the necessity of this proposed collection with two of the comments specifically stating that they support the collection of information as it is necessary for the performance of FDA's functions. However, the comments questioned the FDA's burden collection estimates.

FDA believes that this proposed collection is necessary in keeping with the Agency's mission of ensuring the safety and efficacy of human drugs. Regarding the estimates included, FDA has taken a generalized approach for these estimates, assuming that corporate firms will take on certain burdens for all facilities under their purview, rather than calculating all burdens per facility, and understanding that due to variation among facilities the number of batches and products being produced will vary. We have also only included estimates for tasks that are included within part 212 and note that three comments referenced tasks, such as annual product review, that are outside the scope. We also note that there are no new information collections or revisions to these existing information collections since 2019. We will continue to update the burden estimate as circumstances warrant.

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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 through 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 and 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 and 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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 through 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 and 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 (30 minutes)	662
Subparts C and H; §§ 212.20 and 212.71					
OOS Investigations (SOP) §§ 212.20(c) and 212.71(a) and (b)	63	1	63	8	504
Subpart J; § 212.90					
Distribution Records (SOP) § 212.90(a)	63	1	63	8	504
Subparts C and K; §§ 212.20 and 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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 (30 minutes)	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, 212.50, and 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 (15 minutes)	10,920
Subparts C and E; §§ 212.20 and 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 through 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

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR CORPORATE FIRMS [1]—Continued

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Subpart H; § 212.71					
OOS Investigations (record events and investigations) § 212.71(b)	91	2	182	2	364
Subparts H and K; §§ 212.70 and 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 (15 minutes)	5,460
Subpart J; § 212.90					
Distribution Records § 212.90(b)	91	240	21,840	0.25 (15 minutes)	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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 (30 minutes)	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, 212.50, and 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 (30 minutes)	11,760
Subparts C and E; §§ 212.20 and 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 (30 minutes)	294
Subparts G and H; §§ 212.60 through 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 (30 minutes)	2,352
Subpart H; § 212.71					
OOS Investigations (record events and investigations) (§ 212.71(b))	49	2	98	2	196
Subparts H and K; §§ 212.70 and 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 (15 minutes)	1,176
Subpart J; § 212.90					
Distribution Records § 212.90(b)	49	96	4,704	0.25 (15 minutes)	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 recordkeeping	Total hours [2]
Subparts C and F; §§ 212.20 and 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 (30 minutes)	168
Subparts D, F, and G; §§ 212.30, 212.50, and 212.60					
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 (30 minutes)	910
Subparts C and E; §§ 212.20 and 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 (30 minutes)	168
Subparts G and H; §§ 212.60 through 212.70					
Laboratory Testing Records (record QC test results) §§ 212.60(g), 212.61(b), and 212.70(d)(2) and (3)	14	24	336	0.5 (30 minutes)	168
Subpart H; §§ 212.70 and 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 (15 minutes)	84
Subpart J; § 212.90					
Distribution Records § 212.90(b)	14	24	336	0.25 (15 minutes)	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 section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	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 (30 minutes)	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 (30 minutes)	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 (15 minutes)	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 (30 minutes)	46

TABLE 6—ESTIMATED ONE-TIME AND ANNUAL RECORDKEEPING BURDEN FOR EXTERNAL CONTROL TESTING LABORATORIES [1]—Continued

Information collection activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
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	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 one notification is sent to the receiving site.

Our estimated burden for the information collection reflects an overall increase of 25,463 hours and a corresponding increase of 84,709 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: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21842 Filed 10–6–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2375]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Monkeypox Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of monkeypox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Quest Diagnostics Nichols Institute (Quest Diagnostics). The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States (U.S.) citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of September 7, 2022.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military

emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

II. Criteria for EUA Authorization

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorization

The Authorization follows the August 9, 2022, determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. Notice of the Secretary's determination was provided in the **Federal Register** on August 15, 2022 (87 FR 50090). On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on September 13, 2022 (87 FR 56074). On September 7, 2022, having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA issued an EUA to Quest Diagnostics for the Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR, subject to the terms of the Authorization. The Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent revision to the Authorization can be found on FDA's web page at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

U.S. FOOD & DRUG ADMINISTRATION

September 7, 2022

Michael J. Wagner, Esq.
Senior Corporate Counsel
Quest Diagnostics Incorporated
33608 Ortega Highway
San Juan Capistrano, CA 92675

Device:	Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR
EUA Number:	EUA220415
Company:	Quest Diagnostics Nichols Institute ("Quest Diagnostics")
Indication:	This test is authorized for the qualitative detection of DNA from monkeypox virus (West African clade; clade II)[1] and non-variola *Orthopoxvirus* in lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) in universal viral transport media (UTM) from individuals suspected of monkeypox virus infection by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

Dear Mr. Wagner:

This letter is in response to your[2] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[3] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On August 9, 2022, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health

[1] On August 12, 2022, following a meeting convened by the World Health Organization (WHO) monkeypox virus variants were renamed to align with current best practices under the International Classification of Diseases and the WHO Family of International Health Related Classifications (WHO-FIC). This letter will refer to the former West African clade as clade two (II). Refer to: https://www.who.int/news/item/12-08-2022-monkeypox--experts-give-virus-variants-new-names.

[2] For ease of reference, this letter will use the term "you" and related terms to refer to Quest Diagnostics Nichols Institute ("Quest Diagnostics"), a subsidiary of Quest Diagnostics Incorporated.

[3] For ease of reference, this letter will use the term "your product" to refer to the Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR used for the indication identified above.

emergency, or a significant potential for a public health emergency, that affects or has a significant potential to affect national security or the health and security of United States citizens living abroad that involves monkeypox virus.[4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on September 7, 2022 that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, subject to the terms of any authorization issued under Section 564(a) of the Act.[5]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the EUA Summary (identified below). There is an FDA-cleared test for the qualitative detection of non-variola *Orthopoxvirus*, that includes monkeypox virus, but this is not an adequate and available alternative to your product.[6]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The monkeypox virus can cause a serious or life-threatening disease or condition, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, and that the known and potential benefits of your product when used for diagnosing monkeypox virus, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[7]

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[4] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 87 FR 50090 (August15, 2022).

[5] U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying An Authorization Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.

[6] To date, the FDA-cleared CDC Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set (Product Code: PBK; DEN070001, K181205, K221658, K221834, K222558) is the only test available in the United States with FDA clearance for the detection of non-variola *Orthopoxvirus* DNA, including vaccinia, cowpox, monkeypox and ectromelia viruses at varying concentrations. Available information indicates that timely detection of monkeypox cases in the United States requires wide availability of diagnostic testing to control the spread of this contagious infection and there is currently a need for additional diagnostic testing for monkeypox virus in the United States.

[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a real-time PCR test intended for the qualitative detection of DNA from monkeypox virus (clade II) and non-variola *Orthopoxvirus* in lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) in universal viral transport media (UTM) from individuals suspected of monkeypox infection by their healthcare provider. Testing is limited to laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

The monkeypox virus (clade II) and non-variola *Orthopoxvirus* nucleic acid is generally detectable in human pustular or vesicular rash specimens during the acute phase of infection. Positive results are indicative of the presence of monkeypox virus (clade II) and/or other non-variola *Orthopoxvirus* DNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results obtained with this device do not preclude monkeypox virus (clade II) or non-variola *Orthopoxvirus* infection and should not be used as the sole basis for treatment or other patient management decisions.

To use your product, monkeypox virus (clade II) or non-variola *Orthopoxvirus* nucleic acid is first extracted, isolated and purified from lesion swab specimens followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument described in the authorized labeling (described below).

Your product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents (as may be requested under Condition J. below) commonly used in clinical laboratories, as described in the authorized labeling (described below).

Your product requires use of control materials or other authorized control materials (as may be requested under Condition J. below) that are described in the authorized labeling (described below). All controls must generate expected results in order for the test result to be valid, as outlined in the authorized labeling (described below).

The labeling entitled"Monkeypox Virus Qualitative Real-Time PCR (Test Code 12084 Package Insert", the EUA Summary (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices), and the following fact sheets pertaining to the emergency use, are required to be made available as set forth below and in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Quest Diagnostics Nichols Institute - Quest

Diagnostics Monkeypox Virus Qualitative Real-Time PCR

- Fact Sheet for Patients: Quest Diagnostics Nichols Institute - Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR

The above described product, when accompanied by the "Monkeypox Virus Qualitative Real-Time PCR (Test Code 12084) Package Insert," the EUA Summary (identified above), and the two Fact Sheets as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by the authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Quest Diagnostics Nichols Institute (You)

A. Your product must comply with the following labeling requirements: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

C. You must make your product available with the authorized labeling to authorized laboratories.

D. You must make available on your website(s) the Fact Sheet for Healthcare Providers and Fact Sheet for Patients.

E. You must ensure that the authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

F. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.

G. You are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You must maintain customer complaint files concerning your product and must report to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics /Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov) any significant deviations from the established performance characteristics of your product of which you become aware.

I. You must have a process in place to track adverse events and report to FDA pursuant to 21 CFR Part 803.

J. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling. Any request for changes to this EUA should be submitted to DMD/OHT7/OPEQ/CDRH and requires appropriate authorization from FDA prior to implementation.

K. You must evaluate the analytical limit of detection and assess traceability of your

product with any FDA-recommended reference material(s), if requested by FDA.[8] After submission to and concurrence with the data by FDA, you will update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH. FDA will update the EUA Summary to reflect the additional testing.

L. You must evaluate the impact of monkeypox viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

M. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

N. You must further evaluate the clinical performance of your product using natural clinical lesion swab specimens in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

O. You must complete the agreed upon specimen stability study to evaluate frozen UTM specimens within 3 months of the date of this letter (unless otherwise agreed to with DMD/OHT7 /OPEQ/CDRH). After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

P. You must submit to FDA a summary report within 30 calendar days of the date of this letter summarizing the results of any testing performed during that timeframe, including how many specimens were received, the positivity rate for specimens received and the results for the RNase P specimen control including the invalid rate.

Authorized Laboratories

[8] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

Q. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

R. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

S. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

T. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

U. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (michael.j.wagner@questdiagnostics.com) any significant deviations from the established performance characteristics of your product of which they become aware.

V. Authorized laboratories must have a process in place to track adverse events and report to you (via email: michael.j.wagner@questdiagnostics.com) and to FDA pursuant to 21 CFR Part 803.

W. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling your product and use your product in accordance with the authorized labeling.

Quest Diagnostics Nichols Institute (You) and Authorized Laboratories

X. You and authorized laboratories must ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

Y. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Z. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of monkeypox virus or other non-variola orthopoxviruses.

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Page 8 – Michael J. Wagner, Esq., Quest Diagnostics Nichols Institute ("Quest Diagnostics")

AA. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from monkeypox virus or other non-variola orthopoxviruses, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21829 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1427]

Agency Information Collection Activities; Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

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 the information collection provisions of our regulations mandating the application of hazard

analysis and critical control point (HACCP) principles to the processing and importing of fruit and vegetable juices.

DATES: Either electronic or written comments on the collection of information must be submitted by December 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–1427 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice.'' 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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice—21 CFR Part 120 OMB Control Number 0910–0466—Extension

This information collection supports regulations in part 120 (21 CFR part 120) which mandate the application of HACCP procedures to the processing of fruit and vegetable juices. HACCP is a preventative system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)). Under section 402(a)(4) of the FD&C Act, a food is adulterated if it is prepared, packed, or held under

insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. The Agency also has authority under section 361 of the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State, territory, or possession to another, or from outside the United States into this country. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Under HACCP, processors of fruit and vegetable juices establish and follow a preplanned sequence of operations and observations (the HACCP plan) designed to avoid or eliminate one or more specific food hazards, and thereby ensure that their products are safe, wholesome, and not adulterated; in compliance with section 402 of the FD&C Act. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety.

In an effort to reduce burden and assist respondents, our website (*https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/juice-haccp*) offers guidance for industry, training and education, and background information to assist the food industry in developing and implementing a Juice HACCP. Included in this information are guidance documents entitled ''Juice HACCP and the FDA Food Safety and Modernization Act'' (December 2021) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-haccp-and-fda-food-safety-modernization-act*) and ''Juice HACCP Hazards and Controls Guidance—First Edition'' (March 2004) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first*). All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
120.6(c) and 120.12(a)(1) and (b); require written monitoring and correction records for Sanitation Standard Operating Procedures.	1,875	365	684,375	0.1 (6 minutes).	68,438
120.7; 120.10(a); and 120.12(a)(2), (b) and (c); require written hazard analysis of food hazards.	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b); require a record-keeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan.	1,450	14,600	21,170,000	0.01 (1 minute).	211,700
120.10(c) and 120.12(a)(4)(ii) and (b); require that all corrective actions taken in response to a deviation from a critical limit be documented.	1,840	12	22,080	0.1 (6 minutes).	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12 (a)(5) and (b); require records showing that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures.	1,840	52	95,680	0.1 (6 minutes).	9,568
120.11(b) and (c); and 120.12(a)(5) and (b); require that every processor record the validation that the HACCP plan is adequate to control food hazards that are likely to occur.	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b); require documentation of revalidation of the hazard analysis upon any changes that might affect the original hazard analysis (applies when a firm does not have a HACCP plan because the original hazard analysis did not reveal hazards likely to occur).	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d) and 120.12(b); require that importers of fruit or vegetable juices, or their products used as ingredients in beverages, have written procedures to ensure that the food is processed in accordance with our regulations in part 120.	308	1	308	4	1,232
120.8(a), 120.8(b), and 120.12(a)(3), (b), and (c); require written HACCP plan.	1,560	1.1	1,716	60	102,960
Total	.....	.....	.....	.....	461,426

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 provides our estimate for the next 3 years for the total annual recordkeeping burden of our regulations in part 120. Based on our experience with the information collection over the past 3 years, our burden estimate remains unchanged since our last review of the information collection.

Dated: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21862 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–D–0049, FDA–2018–N–3031, FDA–2021–N–1302, FDA–2022–N–0117, FDA–2013–N–0377, FDA–2013–N–0297, FDA–2012–D–0429, and FDA–2011–N–0921]

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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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
Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act	0910–0732	8/31/2025
Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	0910–0749	8/31/2025
Registration of Food Facilities	0910–0502	9/30/2025
Authorization of Medical Products for Use Emergencies	0910–0595	9/30/2025
Tobacco Health Document Submission	0910–0654	9/30/2025
Production, Storage, and Transportation of Shell Eggs (preventing *Salmonella Enteritidis* (SE))	0910–0660	9/30/2025
Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products	0910–0731	9/30/2025
Standards for the Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption	0910–0816	9/30/2025

Dated: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21864 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that BYLVAY (odevixibat) manufactured by Albireo AB, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that BYLVAY (odevixibat) manufactured by Albireo AB, meets the criteria for a priority review voucher. BYLVAY (odevixibat) capsules and oral pellets are indicated for the treatment of pruritus in patients 3 months of age and older, with progressive familial intrahepatic cholestasis.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about BYLVAY (odevixibat), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: September 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21865 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the applicant of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review

vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that SKYSONA (elivaldogene autotemcel), manufactured by bluebird bio, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the applicant of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that SKYSONA (elivaldogene autotemcel), manufactured by bluebird bio, Inc., meets the criteria for a priority review voucher. SKYSONA is indicated to slow the progression of neurologic dysfunction in boys 4 to 17 years of age with early active cerebral adrenoleukodystrophy.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about SKYSONA, go to the Center for Biologics Evaluation and Research Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21851 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on November 10, 2022, from 9 a.m. to 5 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 including information regarding special accommodations due to a disability may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *Jarrod.Collier@fda.hhs.gov,* 240–672–5763, 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 Agency'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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On November 10, 2022, the committee will discuss and make recommendations on the classification of ophthalmic dispensers, which are currently unclassified pre-amendment devices to class I (general controls). This will include a discussion of the known risks and safety/effectiveness concerns and a general classification recommendation for ophthalmic dispensers.

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, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Select 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 committee. Written submissions may be made to the contact person on or before October 20, 2022. Oral presentations from the public will be scheduled on November 10, 2022, between approximately 9:15 a.m. and 10:15 a.m. Eastern Time. 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 October 12, 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 October 13, 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 Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21831 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0022]

Technical Mapping Advisory Council; Meeting

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of federal advisory committee meeting.

SUMMARY: The Federal Emergency Management Agency (FEMA) Technical Mapping Advisory Council (TMAC) will hold an in-person public meeting with a virtual option on Monday, October 24, 2022, and Tuesday, October 25, 2022. The meeting will be open to the public in-person and via a Microsoft Teams Video Communications link.

DATES: The TMAC will meet on Monday, October 24, 2022, and Tuesday, October 25, 2022, from 8 a.m. to 5 p.m. eastern time (ET). Please note that the meeting will close early if the TMAC has completed its business.

ADDRESSES: The meeting will be held in-person at FEMA Headquarters, 400 C Street SW, Washington, DC 20024, and virtually using the following Microsoft Teams Video Communications link (Monday Link: *https://bit.ly/3qNkBu7*; Tuesday Link: *https://bit.ly/3Lxe2pm*). Members of the public who wish to attend the in-person or virtual meeting must register in advance by sending an email to *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper) by 5 p.m. ET on Thursday, October 20, 2022. For information on services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** caption below as soon as possible.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the TMAC, as listed in the **SUPPLEMENTARY INFORMATION** caption below. Associated meeting materials will be available upon request after Monday, October 17, 2022. The draft 2022 TMAC Annual Report Outline will be available for review after Monday, October 17, 2022. To receive a copy of any relevant materials, please send the request to: *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper). Written comments to be considered by the committee at the time of the meeting must be submitted and received by Wednesday, October 19, 2022, 5 p.m. ET identified by Docket ID FEMA–2014–0022, and submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address the email to: *FEMA-TMAC@fema.dhs.gov.* Include the docket number in the subject line of the message. Include name and contact information in the body of the email.
- *Instructions:* All submissions received must include the words ''Federal Emergency Management Agency'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For docket access to read background documents or comments received by the TMAC, go to *http://www.regulations.gov* and search for the Docket ID FEMA–2014–0022.

A public comment period will be held on Monday, October 24, 2022, from 3:30 p.m. to 4 p.m. ET and Tuesday, October 25, 2022, from 11:45 a.m. to 12:15 p.m. ET. The public comment period will not exceed 30 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker by Wednesday, October 19, 2022, 5 p.m. ET.

FEMA is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** caption as soon as possible.

FOR FURTHER INFORMATION CONTACT: Brian Koper, Designated Federal Officer for the TMAC, FEMA, 400 C Street SW, Washington, DC 20024, telephone 202–646–3085, and email *brian.koper@fema.dhs.gov.* The TMAC website is: *https://www.fema.gov/flood-maps/guidance-partners/technical-mapping-advisory-council.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. app.

In accordance with the *Biggert-Waters Flood Insurance Reform Act of 2012,* the TMAC makes recommendations to the FEMA Administrator on: (1) how to improve, in a cost-effective manner, the (a) accuracy, general quality, ease of use, and distribution and dissemination of flood insurance rate maps and risk data; and (b) performance metrics and milestones required to effectively and efficiently map flood risk areas in the United States; (2) mapping standards and guidelines for (a) flood insurance rate maps, and (b) data accuracy, data quality, data currency, and data eligibility; (3) how to maintain, on an ongoing basis, flood insurance rate maps and flood risk identification; (4) procedures for delegating mapping activities to State and local mapping partners; and (5)(a) methods for improving interagency and intergovernmental coordination on flood mapping and flood risk determination, and (b) a funding strategy to leverage and coordinate budgets and expenditures across Federal agencies. Furthermore, the TMAC is required to submit an annual report to the FEMA Administrator that contains: (1) a description of the activities of the Council; (2) an evaluation of the status and performance of flood insurance rate maps and mapping activities to revise and update Flood Insurance Rate Maps; and (3) a summary of recommendations made by the Council to the FEMA Administrator.

Agenda: The purpose of this meeting is for the TMAC members to discuss and vote on the content of the 2022 TMAC Annual Report Outline. Any related materials will be available upon request prior to the meeting to provide the public an opportunity to review the materials. The full agenda and related meeting materials will be available upon request by Monday, October 17, 2022. To receive a copy of any relevant materials, please send the request to:

FEMA-TMAC@fema.dhs.gov (Attn: Brian Koper).

Michael M. Grimm,

Assistant Administrator for Risk Management, Federal Emergency Management Agency.

[FR Doc. 2022–21867 Filed 10–6–22; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0122]

Agency Information Collection Activities; Revision of a Currently Approved Collection: USCIS Online Account Access

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until November 7, 2022.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2011–0015. All submissions received must include the OMB Control Number 1615–0122 in the body of the letter, the agency name and Docket ID USCIS–2011–0015.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on July 25, 2022, at 87 FR 44142, allowing for a 60-day public comment period. USCIS did not receive any comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2011–0015 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* USCIS Online Account Access.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No Agency Form Number; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. In order to create a new USCIS Online Account, members of the public (*i.e.* users) must submit a valid email address; create a password; select their preferred method for interacting with a two-step verification process (authentication app, text message, or email); and provide responses to five password reset questions of their choice. Any given email address may be associated with only one USCIS Online Account; users may not establish multiple accounts using the same email address. A user is required to complete a two-step verification process upon creation of a new account and during each subsequent log-in. USCIS makes use of the information received during the account creation process to set up the user's profile. Once the account is established/the user has logged in, the user can edit/add certain profile information or select a USCIS online system with which to interact.

USCIS systems currently accessible by logging in through the USCIS Online Account Access process are: myUSCIS, the Freedom of Information Act electronic request system (FIRST), and myE-Verify. These systems serve specific, unique purposes and may require the user to provide information beyond what is required to create an account/log in through the USCIS Online Account Access process. Each system may be considered a collection of information in its own right and be covered by its own OMB Control Numbers. USCIS may add additional online systems for public use in the future.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the USCIS Online Account Access information collection is 3,397,160 and the estimated hour burden per response is 0.167 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 567,326 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0.

Dated: September 30, 2022.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–21837 Filed 10–6–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–36]

60-Day Notice of Proposed Information Collection: Section 202 Housing for the Elderly and Section 811 Housing for the Disabled Capital Advance and Project Rental Assistance, OMB Control No.: 2502–0470

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 6, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Section 202 Housing for Elderly and Section 811 Housing for Disabled.

OMB Approval Number: 2502–0470.

OMB Expiration Date: May 31, 2020.

Type of Request: Reinstatement with change of previously approved collection for which approval has expired.

Form Number: HUD–: 2328; 2453.1–CA; 2530; 2554; 2880; 935.2; 9832; 9839–A; 9839–B; 9839–C; 51994; 90163–CA; 90163.1–CA; 90164–CA; 90165–CA; 90166–CA; 90166a–CA; 90167–CA; 90169–CA; 90169.1–CA; 90170–CA; 90171–CA; 90172–A–CA; 90172–B–CA; 90173–A–CA; 90173–B–CA; 90173–C–CA; 90175–CA; 90175.1–CA; 90176–CA; 90177–CA; 90178–CA; 90179–CA; 91732–A–CA; 92013; 92013–SUPP; 92264; 92330; 92330–A; 92329; 92331; 92403.1; 92403–CA; 92408–M; 92412–CA, 92433–CA; 92434–CA; 92435–CA; 92437; 92442–CA; 92442–A–CA; 92443–CA; 92448; 92450–CA; 92452; 92452a; 92452–CA; 92457; 92458; 92464; 92466–CA; 92466.1–CA; 92476–A; 92476–A–CA; 92485; 92580–CA; 93432–CA; 93479; 93480–CA; 93481; 93566–CA; 93566.1–CA; 27054; 50080–CAH, SF–425; SF–1199a; SF–LLL; and FM–1006.

Description of the need for the information and proposed use: This submission is to permit the continued processing of all sections 202 and 811 capital advance projects that have not yet been finally closed. The submission includes processing of the application for firm commitment to final closing of the capital advance. It is needed to assist HUD in determining the Owner's eligibility and capacity to finalize the development of a housing project under the section 202 and section 811 Capital Advance Programs. HUD is also adding a new standard form to facilitate the renewal of project rental assistance contracts (PRACs). The form will reflect long-standing contract amendment language with updates to accommodate availability of both 5-year and annual terms for Section 202 PRACs. The number of annual contract renewal amendments is expected decrease for each of the next three years as additional properties switch from annual to five-year contracts. The Department also notes that PRAC contract renewal amendments may be executed utilizing DocuSign to obtain owner and HUD staff signatures.

Respondents: Business or other for-profit, Multifamily HUD sponsored property owners and developers.

Estimated Number of Respondents: 5,995. (195 new projects/5,800 renewing projects).

Estimated Number of Responses: 13,609. (7,809 for new projects/5,800 for renewing projects).

Frequency of Response: Occasion or Annual.

Average Hours per Response: 1.07.

Total Estimated Burden: 14,561.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–21855 Filed 10–6–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–30]

60-Day Notice of Proposed Information Collection: Mortgagor's Certificate of Actual Cost; OMB Control No.: 2502–0112

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 6, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in section A.

A. Overview of Information Collection

Title of Information Collection: Mortgagor's Certificate of Actual Cost.

OMB Approval Number: 2502–0112.

Type of Request: Reinstatement, without change, of previously approved collection for which approval has expired.

Form Number: HUD–92330.

Description of the Need for the Information and Proposed Use: HUD uses form HUD–92330 to obtain data from a mortgagor relative to actual cost of a project. The mortgagor is required to certify to HUD the project's actual cost by submitting the form. HUD uses the cost information to determine the maximum insurable mortgage for final endorsement of an insured mortgage. Actual cost is defined in section 227c of National Housing Act. In addition, form HUD–92330 must be accompanied by an audited balance sheet certified by an accountant unless the project has less than 40 units, or if it is a refinancing or a purchase of an existing project under sections 207/223f or 232/223f of the National Housing Act.

Estimated Number of Respondents: 1,168.

Estimated Number of Responses: 1,168.

Frequency of Response: 1.

Average Hours per Response: 8.

Total Estimated Burden: 9,344.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–21853 Filed 10–6–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–41]

60-Day Notice of Proposed Information Collection: COVID–19 Supplemental Payment Requests OMB Control No.: 2502–0619

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 6, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments can dial 7–1–1 to access the Telecommunications Relay Service (TRS), which permits users to make

text-based calls, including Text Telephone (TTY) and Speech to Speech (STS) calls. Individuals who require an alternative aid or service to communicate effectively with HUD should email the point of contact listed above and provide a brief description of their preferred method of communication. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: COVID–19 Supplemental Payment Requests.

OMB Approval Number: 2502–0619.

OMB Expiration Date: December 31, 2022.

Type of Request: Extension of a currently approved collection.

Form Number: HUD Form 52671–E.

Description of the need for the information and proposed use: Form 52671–E, will continue to be completed by owners of properties with Section 8 Housing Assistance Payment contracts, Section 202 and Section 811 Project Rental Assistance contracts, Section 202/162 Project Assistance contracts, and Section 202 Senior Preservation Rental Assistance contacts, who wish to receive a supplemental payment to offset operating cost increases to prevent, prepare, and respond to the effects of COVID–19. HUD expects to reissue the form in 2022 with minor updates to reflect additional funding periods and other Housing Notice cross-references. Similar updates may be made in subsequent years should funding for the activity remain available and again be offered to owners. HUD anticipates continuing use of DocuSign to complete targeted follow-up with respondents for the portion of HUD 52671–E submissions that involve delayed certification of completed installation for capital equipment purchases. DocuSign templates used under this collection may be updated periodically with new dates and to improve clarity about the requirements, as needed.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 23,200.

Estimated Number of Responses: 46,400.

Frequency of Response: 1.

Average Hours per Response: .55 hours per response.

Total Estimated Burden: 25,520.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–22051 Filed 10–6–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

[DT64101000.DSB4A0000.T7AC00.24IA; OMB Control Number 1035–0003]

Agency Information Collection Activities; Application To Withdraw Tribal Funds From Trust Status, 25 CFR 1200

AGENCY: Office of Assistant Secretary-Indian Affairs, Bureau of Trust Funds Administration (formerly known as the Office of the Special Trustee for American Indians), Department of the Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Trust Funds Administration (BTFA), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before November 7, 2022.

ADDRESSES: Send written comments on this information collection request (ICR) by mail to Nina Alexander, Bureau of Trust Funds Administration, Director of Federal Information Resources, 4400 Masthead Street NE, Albuquerque, NM 87109; or by email to *Nina_Alexander@btfa.gov.* Please reference Office of Management and Budget (OMB) Control Number 1035–0003 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Nina Alexander, Director, Federal Information Resources, Bureau of Trust Funds Administration at 4400 Masthead Street NE, Albuquerque, NM 87109; or by email at *Nina_Alexander@btfa.gov* or via telephone at 505–273–1620.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice (87 FR 35241) with a 60-day public comment period soliciting on this collection of information was published on June 9, 2022. No comments were received in response to that notice.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following: (1) Whether the collection of information is necessary for the proper performance of the functions of the BTFA, including whether or not the information will have practical utility; (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) How might the agency minimize the burden of the collection of information on those who are to respond, including 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 response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire

comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: U.S.C. 25 chapter 42, subchapter 11, The American Indian Trust Fund Management Reform Act of 1994 (the Act) allows Indian Tribes on a voluntary basis to take their funds out of trust status within the Department of the Interior (and the Federal Government) in order to manage such funds on their own. 25 CFR part 1200, subpart B, section 1200.13, ''How does a Tribe apply to withdraw funds?'' describes the requirements for application for withdrawal. The Act generally covers all tribal trust funds including judgment funds as well as some settlements funds, but excludes funds held in Individual Indian Money accounts and Other Trust Funds. Both the Act and the regulations state that upon withdrawal of the funds, the Department of the Interior (and the Federal Government) have no further liability for such funds. Accompanying their application for withdrawal of trust funds, Tribes are required to submit a Management Plan for managing the funds being withdrawn, to protect the funds once they are out of trust status.

This information collection allows the BTFA to collect the Tribe's applications for withdrawal of funds held in trust by the Department of the Interior. If BTFA did not collect this information, the BTFA would not be able to comply with the Act, and Tribes would not be able to withdraw funds held for them in trust by the Department of the Interior.

Title of Collection: Application to Withdraw Tribal Funds from Trust Status, 25 CFR 1200.

OMB Control Number: 1035–0003.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Tribal governments.

Total Estimated Number of Annual Respondents: One respondent, on average, every three years.

Total Estimated Number of Annual Responses: 1.

Estimated Completion Time per Response: 750 hours.

Total Estimated Number of Annual Burden Hours: 750.

Respondent's Obligation: Required to obtain or maintain a benefit.

Frequency of Collection: One per Tribe per trust fund withdrawal application.

Total Estimated Annual Non-Hour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Jeffrey Parrillo,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–21873 Filed 10–6–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[XXXD5198NI DS61100000 DNINR0000.000000 DX61104]

Exxon Valdez Oil Spill Public Advisory Committee Charter

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of renewal.

SUMMARY: The U.S. Department of the Interior announces the charter renewal of the *Exxon Valdez* Oil Spill Public Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Grace Cochon, U.S. Department of the Interior, Office of Environmental Policy and Compliance, 1011 E Tudor Road, Anchorage, Alaska 99503, 907–227–3781.

SUPPLEMENTARY INFORMATION: The Court Order establishing the *Exxon Valdez* Oil Spill Trustee Council also requires a public advisory committee. The Public Advisory Committee was established to advise the Trustee Council and began functioning in October 1992. The Public Advisory Committee consists of 10 members representing the following principal interests: aquaculture/mariculture, commercial fishing, commercial tourism, recreation, conservation/environmental, Native landownership, sport hunting/fishing, subsistence, science/technology, and public-at-large. In order to ensure that a broad range of public viewpoints continues to be available to the Trustee Council, and in keeping with the settlement agreement, the continuation of the Public Advisory Committee is recommended.

In accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C., app. 2), and in consultation with the General Services Administration, the Secretary of the Interior hereby renews the charter for the *Exxon Valdez* Oil Spill Public Advisory Committee.

Certification Statement: I hereby certify that the renewal of the charter for the *Exxon Valdez* Oil Spill Public Advisory Committee is necessary and in the public interest in connection with the performance of duties mandated by the settlement of *United States* v. *State of Alaska,* No. A91–081 CV, and is in accordance with the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended and supplemented.

Authority: 5 U.S.C. appendix 2.

Dated: October 3, 2022.

Deb Haaland,

Secretary of the Interior.

[FR Doc. 2022–21944 Filed 10–6–22; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–34644; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before September 24, 2022, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by October 24, 2022.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before September

24, 2022. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

Key: State, County, Property Name, Multiple Name (if applicable), Address/Boundary, City, Vicinity, Reference Number.

KENTUCKY

McCracken County

Paducah Northside Historic District, Roughly bounded by North 10th St., Park Ave., North 15th, and Northview St., Paducah, SG100008325

MISSOURI

Jasper County

Joplin East Town Historic District, Roughly bounded by Broadway Langston Hughes, Landreth Ave., Hill St., and Division Ave, Joplin, SG100008307

NEBRASKA

Colfax County

Merchant Park, (New Deal Work Relief Projects in Nebraska MPS), Corner of Higgins Dr. and Adams St., Schuyler, MP10000831

Douglas County

Stephenson and Williams Livery, (Warehouses in Omaha MPS), 1114 Florence Blvd., Omaha, MP100008314

Florence Commercial Historic District, (Streetcar-Era Commercial Development in Omaha, Nebraska MPS), 8500–8702 North 30th St., Omaha, MP100008315

Clifton Hill Commercial Historic District, (Streetcar-Era Commercial Development in Omaha, Nebraska MPS), 1900–2200 blks. Military Ave., Omaha, MP100008316

NEW YORK

Columbia County

Red Rock Schoolhouse, 459 Cty. Rd. 24, Red Rock, SG100008311, Muldor-Miller House, (Claverack MPS), 571 NY 23B, Claverack, MP100008312

Monroe County

Hickey-Freeman Company Building, 1155 North Clinton Ave., 24 Morrill St., and 313 Ave. D, Rochester, SG100008310

Crosman Terrace Historic District, 21 to 188 Crosman Terr., Rochester, SG100008317

Montgomery County

Fort Plain Historic District (Boundary Increase), Portions of Abbott, Canal, Hancock, Beck, Clyde, Douglas, Edwards, Erie, Garfield, Hancock, Henry, Herkimer, High, Main, Reid, River, Roof, State, Wagner, Webster, Willett, and Witter Sts.., Clark, Clinton, Gilbert, Silk, and Waddell Aves., Fort Plain, BC100008321

Ontario County

Bristol Center Methodist Episcopal Church, 4471 NY 64, Bristol vicinity, SG100008319

Wyoming County

Perry Village Hall, 46 North Main St., Perry, SG100008318

OREGON

Clatsop County

Cahill-Nordstrom Farm, 85926 Cahill Rd., Clatskanie vicinity, SG100008331

Marion County

Salem Civic Center Historic District, 555 Liberty St. SE, Salem, SG100008330

Multnomah County

Carey, Judge Charles Henry and Mary Bidwell, House, 1950 South Carey Ln., Portland, SG100008329

Polk County

Dallas Cinema, 166 SE Mill St., Dallas, SG100008328

VIRGINIA

Nelson County

Blue Ridge Tunnel, 215 Afton Depot Ln., Afton vicinity, SG100008324

Virginia Beach Independent City

Blue Marlin Lodge, (Virginia Beach Oceanfront Resort Motels and Hotels, 1955–1970 MPS), 2411 Pacific Ave., Virginia Beach, MP100008322

Crest Kitchenette Motel, (Virginia Beach Oceanfront Resort Motels and Hotels, 1955–1970 MPS), 3614 Atlantic Ave., Virginia Beach, MP100008323

Additional documentation has been received for the following resources:

ARKANSAS

Monroe County

La Belle House (Additional Documentation), (Thompson, Charles L., Design Collection TR), 312 New York Ave., Brinkley, AD82000866

NEW YORK

Montgomery County

Fort Plain Historic District (Additional Documentation), Portions of Abbott, Canal, Hancock, Beck, Clyde, Douglas, Edwards, Erie, Garfield, Hancock, Henry, Herkimer, High, Main, Reid, River, Roof, State, Wagner, Webster, Willett, and Witter Sts., Clark, Clinton, Gilbert, Silk, and Waddell Aves., Fort Plain, AD12000510

Authority: Section 60.13 of 36 CFR part 60.

Dated: September 28, 2022.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2022–21859 Filed 10–6–22; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1236]

Certain Polycrystalline Diamond Compacts and Articles Containing Same; Notice of the Commission's Final Determination Finding No Violation of Section 337; 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 to find no violation of section 337 of the Tariff Act of 1930, as amended, in this investigation. The investigation is terminated in its entirety.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2392. 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 December 29, 2020, based on a complaint filed by US Synthetic Corporation (''USS'') of Orem, Utah. 85 FR 85661 (Dec. 29, 2020). The complaint 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 polycrystalline diamond compacts and articles containing same by reason of infringement of certain claims of U.S.

Patent No. 10,507,565 (''the '565 patent''); U.S. Patent No. 10,508,502 (''the '502 patent''); U.S. Patent No. 8,616,306 (''the '306 patent''); U.S. Patent No. 9,932,274 (''the '274 patent''); and U.S. Patent No. 9,315,881 (''the '881 patent''). *Id.* The complaint further alleged that an industry in the United States exists as required by section 337. *Id.* The notice of investigation named as respondents: SF Diamond Co., Ltd., and SF Diamond USA, Inc. (collectively, ''SF Diamond''); Element Six Abrasives Holdings Ltd., Element Six Global Innovation Centre, Element Six GmbH, Element Six Limited, Element Six Production (Pty) Limited, Element Six Hard Materials (Wuxi) Co. Limited, Element Six Trading (Shanghai) Co., Element Six Technologies US Corporation, Element Six US Corporation, ServSix US, and Synergy Materials Technology Limited (collectively, ''Element Six''); Iljin Diamond Co., Ltd., Iljin Holdings Co., Ltd., Iljin USA Inc., Iljin Europe GmbH, Iljin Japan Co., and Ltd., Iljin China Co., Ltd. (collectively, ''Iljin''); Henan Jingrui New Material Technology Co., Ltd. (''Jingrui''); Zhenzghou New Asia Superhard Materials Composite Co., Ltd., and International Diamond Services, Inc. (collectively, ''New Asia/IDS''); CR Gems Superabrasives Co., Ltd. (''CR Gems''); FIDC Beijing Fortune International Diamond (''FIDC''); Fujian Wanlong Superhard Material Technology Co., Ltd. (''Wanlong''); Zhujau Juxin Technology (''Juxin''); [1] and Shenzhen Haimingrun Superhard Materials Co., Ltd. (''Haimingrun'') (together, ''the Respondents''). *Id.* at 85662. The Office of Unfair Import Investigations did not participate in the investigation. *Id.*

USS moved to terminate the investigation as to Element Six and FIDC over the course of the investigation. All of the motions were granted by non-final initial determinations (''ID''), and the Commission did not review them. *See* Order Nos. 6 (Feb. 1, 2021), 8 (Feb. 8, 2021), 10 (Feb. 24, 2021), and 16 (Apr. 1, 2021). Thus, the only remaining respondents are Iljin, SF Diamond, New Asia/IDS, Haimingrun, Juxin, CR Gems, Jingrui, and Wanlong.

USS also moved for partial termination of the investigation with respect to certain asserted patents and claims. All the motions were granted by non-final IDs, and the Commission did not review them. *See* Order Nos. 26 (Jul. 14, 2021), 32 (Aug. 9, 2021), and 57 (Oct. 19, 2021). As such, the '274 and '881 patents have been terminated from the investigation. Claims 1, 2, 4, 6, and 18 of the '565 patent; claims 1, 2, 11, 15, and 21 of the '502 patent; and claim 15 of the '306 patent remain in this investigation (collectively, ''the Asserted Patents'').

On April 27, 2021, a technology tutorial and *Markman* hearing was held. On May 24, 2021, Order No. 23 issued, which construed certain claim terms of the patents at issue. An evidentiary hearing took place during the week of October 18–22, 2021.

On March 3, 2022, the administrative law judge (''ALJ'') issued his final ID, finding no violation of section 337 by Respondents. Specifically, the ID found at least one accused product infringes all asserted claims of the Asserted Patents, but those claims are invalid under 35 U.S.C. 101 and/or 102. The ID also found that Complainant has shown that the domestic industry requirement has been satisfied with respect to the Asserted Patents. Complainant and Respondents filed separate petitions for review and responses to the petitions for review. On March 31, 2022, Iljin submitted a public interest statement.

On May 9, 2022, the Commission determined to review the ID in part. 87 FR 29375–377 (May 13, 2022). Specifically, the Commission determined to review: (1) the ID's finding that the asserted claims are invalid under 35 U.S.C. 101; (2) the ID's finding that the asserted claims of the '565 patent are not entitled to an earlier priority date and, thus, they are invalid as anticipated by the sale of the CT–57 product; (3) the ID's finding that the Mercury product anticipates claims 1 and 2 of the '565 patent and claims 1 and 11 of the '502 patent; (4) the ID's finding that Respondents did not prove that the asserted claims are not enabled; and (5) the ID's findings regarding the economic prong of the domestic industry requirement (including the ruling allowing USS to supplement its domestic industry contentions with a revenue-based allocation method). The Commission determined not to review any other findings presented in the ID, including the ID's finding of no violation of section 337 with respect to the '306 patent. The Commission requested briefing from the parties on certain issues under review and on remedy, the public interest, and bonding. Complainant and Respondents filed their opening written submissions on May 23, 2022, and their responsive written submissions on May 31, 2022. The Commission did not receive comments from the public on public interest issues raised by the ALJ's recommended relief.

Having reviewed the record of the investigation, including the final ID and the parties' submissions, the Commission has found no violation of section 337 as to claims 1, 2, 4, 6, and 18 of the '565 patent and claims 1, 2, 11, 15, and 21 of the '502 patent. Specifically, the Commission affirms with modifications the ID's finding that the asserted claims of the '502, '565, and '306 patents are directed to an abstract idea and, thus, are patent ineligible under 35 U.S.C. 101. The Commission also affirms with modifications the ID's finding that the asserted claims of the '565 patent are not entitled to an earlier priority date and, thus, the claims are anticipated by the prior art CT–57. The Commission reverses the ID's finding that the Mercury PDC, manufactured by Diamond Innovations, Inc., anticipates claims 1 and 2 of the '565 patent and claims 1 and 11 of the '502 patent. The Commission affirms with modifications the ID's finding that Respondents have not proven that the asserted claims of the '502, '565, and '306 patents are not enabled. Having affirmed the ID's findings that the asserted claims are invalid, the Commission has determined to take no position on the economic prong of the domestic industry requirement.

Commissioner Schmidtlein joins the Commission's decision affirming the ID's section 102 findings as modified in the Majority opinion but dissents from the Majority's decision to affirm the ID's section 101 findings as explained in her dissenting views. She would also affirm with modifications the ID's conclusion that USS established the economic prong of the domestic industry requirement for the '565 patent and the '502 patent under subsections (A), (B), and (C) of section 337(a)(3). Accordingly, she would find a violation based on infringement of claims 1, 2, 11, 15, and 21 of the '502 patent.

The investigation is terminated with a finding of no violation. The Commission's reasoning in support of its determinations is set forth more fully in its opinion issued concurrently herewith.

The Commission vote for this determination took place on October 3, 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.

[1] On February 8, 2021, Guangdong Juxin Materials Technology Co., Inc. was substituted in place of Zhuhai Juxin Technology. *See* Order No. 8 (Feb. 8, 2021).

Issued: October 3, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–21828 Filed 10–6–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1073]

Bulk Manufacturer of Controlled Substances Application: Cambridge Isotope Laboratories Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cambridge Isotope Laboratories, has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before December 6, 2022. Such persons may also file a written request for a hearing on the application on or before December 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 July 18, 2022, Cambridge Isotope Laboratories, Inc., 50 Frontage Road Andover, Massachusetts 01810–5413, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

The company plans to synthetically bulk manufacture the controlled substance Tetrahydrocannabinols to produce analytical standards for distribution to its customers. No other activities for these drug codes are authorized for this registration.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–21923 Filed 10–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1074]

Importer of Controlled Substances Application: Cardinal Health, DBA Specialty Pharmaceutical Service

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cardinal Health, DBA Specialty Pharmaceutical Service has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before November 7, 2022. Such persons may also file a written request for a hearing on the application on or before November 7, 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. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 25, 2022, Cardinal Health, DBA Specialty Pharmaceutical Service, 15 Ingram Boulevard, La Vergne, Tennessee 37086–3630, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Nabilone	7379	II

The company plans to import the above controlled substance in finished dosage form for distribution to licensed registrants for the purpose of medical use only. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2).

Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–21924 Filed 10–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1071]

Importer of Controlled Substances Application: Fresenius Kabi USA, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Fresenius Kabi USA, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit

electronic comments on or objections to the issuance of the proposed registration on or before November 7, 2022. Such persons may also file a written request for a hearing on the application on or before November 7, 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. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on August 3, 2022, Fresenius Kabi USA, LLC, 3159 Staley Road, Grand Island, New York 14072–2028, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Remifentanil	9739	II

The company plans to import the listed controlled substance(s) as bulk material in order to manufacture Food and Drug Administration (FDA)-approved dosage forms. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA-approved or non-approved finished dosage forms for commercial sale.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–21920 Filed 10–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1075]

Importer of Controlled Substances Application: Cambrex High Point, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cambrex High Point, Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before November 7, 2022. Such persons may also file a written request for a hearing on the application on or before November 7, 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. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 26, 2022, Cambrex High Point, Inc., 4180 Mendenhall Oaks Parkway, High Point, North Carolina 27265–8017, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Poppy Straw Concentrate	9670	II

The company plans to import the listed controlled substance for research and development purposes. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–21929 Filed 10–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employment and Training Administration

Labor Surplus Area Classification

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce the annual Labor Surplus Area (LSA) list for Fiscal Year (FY) 2023.

DATES: The annual LSA list is effective October 1, 2022, for all states, the District of Columbia, and Puerto Rico.

FOR FURTHER INFORMATION CONTACT: Samuel Wright, Office of Workforce Investment, Employment and Training

Administration, 200 Constitution Avenue NW, Room C–4514, Washington, DC 20210. Telephone: (202) 693–2870 (This is not a toll-free number) or email *wright.samuel.e@dol.gov.*

SUPPLEMENTARY INFORMATION: The Department of Labor's regulations implementing Executive Orders 12073 and 10582 are set forth at 20 CFR part 654, subpart A. These regulations require the Employment and Training Administration (ETA) to classify jurisdictions as LSAs pursuant to the criteria specified in the regulations, and to publish annually a list of LSAs. Pursuant to those regulations, ETA is hereby publishing the annual LSA list.In addition, the regulations provide exceptional circumstance criteria for classifying LSAs when catastrophic events, such as natural disasters, plant closings, and contract cancellations are expected to have a long-term impact on labor market area conditions, discounting temporary or seasonal factors.

Eligible Labor Surplus Areas

A LSA is a civil jurisdiction that has a civilian average annual unemployment rate during the previous two calendar years of 20 percent or more above the average annual civilian unemployment rate for all states during the same 24-month reference period. ETA uses only official unemployment estimates provided by the Bureau of Labor Statistics in making these classifications. The average unemployment rate for all states includes data for the Commonwealth of Puerto Rico. The LSA classification criteria stipulate a civil jurisdiction must have a ''floor unemployment rate'' of 6 percent or higher to be classified a LSA. Any civil jurisdiction that has a ''ceiling unemployment rate'' of 10 percent or higher is classified a LSA.

Civil jurisdictions are defined as follows:

1. A city of at least 25,000 population on the basis of the most recently available estimates from the Bureau of the Census; or

2. A town or township in the States of Michigan, New Jersey, New York, or Pennsylvania of 25,000 or more population and which possess powers and functions similar to those of cities; or

3. All counties, except for those counties which contain any type of civil jurisdictions defined in ''1'' or ''2'' above; or

4. A ''balance of county'' consisting of a county less any component cities and townships identified in ''1'' or ''2'' above; or

5. A county equivalent which is a town in the States of Connecticut, Massachusetts, and Rhode Island, or a municipio in the Commonwealth of Puerto Rico.

Procedures for Classifying Labor Surplus Areas

The Department of Labor (DOL) issues the LSA list on a fiscal year basis. The list becomes effective each October 1, and remains in effect through the following September 30. The reference period used in preparing the current list was January 2020 through December 2021. The national average unemployment rate (including Puerto Rico) during this period is rounded to 6.71 percent. Twenty percent higher than the national unemployment rate during this period is rounded to 8.05 percent. To ensure that all areas classified as labor surplus meet the requirements, when a city is part of a county and meets the unemployment qualifier as a LSA, that city is identified in the LSA list, the balance of county, not the entire county, will be identified as a LSA if the balance of county also meets the LSA unemployment criteria. The data on the current and previous years' LSAs are available at *www.dol.gov/agencies/eta/lsa.*

Petition for Exceptional Circumstance Consideration

The classification procedures also provide criteria for the designation of LSAs under exceptional circumstances criteria. These procedures permit the regular classification criteria to be waived when an area experiences a significant increase in unemployment which is not temporary or seasonal and which was not reflected in the data for the 2-year reference period. Under the program's exceptional circumstance procedures, LSA classifications can be made for civil jurisdictions, Metropolitan Statistical Areas or Combined Statistical Areas, as defined by the U.S. Office of Management and Budget. In order for an area to be classified as a LSA under the exceptional circumstance criteria, the state workforce agency must submit a petition requesting such classification to the Department of Labor's ETA. The current criteria for an exceptional circumstance classification are:

1. An area's unemployment rate is at least 6 percent for each of the three most recent months; and

2. A projected unemployment rate of at least 6 percent for each of the next 12 months because of an event.

When submitting such a petition, the state workforce agency must provide documentation that the exceptional circumstance event has occurred. The state workforce agency may file petitions on behalf of civil jurisdictions, Metropolitan Statistical Areas, or Micropolitan Statistical Areas.

State Workforce Agencies may submit petitions in electronic format to *wright.samuel.e@dol.gov,* or in hard copy to the U.S. Department of Labor, Employment and Training Administration, Office of Workforce Investment, 200 Constitution Avenue NW, Room C–4514, Washington, DC 20210, Attention Samuel Wright. Data collection for the petition is approved under OMB 1205–0207, expiration date May 31, 2023.

Signed at Washington, DC.

Brent Parton,

Acting Assistant Secretary for Employment and Training Administration.

[FR Doc. 2022–21885 Filed 10–6–22; 8:45 am]

BILLING CODE 4510–FN–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 22–14]

Notice of Entering Into a Compact With the Government of Malawi

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the provisions of the Millennium Challenge Act of 2003, as amended, the Millennium Challenge Corporation (MCC) is publishing a summary of the Millennium Challenge Compact (Compact) between the United States of America and the Republic of Malawi. Representatives of MCC and the Government of Malawi executed the Compact on September 28, 2022. The complete text of the Compact has been posted at: *https://assets.mcc.gov/content/uploads/compact-malawi-transport-land.pdf.*

(Authority: 22 U.S.C. 7709 (b)(3))

Dated: October 4, 2022.

Thomas G. Hohenthaner,

Acting VP/General Counsel and Corporate Secretary.

Summary of Malawi Compact

Overview of MCC Malawi Compact

MCC's five-year, $350,000,000 Compact with the Republic of Malawi (Government) aims to reduce poverty through economic growth by targeting key binding constraints in the transport and land sectors. The Compact will address these constraints through three projects that seek to achieve this goal by

reducing costs of transport in targeted rural areas and improving land services. The Government also will contribute approximately $26,250,000 to support the Compact program.

Project Summaries

The Compact is comprised of three projects:

1. *Accelerated Growth Corridors Project:* The objective of the Accelerated Growth Corridors Project is to reduce costs of transport in targeted rural areas. The Project includes two activities:

- *Road Corridor Improvement Activity:* This activity aims to target investment in physical upgrades and improvements across different classes of roads within four selected corridors to improve rural access by addressing road conditions and reducing transport costs.
- *Policy and Institutional Reform and Capacity Building Activity:* This activity focuses on assistance to the Government to address policy, legislative, institutional, and funding issues to ensure that road transport in Accelerated Growth Corridors is well-maintained and managed.

2. *Increased Land Productivity Project:* The objective of the Increased Land Productivity Project is to improve land services. The Project includes two activities:

- *Land Administration Resourcing and Institutions Activity:* This aims to support analysis, reform, and implementation of reforms to expand national land-based revenues, address institutional change, and address the land rights records that underpin land institution work.
- *City Council Land-Based Revenue Modernization Activity:* This activity aims to expand coverage and collection of land-based revenues, as well as to increase resources for key services and increase investment in land. MCC Funding shall support a sequence of activities in up to four cities (Lilongwe, Blantyre, Mzuzu, and Zomba).

3. *ACFD Project:* The compact program also includes allocation for the American Catalyst Facility for Development (ACFD) Project. The purpose of this funding is to facilitate U.S. International Development Finance Corporation (DFC) investments in Malawi. MCC and DFC will discuss specific transactions to be supported by the ACFD Project which shall be agreed to by the Parties in writing after proposals submitted by the DFC have undergone the ACFD screening and approvals process. Transactions supported by the ACFD Project shall be consistent with the missions of both MCC and DFC, as well as all applicable statutory requirements and authorities.

Malawi Compact Budget

The table below presents the Compact budget and sets forth both the MCC funding allocation by Compact components and the Government's expected $26,250,000 contribution toward the objectives of the Compact.

MALAWI COMPACT TOTAL BUDGET

Component	MCC funding
1. Accelerated Growth Corridors Project	$244,950,000
1.1 Road Corridor Improvement Activity	228,998,000
1.2 Policy and Institutional and Capacity Building Reform Activity	15,952,000
2. Increased Land Productivity Project	44,107,000
2.1 Land Administration Resourcing and Institutions Activity	20,034,685
2.2 City Council Land-Based Revenue Modernization Activity	24,072,315
3. American Catalyst Facility for Development	8,500,000
4. Monitoring and Evaluation	3,000,000
5. Program Management and Administration	49,443,000
Total MCC Funding	350,000,000
Total compact funding	**Amount**
Total MCC Funding	350,000,000
Government of Malawi Contribution	26,250,000
Total Compact	376,250,000

[FR Doc. 2022–21882 Filed 10–6–22; 8:45 am]
BILLING CODE 9211–03–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Geosciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

NAME AND COMMITTEE CODE: Advisory Committee for Geosciences (1755).

DATE AND TIME:

November 3, 2022; 11 a.m.–4:30 p.m. EDT.

November 4, 2022; 11 a.m.–4:00 p.m. EDT.

PLACE: NSF 2415 Eisenhower Avenue, Alexandria, VA 22314/Virtual.

Meeting registration information is available on the GEO Advisory Committee website at *https://www.nsf.gov/geo/advisory.jsp*).

TYPE OF MEETING: Open.

CONTACT PERSON: Melissa Lane, National Science Foundation, Room C 8000, 2415 Eisenhower Avenue, Alexandria, Virginia 22314; Phone 703–292–8500.

MINUTES: May be obtained from the contact person listed above.

PURPOSE OF MEETING: To provide advice, recommendations, and oversight on support for geoscience research and education including atmospheric, geospace, earth, ocean, and polar sciences.

Agenda

November 3, 2022

- Directorate and NSF activities and plans
- Panel Discussion with NSF Program Officers on Broader Impacts
- Discussion of AC GEO Report on 21st Century Geosciences (September 2021)

November 4, 2022

- Review and Vote on OCE Integrative Programs Section COV Report/ Response
- Update on NSF Learning Agenda Related to Climate Equity

- Meeting with the NSF Chief Operating Officer
- Action Items/Planning for Spring 2023 Meeting

Dated: 10/4/2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–21856 Filed 10–6–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of October 10, 17, 24, 31, November 7, 14, 2022. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Tyesha.Bush@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of October 10, 2022

Tuesday, October 11, 2022

10:00 a.m. NRC All Employees Meeting (Public Meeting); (Contact: Anthony DeJesus: 301–287–9219)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Thursday, October 13, 2022

9:00 a.m. Strategic Programmatic Overview of the Operating Reactors and New Reactors Business Lines (Public Meeting), (Contact: Jennie Rankin, 301–415–1530)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of October 17, 2022—Tentative

There are no meetings scheduled for the week of October 17, 2022.

Week of October 24, 2022—Tentative

There are no meetings scheduled for the week of October 24, 2022.

Week of October 31, 2022—Tentative

There are no meetings scheduled for the week of October 31, 2022.

Week of November 7, 2022—Tentative

Tuesday, November 8, 2022

9:00 a.m. Briefing on Regulatory Approaches for Fusion Energy Devices (Public Meeting) (Contact: Samantha Lav: 301–415–3487)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Thursday, November 10, 2022

10:00 a.m. Briefing on NRC International Activities (Public Meeting) (Contact: Jen Holzman, 301–287–9090)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of November 14, 2022—Tentative

There are no meetings scheduled for the week of November 14, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: October 5, 2022.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2022–22080 Filed 10–5–22; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–250 and 50–251; NRC–2022–0172]

Notice of Intent To Conduct Scoping Process and Prepare Environmental Impact Statement Florida Power & Light Company Turkey Point Nuclear Generating Unit Nos. 3 and 4

AGENCY: Nuclear Regulatory Commission.

ACTION: Subsequent license renewal application supplement; intent to conduct scoping process and prepare environmental impact statement; and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received Environmental Report, Supplement 2, from Florida Power & Light Company (FPL, the applicant), dated June 9, 2022, related to FPL's application for subsequent license renewal (SLR) of Renewed Facility Operating License Nos. DPR–31 and DPR–41 for Turkey Point Nuclear Generating Unit Nos. 3 and 4 (Turkey Point). The NRC staff has determined that the Environmental Report, Supplement 2, is acceptable for docketing, and that the staff will prepare a supplement to its final supplemental environmental impact statement (FSEIS) for Turkey Point subsequent license renewal, *i.e.,* NUREG–1437, Supplement 5, Second Renewal, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Supplement 5, Second Renewal, Regarding Subsequent License Renewal for Turkey Point Nuclear Generating Unit Nos. 3 and 4, Final Report'' (October 2019). The subsequent renewed operating licenses would authorize the applicant to operate Turkey Point for an additional 20 years beyond the period specified in each of the current licenses. The current operating licenses for Turkey Point Unit Nos. 3 and 4 expire on July 19, 2032, and April 10, 2033, respectively. The NRC will conduct a limited scoping process to gather information necessary to prepare a supplement to its environmental impact statement (EIS) to evaluate the environmental impacts of SLR of the operating licenses for Turkey Point. The NRC is seeking public comment on the proper scope of the EIS

supplement to be prepared for this action.

DATES: Submit comments by November 7, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*).

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0172. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–287–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email:* Comments may be submitted to the NRC electronically using the email address *TurkeyPoint34Environmental@nrc.gov.*
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information, see ''Obtaining Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lance Rakovan, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2589; email: *Lance.Rakovan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0172 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0172.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.
- *Public Library:* A copy of the subsequent license renewal report supplement for Turkey Point, is available for public review at the Naranja Branch Library, 14850 SW 280 Street, Homestead, Florida 33032.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2022–0172 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

By letters dated January 30, 2018; February 9, 2018, February 16, 2018, March 1, 2018, and April 10, 2018, the NRC received an application from FPL, filed pursuant to Section 103 of the Atomic Energy Act of 1954, as amended (the Act), and Part 54 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Requirements for Renewal of Operating Licenses for Nuclear Power Plants,'' to renew the operating licenses for Turkey Point at 2,644 megawatt thermal each. The Turkey Point nuclear units are located in Miami-Dade County, east of Florida City, Florida. Each unit consists of a Westinghouse pressurized-water reactor nuclear steam supply system. A notice of receipt of the subsequent license renewal application (SLRA) was published in the **Federal Register** on April 18, 2018 (83 FR 17196). A notice of acceptance for docketing of the supplemented application and opportunity for hearing regarding subsequent license renewal of the facility operating licenses was published in the **Federal Register** on May 2, 2018 (83 FR 19304).

On December 10, 2019 (84 FR 67482), notice was given that the NRC had issued Subsequent Renewed Facility Operating License Nos. DPR–31 and DPR–41 to FPL. Subsequent Renewed Facility Operating License No. DPR–31 authorized operation of Turkey Point Unit 3 through July 19, 2052, at reactor core power levels not in excess of 2,644 megawatts thermal, in accordance with the provisions of the Turkey Point Unit 3 operating license and technical specifications. Subsequent Renewed Facility Operating License No. DPR–41 authorized operation of Turkey Point Unit 4 through April 10, 2053, at reactor core power levels not in excess of 2,644 megawatts thermal, in accordance with the provisions of the Turkey Point Unit 4 operating license and technical specifications. The NRC's Record of Decision (ROD), which supported the NRC's decision to issue Subsequent Renewed Facility Operating License Nos. DPR–31 and DPR–41, is available in the following ''Availability of the Documents'' table.

As discussed in the ROD and the FSEIS for Turkey Point SLR, the NRC staff considered the reasonably foreseeable impacts of subsequent license renewal for Turkey Point Units 3 and 4, as well as a range of reasonable alternatives. In the FSEIS, the NRC staff (a) relied upon the NRC's ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants,'' NUREG–1437 (June 2013) (the GEIS) and 10 CFR part 51, subpart A, Appendix B, Table B–1, to evaluate the environmental impacts of generic (''Category 1'') issues, and (b) evaluated the environmental impacts of site-specific (''Category 2'') issues. The FSEIS documents the staff's environmental review, including the determination that the adverse environmental impacts of subsequent

license renewal for Turkey Point are not so great that preserving the option of subsequent license renewal for energy-planning decisionmakers would be unreasonable.

In the Commission's Memorandum and Order, CLI–22–02, dated February 24, 2022, the Commission reversed its previous decision that, when considering the environmental impacts of subsequent license renewal, the NRC staff may rely on the 2013 GEIS and 10 CFR part 51, subpart A, Appendix B, Table B–1, to evaluate the environmental impacts of generic ''Category 1'' issues. Specifically, the Commission held that 10 CFR 51.53(c)(3) only applies to an initial license renewal applicant's preparation of an environmental report and that the 2013 GEIS did not address subsequent license renewal. As a result, the Commission determined, among other things, that the NRC staff's environmental review of the subsequent license renewal application for Turkey Point Units 3 and 4 was incomplete. In a further Order (CLI–22–06) issued on June 3, 2022, the Commission reaffirmed its determination that the subsequently renewed operating licenses for Turkey Point Unit Nos. 3 and 4 be revised to expire on July 19, 2032, and April 10, 2033, respectively.

Following the issuance of CLI–22–02, the NRC received an Environmental Report, Supplement 2, from FPL, dated June 9, 2022, and noticed in the **Federal Register** on July 26, 2022 (87 FR 44430), related to the subsequent renewal of the operating licenses for Turkey Point. By letter dated September 28, 2022, the NRC staff determined that FPL had submitted sufficient information in accordance with 10 CFR 54.19, 54.21, 54.22, 54.23, 51.45, and 51.53(c), to enable the staff to undertake a review of the environmental report supplement (the supplement), and that the supplement is, therefore, acceptable for docketing. The current Docket Nos. 50–250 and 50–251 for Renewed Facility Operating License Nos. DPR–31 and DPR–41, respectively, will be retained. The determination to accept the supplement for docketing does not constitute a determination that a subsequent renewed operating license should be issued and does not preclude the NRC staff from requesting additional information as the review proceeds.

Given recent circumstances requiring the preparation of a supplement to the previous FSEIS for subsequent license renewal for Turkey Point Unit Nos. 3 and 4, the NRC staff will conduct a limited scoping process associated with this action. Consistent with Commission direction, the NRC staff intends to prepare a draft supplement to the Turkey Point FSEIS for public comment, in which it will review all applicable ''Category 1'' (generic) issues listed in the FSEIS at Table 4–1, for the purpose of making site-specific findings (*e.g.,* SMALL, MODERATE, LARGE) on those issues. The NRC staff also intends to review ''Category 2'' (site-specific) issues listed in the FSEIS at Table 4–2 for any significant new information that may have arisen following the issuance of the FSEIS (*i.e.,* October 2019) and will update the site-specific analyses, as appropriate. Environmental scoping comments should address matters that fit within these two categories; comments that do not fit into these two categories will not be considered.

III. Request for Comment

This notice informs the public of the NRC's intention to prepare an FSEIS supplement related to the subsequent license renewal application and to provide the public an opportunity to participate in the environmental scoping process, as defined in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.''

Participation in the scoping process by members of the public and local, State, Tribal, and Federal government agencies is encouraged. The scoping process for the supplement to the FSEIS will be used to accomplish the following:

a. Define the proposed action, which is to be the subject of the supplement to the FSEIS, to the extent not addressed in the FSEIS;

b. Determine the scope of the supplement to the FSEIS and identify the significant issues to be analyzed in depth;

c. Identify and eliminate from detailed study those issues that are peripheral or are not significant; or were covered by a prior environmental review;

d. Identify any environmental assessments and other EISs that are being or will be prepared that are related to, but are not part of, the scope of the supplement to the FSEIS being considered;

e. Identify other environmental review and consultation requirements related to the proposed action;

f. Indicate the relationship between the timing of the preparation of the environmental analyses and the Commission's tentative planning and decisionmaking schedule;

g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completing the supplement to the FSEIS to the NRC and any cooperating agencies; and

h. Describe how the supplement to the FSEIS will be prepared, including any contractor assistance to be used.

The NRC invites the following entities to participate in scoping:

a. The applicant, Florida Power & Light Company;

b. Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved or that is authorized to develop and enforce relevant environmental standards;

c. Affected State and local government agencies, including those authorized to develop and enforce relevant environmental standards;

d. Any affected Indian Tribe;

e. Any person who requests or has requested an opportunity to participate in the scoping process; and

f. Any person who has petitioned or intends to petition for leave to intervene.

Participation in the scoping process for the Turkey Point subsequent license renewal supplement to the FSEIS does not entitle participants to become parties to the proceeding to which the supplement to the FSEIS relates. Matters related to participation in any hearing are outside the scope of matters to be discussed.

IV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document description	Adams Accession No.
Subsequent License Renewal Application—Appendix E Environmental Report Supplement 2, dated June 9, 2022.	ML22160A301.
''Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Supplement 5, Second Renewal, Regarding Subsequent License Renewal for Turkey Point Nuclear Generating Unit Nos. 3 and 4, Final Report,'' dated October 2019.	ML19290H346.

Document description	Adams Accession No.
Turkey Point subsequent license renewal application and initial supplements.	ML18037A812 (Package), ML18044A653, ML18053A137, ML18078A027, ML18072A230, ML18072A232, ML18102A521, ML18113A134, ML18113A141, ML18113A142, ML18113A145, ML18113A146, and ML18113A148.
NRC's Record of Decision pertaining to Subsequent Renewed Facility Operating License Nos. DPR–31 and DPR–41, dated December 4, 2019.	ML19309F859.
Commission Memorandum and Order CLI–22–02, dated February 24, 2022.	ML22055A496.
Commission Memorandum and Order CLI–22–06, dated June 3, 2022	ML22154A215.
Letter to William D. Maher, Licensing Director, Nuclear Licensing Projects, FPL—Turkey Point Units 3 and 4 Subsequent License Renewal Application Supplement Environmental Review, dated September 28, 2022.	ML22268A003.

Dated: October 4, 2022.

For the Nuclear Regulatory Commission.

John M. Moses,

Deputy Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Materials, Safety and Safeguards.

[FR Doc. 2022–21919 Filed 10–6–22; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–465, OMB Control No. 3235–0528]

Submission for OMB Review; Comment Request; Extension: Rule 237

Upon Written Request, Copies Available From: Securities and Exchange Commission Office of FOIA Services 100 F Street NE

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension and approval of the collection of information discussed below.

In Canada, as in the United States, individuals can invest a portion of their earnings in tax-deferred retirement savings accounts (''Canadian retirement accounts''). These accounts, which operate in a manner similar to individual retirement accounts in the United States, encourage retirement savings by permitting savings on a tax-deferred basis. Individuals who establish Canadian retirement accounts while living and working in Canada and who later move to the United States (''Canadian-U.S. Participants'' or ''participants'') often continue to hold their retirement assets in their Canadian retirement accounts rather than prematurely withdrawing (or ''cashing out'') those assets, which would result in immediate taxation in Canada.

Once in the United States, however, these participants historically have been unable to manage their Canadian retirement account investments. Most securities that are ''qualified investments'' for Canadian retirement accounts are not registered under the U.S. securities laws. Those securities, therefore, generally cannot be publicly offered and sold in the United States without violating the registration requirement of the Securities Act of 1933 (''Securities Act'').[1] As a result of this registration requirement, Canadian-U.S. Participants previously were not able to purchase or exchange securities for their Canadian retirement accounts as needed to meet their changing investment goals or income needs.

The Commission issued a rulemaking in 2000 that enabled Canadian-U.S. Participants to manage the assets in their Canadian retirement accounts by providing relief from the U.S. registration requirements for offers of securities of foreign issuers to Canadian-U.S. Participants and sales to Canadian retirement accounts.[2] Rule 237 under the Securities Act[3] permits securities of foreign issuers, including securities of foreign funds, to be offered to Canadian-U.S. Participants and sold to their Canadian retirement accounts without being registered under the Securities Act.

Rule 237 requires written offering documents for securities offered and sold in reliance on the rule to disclose prominently that the securities are not registered with the Commission and are exempt from registration under the U.S. securities laws. The burden under the rule associated with adding this disclosure to written offering documents is minimal and is non-recurring. The foreign issuer, underwriter, or broker-dealer can redraft an existing prospectus or other written offering material to add this disclosure statement, or may draft a sticker or supplement containing this disclosure to be added to existing offering materials. In either case, based on discussions with representatives of the Canadian fund industry, the staff estimates that it would take an average of 10 minutes per document to draft the requisite disclosure statement.

The Commission understands that there are approximately 2,553 Canadian issuers other than funds that may rely on rule 237 to make an initial public offering of their securities to Canadian-U.S. Participants.[4] The staff estimates that in any given year approximately 25 (or 1 percent) of those issuers are likely to rely on rule 237 to make a public offering of their securities to participants, and that each of those 25 issuers, on average, distributes 3 different written offering documents concerning those securities, for a total of 75 offering documents.

The staff therefore estimates that during each year that rule 237 is in

[1] 15 U.S.C. 77. In addition, the offering and selling of securities of investment companies (''funds'') that are not registered pursuant to the Investment Company Act of 1940 (''Investment Company Act'') is generally prohibited by U.S. securities laws. 15 U.S.C. 80a.

[2] *See* Offer and Sale of Securities to Canadian Tax-Deferred Retirement Savings Accounts, Release Nos. 33–7860, 34–42905, IC–24491 (June 7, 2000) [65 FR 37672 (June 15, 2000)]. This rulemaking also included new rule 7d–2 under the Investment Company Act, permitting foreign funds to offer securities to Canadian-U.S. Participants and sell securities to Canadian retirement accounts without registering as investment companies under the Investment Company Act. 17 CFR 270.7d–2.

[3] 17 CFR 230.237.

[4] This estimate is based on the following calculation: 3,461 total issuers—(82 closed-end funds + 826 exchange-traded products) = 2,553 total equity and bond issuers. *See* The MiG Report, Toronto Stock Exchange and TSX Venture Exchange (January 2022) (providing number of issuers on the Toronto Exchange). This calculation excludes Canadian funds to avoid double-counting disclosure burdens under rule 237 and rule 7d–2.

effect, approximately 25 respondents [5] would be required to make 75 responses by adding the new disclosure statements to approximately 75 written offering documents. Thus, the staff estimates that the total annual burden associated with the rule 237 disclosure requirement would be approximately 13 hours (75 offering documents × 10 minutes per document). The total annual cost of internal burden hours is estimated to be $5,915 (13 hours × $455 per hour of attorney time).[6]

In addition, issuers from foreign countries other than Canada could rely on rule 237 to offer securities to Canadian-U.S. Participants and sell securities to their accounts without becoming subject to the registration requirements of the Securities Act. However, the staff believes that the number of issuers from other countries that rely on rule 237, and that therefore are required to comply with the offering document disclosure requirements, is negligible.

These burden hour estimates are based upon the Commission staff's experience and discussions with the fund industry. The estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act. These estimates are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules.

Compliance with the collection of information requirements of the rule is mandatory and is necessary to comply with the requirements of the rule in general. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view 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 by November 7, 2022 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*.

Dated: October 3, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–21821 Filed 10–6–22; 8:45 am]

BILLING CODE 8011–01–P

[5] This estimate of respondents only includes foreign issuers. The number of respondents would be greater if foreign underwriters or broker-dealers draft stickers or supplements to add the required disclosure to existing offering documents.

[6] The Commission's estimate concerning the wage rate for attorney time is based on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association (''SIFMA''). The $455 per hour figure for an attorney is from SIFMA's *Management & Professional Earnings in the Securities Industry 2013,* modified by Commission staff to account for an 1800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, overhead, and adjusted to account for the effects of inflation.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–026, OMB Control No. 3235–0033]

Submission for OMB Review; Comment Request; Extension: Rule 17a–3

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

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 extension of the previously approved collection of information provided for in Rule 17a–3 (17 CFR 240.17a–3), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17a–3 under the Securities Exchange Act of 1934 establishes minimum standards with respect to business records that broker-dealers registered with the Commission must make and keep current. These records are maintained by the broker-dealer (in accordance with a separate rule), so they can be used by the broker-dealer and reviewed by Commission examiners, as well as other regulatory authority examiners, during inspections of the broker-dealer.

The collections of information included in Rule 17a–3 are necessary to enable Commission, self-regulatory organization (''SRO''), and state examiners to conduct effective and efficient examinations to determine whether broker-dealers are complying with relevant laws, rules, and regulations. If broker-dealers were not required to create these baseline, standardized records, Commission, SRO, and state examiners could be unable to determine whether broker-dealers are in compliance with the Commission's antifraud and anti-manipulation rules, financial responsibility program, and other Commission, SRO, and State laws, rules, and regulations.

As of December 31, 2021 there were 3,528 broker-dealers registered with the Commission. The Commission estimates that these broker-dealer respondents incur a total hour burden of approximately 8,342,195 hours per year to comply with Rule 17a–3.

In addition, Rule 17a–3 contains ongoing operation and maintenance costs for broker-dealers, including the cost of postage to provide customers with account information, and costs for equipment and systems development. The Commission estimates that the total cost burden associated with Rule 17a–3 would be approximately $105,320,999 per year.

Rule 17a–3 does not contain record retention requirements. Compliance with the rule is mandatory. The required records are available only to the staffs of the Commission, self-regulatory organizations of which the broker-dealer is a member, and the states during examination, inspections and investigations.

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 the 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 by November 7, 2022 to (i) *www.reginfo.gov/public/do/PRAMain* 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.*

Dated: October 3, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–21820 Filed 10–6–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold an Open Meeting on Wednesday, October 12, 2022 at 10:00 a.m.

PLACE: The meeting will be webcast on the Commission's website at *www.sec.gov.*

STATUS: This meeting will begin at 10:00 a.m. (ET) and will be open to the public via webcast on the Commission's website at *www.sec.gov.*

MATTERS TO BE CONSIDERED: The Commission will consider whether to adopt certain rule amendments regarding the electronic recordkeeping and prompt production of records requirements for broker-dealers, security-based swap dealers, and major-security based swap participants under the Securities Exchange Act of 1934.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

(Authority: 5 U.S.C. 552b.)

Dated: October 5, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–22073 Filed 10–5–22; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95964; File No. SR–ICEEU–2022–015]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to the ICE Clear Europe Operational Risk and Resilience Policy

October 3, 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 September 22, 2022, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared primarily by ICE Clear Europe. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') proposes to rename and modify its Operational Risk Management Policy, which will now be known as the Operational Risk and Resilience Policy (the ''Operational Risk and Resilience Policy'' or ''Policy''). The amendments would make certain other clarifications and updates. A copy of the proposed amendments is set forth in Exhibit 5 [sic].[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is proposing to rename its existing Operational Risk Management Policy to be the Operational Risk and Resilience Policy, and to make certain amendments thereto to address operational resilience in addition to operational risk. The amendments would, as set forth herein, expand the description of the framework under which the Clearing House manages operational risk and operational resilience, describe the existing lines of defense maintained by the Clearing House against such risks and the roles and responsibilities of Clearing House committees, personnel and the Board in respect of the framework. The proposed amendments are designed to update the documentation of ICE Clear Europe's practices in this regard to be consistent with requirements of the Bank of England (''BoE'') for central counterparties to establish an operational resilience framework by March 31, 2022 that identifies and prioritises ''important business services,'' sets out impact tolerances in respect of such services, identifies and maps dependencies for such important business services and establishes a scenario testing program with respect to such recovery of such services following disruption.[4] Other non-substantive drafting and similar improvements would also be made to the Policy.

The amendments would provide that the purpose of the document is to set out the Operational Risk and Resilience management framework, including identify and managing relevant risks. (The amendments remove certain unnecessary references to ''operational'' risk throughout the Policy as the entire Policy addresses operational risk.) The Policy would apply to all of the Clearing House's departments and functions.

The amendments would add a new subsection which would describe the Clearing House's existing three lines of defense model for managing risks; the first line of defense (or risk owner) (First Line) is responsible for managing risks to within the defined Board risk appetite and for ensuring adherence to the requirements of the Policy. The First Line would include business departments except for the Risk Oversight Department and Internal Audit. The Risk Oversight Department (ROD) and Enterprise Risk Management (ERM) is the second line of defense (Second Line) and is responsible for challenging the first line and monitoring adherence to the requirement of the Policy. The third line of defense (Third Line) would be the Internal Audit function and would provide independent and objective assurance to the Board. The three lines of defense model is currently used within the Clearing House's risk management framework, and the proposed amendments are intended to more formally document that model, with its existing roles and responsibilities, in the Policy.

The amendments would specifically include Operational Resilience policies

[3] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules and the Operational Risk and Resilience Policy.

[4] The BoE requires central counterparties to establish an operational resilience framework which shall, among other requirements, identify important business services and set impact tolerances for such services. See Bank of England, Supervisory Statement: Operational Resilience—Central Counterparties'' (March 2021), available at: Operational Resilience: Central Counterparties Supervisory Statement March 2021 (*bankofengland.co.uk*) (the ''Supervisory Statement''). See also Bank of England Prudential Regulation Authority, Statement of Policy: Operational Resilience (March 2021), available at SoP 'Operational resilience' (*bankofengland.co.uk*).

as part of the architecture of the documentation which supports the Policy. The amendments would define ''operational resilience'' as the ability to prevent, respond to, recover and learn from operational service disruption events.

In a new subsection describing in more detail the Clearing House's operational risk and resilience framework, the Clearing House would describe the purpose of the framework as to reduce the likelihood of an operational disruption event within acceptable tolerance and mitigate and quickly recover from operational disruption events. The framework would be comprised of the following set of existing complementary policies (certain of which are ICE Clear Europe policies and others are ICE group-wide policies): (i) the Policy, which is intended to ensure that the risk of operational failure of important processes is minimized, (ii) Incident Management Policy, which is intended to provide a cohesive framework for the communication, resolution and recording of incidents and to ensure that incidents are resolved in a planned and controlled manner in order to resolve any interruptions quickly and restore service, (iii) Business Continuity & Disaster Recovery Policy, which is intended to ensure that appropriate plans are in place to recover from a business continuity or disaster recover incident, (iv) Information Security and Cyber Security Strategy, which outlines the responsibilities of users and the steps they must take to protect ICE information and information systems, (v) Outsourcing Policy, which governs outsourcing arrangements to ensure that the Clearing House's minimum operational resilience are met by outsourced service providers, and (vi) Vendor Management Policy, which ensures that requisite due diligence is performed and ensures that vendors have the capacity, resiliency and capability to fully support the Clearing House. (Other than the Policy, the listed policies are not being amended hereby.)

The amendments would also add a new subsection describing the Clearing House's important business services. A business service would be considered important if a prolonged disruption of such service would significantly disrupt the orderly functioning of a market which the Clearing House serves, thereby impacting financial stability. Important business services would be required to be identified and documented, and such identification would help prioritization of these services from an operational resilience viewpoint. For each important business service, dependencies relating to people, processes, technology, facilities, and underlying information would be identified. Identified business services would be required to be reviewed at least annually by the First Line, overseen by the Second Line and approved by an appropriate Board-level Committee. These amendments do not reflect a substantive change in the Clearing House's existing risk management approach but rather formally address relevant services already identified by the Clearing House as being critical in light of the requirement described above under the Supervisory Statement that a central counterparty document its framework for identifying and documenting ''important business services''.

The amendments would include a new subsection which would describe the Clearing House's impact tolerances, which would be defined as the maximum tolerable level of disruption for an important business service, whereby further disruption would pose a significant impact to the market(s) serve by the Clearing House. For each important business service an appropriate impact tolerance would be established, considering the duration of any outage and additional relevant metrics, such as the magnitude of the impact. Additionally, the Clearing House would be required to ensure that appropriate controls and recovery procedures are in place for important business services in order to aid with recovery in the case of service disruption. Monitoring of impact tolerances would need to be in place, with any breach escalated to the Clearing House's Executive Risk Committee and Board. Breaches to impact tolerances would be reviewed by the First Line and a remediation plan established for any identified weakness. Such review outcome and remediation plan would need to be agreed with the Second Line before presentation to the Board. Impact tolerances must be reviewed at least annually by the First Line, overseen by the Second Line and approved by appropriate Board-level Committee. Such amendments are intended to implement the requirement under the Supervisory Statement that the Clearing House identify impact tolerances in consideration of business services identified as ''important business services. Although this requirement is new, the Clearing House's implementation builds on its existing risk management framework which already covers incident management based on levels of severity linked to financial, reputational, operational and regulatory impacts.

Also further to the requirement under the Supervisory Statement, the amendments would add a new subsection addressing scenario analysis and testing to identify any operational resilience weakness. Such analysis or testing must be conducted on important business services to determine if the Clearing House can remain within the impact tolerances under a range of extreme but plausible disruption scenarios and must include scenarios which disrupt more than one important business service simultaneously and take into account dependencies. The First Line and Second Line would have to agree on any remediation line for weaknesses identified related to extreme but plausible scenarios. Scenario analysis and testing results would be reported to the ERC and the Board. Such amendments do not represent a substantive change from the Clearing House's existing risk management practices and are intended to document those practices in light of the Supervisory Statement, reflecting existing roles and responsibilities.

The section formerly titled ''The Policy for Operational Risk Management'' would be renamed ''Risk and Control Assessments'' in order to more clearly reflect the information contained in the subsection. Other stylistic changes would be made in the Policy to improve clarity and readability. Certain non-substantive fixes would also be made, including providing that risk assessments (and not ''risks'') are documented in the Enterprise Risk Register, reflecting that the correct name of Appendix A to the Policy is ''Enterprise Risk Register'', and correcting internal section references.

In respect of risk monitoring, the amendments would provide that the ERM would coordinate with the First and Third Lines to develop control monitoring plans for Key Controls. This change is to reflect the Clearing House's current practice.

In line with other Clearing House policies, the amendments would provide that the Policy is subject to at least annual review (rather than biennial review) or earlier in the event of a material change.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments to the Operational Risk and Resilience Policy are consistent with the requirements of Section 17A of the Act [5] and the regulations thereunder applicable to it.

[5] 15 U.S.C. 78q–1.

In particular, Section 17A(b)(3)(F) of the Act[6] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest.

The proposed changes to the Policy are designed to strengthen ICE Clear Europe's tools to manage the risk of losses resulting from operational errors or failures. The amendments would formally extend the Policy to cover operational resilience as well as operational risk. The amendments would more clearly tie together existing policies and procedures relevant to operational risk and resilience, as required by the Supervisory Statement as described herein. The amendments would also address important business services, and the procedures to be used by the Clearing House to identify such services and address related risks and dependencies and implement adequate controls. The Policy would also address impact tolerances and scenario analyses and testing. Taken together, the Policy is designed to augment the Clearing House's ability to manage operational risk and enhance its operational resilience. The proposed amendments would thus promote the stability of the Clearing House and the prompt and accurate clearance and settlement of cleared contracts and the safeguarding of securities and funds in ICE Clear Europe's custody or control or for which it is responsible. The enhanced risk management is therefore also generally consistent with the protection of investors and the public interest in the safe operation of the Clearing House. Accordingly, the amendments satisfy the requirements of Section 17A(b)(3)(F).[7]

The amendments to the Policy are also consistent with relevant provisions of Rule 17Ad–22.[8] Rule 17Ad–22(e)(3) provides that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonable designed to, as applicable [. . .] maintain a sound risk management framework for comprehensively managing . . . operational . . . and other risks that arise in or are borne by the covered clearing agency.'' [9] As set forth above, the amendments are intended to clarify and enhance the Clearing House's risk management framework as it relates to operational risks, including through the extension of the Policy to formally address resilience. The amendments would thus strengthen the management of operational risks and risk management more generally. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad–22(e)(3).[10]

Rule 17Ad–22(e)(2) provides that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonable designed to, as applicable [. . .] provide for governance arrangements that are clear and transparent'' [11] and ''[s]pecify clear and direct lines of responsibility'' [12]. The amendments to the Policy would clarify and describe the responsibilities of the Clearing House's lines of defense and committees, management and the Board in relation the Clearing House's resilience framework and the Policy. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad–22(e)(2).[13]

The proposed amendments are also consistent with Rule 17Ad–22(e)(17)(i), which provides that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonable designed to, as applicable [. . .] manage the clearing agency's operational risks by identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls.'' [14] The amendments to the Policy facilitate ongoing identification of operational risks, enhancement of resilience in the face of such risks and mitigation of the impact of such risks through improved procedures and controls. As noted above, these enhancements include the expansion of the Policy to address resilience, the identification of important business services, the establishment of impact tolerances and scenario analysis, together with related controls. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad–22(e)(17)(i).[15]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments are being adopted to update and enhance the Clearing House's Operational Risk and Resilience Policy which relates to the Clearing House's internal processes for operational risk management. The amendments would not change the Rules or Procedures, or the rights or obligations of Clearing Members or the Clearing House. ICE Clear Europe does not believe the amendments and adoption would affect the costs of clearing, the ability of market participants to access clearing, or the market for clearing services generally. Therefore, ICE Clear Europe does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any written comments received with respect to the proposed rule change.

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.

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.

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 17 CFR 240.17 Ad–22.

[9] 17 CFR 240.17 Ad–22(e)(3).

[10] 17 CFR 240.17 Ad–22(e)(3).

[11] 17 CFR 240.17 Ad–22(e)(2)(i).

[12] 17 CFR 240.17 Ad–22(e)(2)(v).

[13] 17 CFR 240.17 Ad–22(e)(2).

[14] 17 CFR 240.17 Ad–22(e)(17)(i).

[15] 17 CFR 240.17 Ad–22(e)(17)(i).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2022–015 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2022–015. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.* All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2022–015 and should be submitted on or before October 28, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–21823 Filed 10–6–22; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34723; File No. 812–15305]

PennantPark Investment Advisers, LLC, et al.

October 3, 2022.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to supersede a previous order granted by the Commission that permits certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

APPLICANTS: PennantPark Investment Advisers, LLC, PennantPark Investment Corporation, PennantPark Floating Rate Capital Ltd., PennantPark Credit Opportunities Fund II, LP, PennantPark Credit Opportunities Fund III, LP, PennantPark Credit Opportunities Fund IV Aggregator, LP, PennantPark Capital Liquidity Solutions, LP, PennantPark Senior Credit Fund, LLC, PennantPark Senior Credit Fund Levered, LP, Berkeley Road WC Funding SPV, LP, Berkeley Road WC Funding SPV 2, LP, SP Credit Acquisitions, LLC, PennantPark Senior Credit Fund, SMA, LP, TPDS I Platinum Holdings LP.

FILING DATES: The application was filed on January 28, 2022, and amended on March 11, 2022, April 29, 2022 and July, 28, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on October 27, 2022, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Arthur H. Penn, 1691 Michigan Avenue, Suite 500, Miami Beach, FL 33139.

FOR FURTHER INFORMATION CONTACT: Bruce R. MacNeil, Senior Counsel, or Lisa Reid Ragen, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' third amended and restated application, dated July 28, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–21824 Filed 10–6–22; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17649 and #17650; PUERTO RICO Disaster Number PR–00043]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Commonwealth of Puerto Rico

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Puerto Rico (FEMA–4671–DR), dated 09/29/2022.

Incident: Hurricane Fiona.

Incident Period: 09/17/2022 and continuing.

DATES: Issued on 10/02/2022.

Physical Loan Application Deadline Date: 11/28/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/29/2023.

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: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of Puerto Rico, dated 09/29/2022, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Municipalities: Bayamon, Camuy, Cayey, Ceiba, Coamo, Corozal, Guanica, Guayama, Guaynabo, Gurabo, Hormigueros, Juncos, Lajas, Maunabo, Mayaguez, Orocovis, Patillas, Penuelas, Ponce, Rincon, Sabana Grande, Villalba, Yabucoa, Yauco.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21899 Filed 10–6–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17667 and #17668; FLORIDA Disaster Number FL–00180]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Florida

AGENCY: U.S. 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 Florida (FEMA–4673–DR), dated 10/03/2022.

Incident: Hurricane Ian.

Incident Period: 09/23/2022 and continuing.

DATES: Issued on 10/03/2022.

Physical Loan Application Deadline Date: 12/02/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 07/03/2023.

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 10/03/2022, 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: Charlotte, Collier, Hardee, Hendry, Highlands, Lake, Lee, Manatee, Polk, Sarasota.

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 17667 8 and for economic injury is 17668 0.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21895 Filed 10–6–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

SBA Council on Underserved Communities Meeting

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice; revision to meeting time.

SUMMARY: The SBA is issuing this notice to announce the time change for the fourth meeting of the Council on Underserved Communities, originally scheduled for October 19, 2022, 1 p.m. to 4 p.m. This meeting time has since changed to October 19, 2022, 2 p.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Tomas Kloosterman, SBA, Office of the Administrator, 409 Third Street SW, Washington, DC 20416, *Tomas.Kloosterman@sba.gov,* (202) 941–8082.

SUPPLEMENTARY INFORMATION: In the **Federal Register** on Tuesday, October 4, 2022, in the FR Document Number 2022–21439, on pages 60232–60233, change the October 19, 2022, meeting time from 1 p.m. to 4 p.m. to 2 p.m. to 5 p.m. The date of the meeting will not be changed.

Dated: October 4, 2022.

Andrienne Johnson,

SBA Committee Management Officer.

[FR Doc. 2022–21869 Filed 10–6–22; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17655 and #17656; SEMINOLE TRIBE of FLORIDA Disaster Number FL–00179]

Presidential Declaration of a Major Disaster for the Seminole Tribe of Florida

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the Seminole Tribe of Florida (FEMA–4675–DR), dated 09/30/2022.

Incident: Hurricane Ian.

Incident Period: 09/23/2022 and continuing.

DATES: Issued on 09/30/2022.

Physical Loan Application Deadline Date: 11/29/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/30/2023.

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 09/30/2022, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Areas (Physical Damage and Economic Injury Loans): Seminole Tribe of Florida.

Contiguous Counties (Economic Injury Loans Only):

Florida: Broward, Collier, Glades, Hendry, Hillsborough, Saint Lucie.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	4.375
Homeowners without Credit Available Elsewhere	2.188
Businesses with Credit Available Elsewhere	6.080
Businesses without Credit Available Elsewhere	3.040
Non-Profit Organizations with Credit Available Elsewhere	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	3.040
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17655 8 and for economic injury is 17656 0.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21846 Filed 10–6–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17644 and #17645; FLORIDA Disaster Number FL–00178]

Presidential Declaration Amendment of a Major Disaster for the State of Florida

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of FLORIDA (FEMA–4673–DR), dated 09/29/2022.

Incident: Hurricane Ian.

Incident Period: 09/23/2022 and continuing.

DATES: Issued on 10/03/2022.

Physical Loan Application Deadline Date: 11/28/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/29/2023.

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: The notice of the President's major disaster declaration for the State of FLORIDA, dated 09/29/2022, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Highlands, Lake.

Contiguous Counties (Economic Injury Loans Only): All contiguous counties previously declared.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21896 Filed 10–6–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17644 and #17645; FLORIDA Disaster Number FL–00178]

Presidential Declaration Amendment of a Major Disaster for the State of Florida

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of FLORIDA (FEMA–4673–DR), dated 09/29/2022.

Incident: Hurricane Ian.

Incident Period: 09/23/2022 and continuing.

DATES: Issued on 09/30/2022.

Physical Loan Application Deadline Date: 11/28/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/29/2023.

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: The notice of the President's major disaster declaration for the State of FLORIDA, dated 09/29/2022, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Flagler, Putnam, Saint Johns, Volusia.

Contiguous Counties (Economic Injury Loans Only):

Florida: Alachua, Bradford, Clay, Duval, Marion.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21847 Filed 10–6–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17653 and #17654; VIRGINIA Disaster Number VA–00101]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Commonwealth of VIRGINIA

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of VIRGINIA (FEMA–4674–DR), dated 09/30/2022.

Incident: Flooding and Mudslides.

Incident Period: 07/13/2022 through 07/14/2022.

DATES: Issued on 09/30/2022.

Physical Loan Application Deadline Date: 11/29/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 06/30/2023.

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 09/30/2022, 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: Buchanan, Tazewell.

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 17653 6 and for economic injury is 17654 0.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21845 Filed 10–6–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17563 and #17564; MISSOURI Disaster Number MO–00113]

Presidential Declaration Amendment of a Major Disaster for the State of Missouri

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Missouri (FEMA–4665–DR), dated 08/08/2022.

Incident: Severe Storms and Flooding.

Incident Period: 07/25/2022 through 07/28/2022.

DATES: Issued on 10/04/2022.

Physical Loan Application Deadline Date: 11/07/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 05/08/2023.

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: The notice of the President's major disaster declaration for the State of Missouri, dated 08/08/2022, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 11/07/2022.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Rafaela Monchek,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2022–21893 Filed 10–6–22; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2022–0032]

Privacy Act of 1974; Matching Program

AGENCY: Social Security Administration (SSA).

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces a new matching program with the United States Department of the Treasury, Internal Revenue Service (IRS). Under this matching program, the IRS will disclose IRS to SSA certain return information for the purpose of verifying eligibility for the Medicare Part D Low Income Subsidy (LIS) and determines the correct subsidy percentage of benefits provided under the Social Security Act (Act).

DATES: Submit comments on the proposed matching program on or before November 7, 2022. The matching program will be applicable on November 28, 2022, or once a minimum of 30 days after publication of this notice has elapsed, whichever is later. The matching program will be in effect for a period of 18 months.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2022–0032 so that we may associate your comments with the correct regulation.

CAUTION: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov.* Use the *Search* function to find docket number SSA–2022–0032 and then submit your comments. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each submission manually. It may take up to a week for your comments to be viewable.

2. *Fax:* Fax comments to (410) 966–0869.

3. *Mail:* Matthew Ramsey, Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, G–401 WHR, 6401 Security Boulevard, Baltimore, MD 21235–6401, or by emailing *Matthew.Ramsey@ssa.gov.* Comments are also available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Interested parties may submit general questions about the matching program to Stephanie Kiley, Acting Division Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, G–401 WHR, 6401 Security Boulevard, Baltimore, MD 21235–6401, at telephone: (410) 965–1416, or send an email to *Stephanie.Kiley@ssa.gov.*

SUPPLEMENTARY INFORMATION: None.

Matthew Ramsey,

Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

PARTICIPATING AGENCIES:

SSA and IRS.

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:

This matching agreement between IRS and SSA is executed pursuant to section 6103(l)(7)(D) of the Internal Revenue Code (IRC) (26 U.S.C. 6103(l)(7)) authorizes IRS to disclose return information with respect to unearned income to Federal, State and local agencies administering certain benefit programs under the Act.

Section 1860D–14 of the Act requires the Commissioner of Social Security to determine the eligibility of applicants for the prescription drug, subsidy who self-certify their income, resources, and family size. Pursuant to section 1860D–14(a)(3) of the Act (42 U.S.C. 1395w–114(a)(3)), SSA must determine whether a Medicare Part D eligible individual is

a The legal authority for the disclosure of SSA data under this agreement subsidy-eligible individual, and whether the individual is an individual as described in section 1860D–14(a) of the Act.

PURPOSE(S):

This agreement sets forth the terms and conditions, and safeguards under which the IRS will to disclose to SSA certain return information for the purpose of verifying eligibility for the Medicare Part D LIS, and determining the correct subsidy percentage of benefits provided under section 1860D–14 of the Act (42 U.S.C. 1395w–114).

CATEGORIES OF INDIVIDUALS:

The individuals whose information is involved in this matching program are beneficiaries for whom SSA must make Mediare Part D Low Income Subsidy determinations.

CATEGORIES OF RECORDS:

SSA will provide electronically to IRS the following data elements in the finder file:

- Social Security number, and
- Name control.

IRS will disclose to SSA the following:

- Payee Account Number,
- Payee Name and Mailing Address,
- Payee Taxpayer Identification Number (TIN),
- Payer Name and Address,
- Payer TIN, and
- Income Type and Amount.

SYSTEM(S) OF RECORDS:

SSA's SOR is the Medicare Database (MDB) File, 60–321, last fully published at 71 **Federal Register** (FR) 42159 (July 25, 2006), and amended at 72 FR 69723 (December 10, 2007), and at 83 FR 54969 (November 1, 2018).

IRS will match SSA's information with its Information Return Master File (IRMF) and disclose to SSA return information with respect to unearned income from the IRMF [Treasury/IRS 22.061], as published at 77 FR 47946 (August 10, 2012), as amended by 80 FR 54081–082 (September 8, 2015), through the *Disclosure of Information to Federal, State and Local Agencies* program.

[FR Doc. 2022–21854 Filed 10–6–22; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 11880]

Notice of Determinations; 26 Additional Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Lives of the Gods: Divinity in Maya Art'' Exhibition

SUMMARY: The Department of State has made determinations with respect to 26 objects being imported from abroad for temporary display.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: On July 27, 2021, notice was published in the **Federal Register** at 86 FR 40225 of determinations pertaining to certain objects to be included in an exhibition entitled ''Lives of the Gods: Divinity in Maya Art.'' On September 30, 2022, notice was published in the **Federal Register** *at* 87 FR 59484 of determinations pertaining to 43 additional objects to be included in the aforesaid exhibition. Notice is hereby given of the following determinations: I hereby determine that 26 additional objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the aforesaid exhibition at The Metropolitan Museum of Art, New York, New York; the Kimbell Art Museum, Fort Worth, Texas; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–21976 Filed 10–5–22; 4:15 pm]

BILLING CODE 4710–05–P

STATE JUSTICE INSTITUTE

Grant Guideline; Notice

AGENCY: State Justice Institute.

ACTION: Grant guideline for FY 2023.

SUMMARY: This guideline sets forth the administrative, programmatic, and financial requirements attendant to Fiscal Year 2023 State Justice Institute grants.

DATES: October 7, 2022.

ADDRESSES: State Justice Institute, 12700 Fair Lakes Circle, Suite 340, Fairfax, VA 22033.

FOR FURTHER INFORMATION CONTACT: Jonathan Mattiello, Executive Director, State Justice Institute, 703–660–4979, *jonathan.mattiello@sji.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the State Justice Institute Act of 1984 (42 U.S.C. 10701 *et seq.*), the State Justice Institute is authorized to award grants, cooperative agreements, and contracts to State and local courts, nonprofit organizations, and others for the purpose of improving the quality of justice in the State courts of the United States.

The following Grant Guideline is adopted by the State Justice Institute for FY 2023.

Table of Contents

I. Eligibility

Pursuant to the State Justice Institute Act of 1984 (42 U.S.C. 10701 *et seq.*), the State Justice Institute (SJI) is authorized to award grants, cooperative agreements, and contracts to State and local courts, national nonprofit organizations, and others for the purpose of improving the quality of justice in the State courts of the United States. SJI is authorized by Congress to award grants, cooperative agreements,

and contracts to the following entities and types of organizations:

- State and local courts and their agencies (42 U.S.C. 10705(b)(1)(A)).
- National nonprofit organizations controlled by, operating in conjunction with, and serving the judicial branches of State governments (42 U.S.C. 10705(b)(1)(B)).
- National nonprofit organizations for the education and training of judges and support personnel of the judicial branch of State governments (42 U.S.C. 10705(b)(1)(C)). An applicant is considered a national education and training applicant under section 10705(b)(1)(C) if:
  - the principal purpose or activity of the applicant is to provide education and training to State and local judges and court personnel; and
  - the applicant demonstrates a record of substantial experience in the field of judicial education and training.
- Other eligible grant recipients (42 U.S.C. 10705 (b)(2)(A) through (D)).
  - Provided that the objectives of the project can be served better, SJI is also authorized to make awards to:
    - Nonprofit organizations with expertise in judicial administration
    - Institutions of higher education
    - Individuals, partnerships, firms, corporations (for-profit organizations must waive their fees)
    - Private agencies with expertise in judicial administration
  - SJI may also make awards to State or local agencies and institutions other than courts for services that cannot be adequately provided through nongovernmental arrangements (42 U.S.C. 10705(b)(3)).

SJI is prohibited from awarding grants to Federal, tribal, and international courts.

II. Grant Application Deadlines

The SJI Board of Directors makes awards on a Federal fiscal year quarterly basis. Applications may be submitted at any time but will be considered for award based only on the timetable below.

TABLE 1—APPLICATION DEADLINES BY FEDERAL FISCAL YEAR QUARTER

Federal fiscal year quarter	Application due date
1	November 1.
2	February 1.
3	May 1.
4	August 1.

To be considered timely, an application must be submitted by the application deadline noted above. Applicants must use the SJI Grants Management System (GMS) to submit all applications and post-award documents. The SJI GMS is accessible at *https://gms.sji.gov.* SJI urges applicants to submit applications at least 72 hours prior to the application due date to allow time for the applicant to receive an application acceptance message and to correct in a timely fashion any problems that may arise, such as missing or incomplete forms.

Questions related to the SJI Grant Program or the SJI GMS should be directed to *contact@sji.gov.*

III. The Mission of the State Justice Institute

The State Justice Institute Authorization Act of 1984 (42 U.S.C. 10701 *et seq.*) established SJI to improve the administration of justice in the State courts of the United States. Incorporated in the State of Virginia as a private, nonprofit corporation, SJI is charged, by statute, with the responsibility to:

- direct a national program of financial assistance designed to ensure that each citizen of the United States is provided ready access to a fair and effective system of justice;
- foster coordination and cooperation with the Federal judiciary;
- promote recognition of the importance of the separation of powers doctrine to an independent judiciary; and
- encourage education for judges and support personnel of State court systems through national and State organizations.

To accomplish these broad objectives, SJI is authorized to provide funding to State courts, national organizations that support and are supported by State courts, national judicial education organizations, and other organizations that can assist in improving the quality of justice in the State courts.

Through the award of grants, contracts, and cooperative agreements, SJI is authorized to perform the following activities:

- support technical assistance, demonstrations, special projects, research, and training to improve the administration of justice in the State courts;
- provide for the preparation, publication, and dissemination of information regarding State judicial systems;
- participate in joint projects with Federal agencies and other private grantors;
- evaluate or provide for the evaluation of programs and projects to determine their impact upon the quality of criminal, civil, and juvenile justice and the extent to which they have contributed to improving the quality of justice in the State courts;
- encourage and assist in furthering judicial education; and
- encourage, assist, and serve in a consulting capacity State and local courts in the development, maintenance, and coordination of criminal, civil, and juvenile justice programs and services.

SJI is supervised by a Board of Directors appointed by the U.S. President, with the advice and consent of the U.S. Senate. The SJI Board of Directors is statutorily composed of six judges; a State court administrator; and four members of the public, no more than two of the same political party. Additional information about SJI, including a list of members of the SJI Board of Directors, is available at *https://www.sji.gov.*

a. Priority Investment Areas

The SJI Board of Directors has established Priority Investment Areas for grant funding. SJI will allocate significant financial resources through grant-making for these Priority Investment Areas. The Priority Investment Areas are applicable to all grant types. SJI strongly encourages potential grant applicants to consider projects addressing one or more of these Priority Investment Areas and to integrate the following factors into each proposed project:

- evidence-based, data-driven decision-making;
- cross-sector collaboration;
- systemic approaches (as opposed to standalone programs);
- institutionalization of new court processes and procedures;
- ease of replication; and
- sustainability.

For FY 2023, the Priority Investment Areas are listed below in no specific order.

1. Opioids and Other Dangerous Drugs, and Behavioral Health Responses

- *Behavioral Health Disparities*—Research indicates that justice-involved persons have significantly greater proportions of mental, substance use, and co-occurring disorders than are found in the public. SJI supports cross-sector collaboration and information sharing that emphasizes policies and practices designed to improve court responses to justice-involved persons with behavioral health and other co-occurring needs.
- *Trauma-Informed Approaches*—Judges, court staff, system stakeholders, and court-involved persons (defendants, respondents, and victims) alike may be

impacted by prior trauma. This is particularly, but not exclusively, true for those with mental illness and/or substance use disorders. SJI supports trauma-informed training, policies, and practices in all aspects of the judicial process.

2. Promoting Access to Justice and Procedural Fairness

- *Self-Represented Litigation*—SJI promotes court-based solutions to address increases in self-represented litigants; helps make courts more user-friendly by simplifying court forms; provides one-on-one assistance; develops guides, handbooks, and instructions on how to proceed; develops court-based self-help centers; and uses internet technologies to increase access. These projects are improving outcomes for litigants and saving valuable court resources.
- *Language Access*—SJI supports language access in the State courts through remote interpretation (outside the courtroom), interpreter training and certification, courtroom services (plain language forms, websites, etc.), and addressing the requirements of Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and the Omnibus Crime Control and Safe Streets Act (34 U.S.C. 10101 *et seq.*).
- *Procedural Fairness*—A fundamental role of courts is to ensure fair processes and just outcomes for litigants. SJI promotes the integration of research-based procedural fairness principles, policies, and practices into State court operations to increase public trust and confidence in the court system, reduce recidivism, and increase compliance with court orders.

3. Reducing Disparities and Protecting Victims, Underserved, and Vulnerable Populations

- *Disparities in Justice*—SJI supports research and data-driven approaches that examine statutory requirements, policies, and practices that result in disparities for justice-involved persons. These disparities can be because of inequities in socioeconomic, racial, ethnic, gender, age, health, or other factors. In addition to identifying disparities, SJI promotes systemic approaches to reducing disparities.
- *Human Trafficking*—SJI addresses the impact of Federal and State human trafficking laws on the State courts, and the challenges faced by State courts in dealing with cases involving trafficking victims and their families. These efforts are intended to empower State courts to identify victims, link them with vital services, and hold traffickers accountable.
- *Rural Justice*—Rural areas and their justice systems routinely have fewer resources and more barriers than their urban counterparts, such as unavailability of services, lack of transportation, and smaller workforces. Programs and practices that are effective in urban areas are often inappropriate and/or lack supported research for implementation in rural areas. SJI supports rural courts by identifying promising and best practices, and promoting resources, education, and training opportunities uniquely designed for rural courts and court users.
- *Guardianship, Conservatorship, and Elder Issues*—SJI assists courts in improving court oversight of guardians and conservators for the elderly and incapacitated adults through visitor programs, electronic reporting, and training.

4. Advancing Justice Reform

- *Criminal Justice Reform*—SJI assists State courts in taking a leadership role in reviewing fines, fees, and bail practices to ensure processes are fair and access to justice is assured; implements alternative forms of sanction; develops processes for indigency review; promotes transparency, governance, and structural reforms that promote access to justice, accountability, and oversight; and implements innovative diversion and reentry programs that serve to improve outcomes for justice-involved persons and the justice system.
- *Juvenile Justice Reform*—SJI supports innovative projects that advance best practices in handling dependency and delinquency cases; promote effective court oversight of juveniles in the justice system; address the impact of trauma on juvenile behavior; assist the courts in identification of appropriate provision of services for juveniles; and address juvenile reentry.
- *Family and Civil Justice Reform*—SJI promotes court-based solutions for the myriad of civil case types, such as domestic relations, housing, employment, and debt collection, which are overwhelming court dockets.

5. Transforming Courts

- *Emergency Response and Recovery*—Courts must be prepared for natural disasters and public health emergencies and institutionalize the most effective and efficient practices and processes that evolve during response and recovery. SJI supports projects that look to the future of judicial service delivery by identifying and replicating innovations and alternate means of conducting court business due to public health emergencies such as pandemics and natural disasters such as hurricanes, earthquakes, and wildfires.
- *Cybersecurity*—Courts must also be prepared for cyberattacks on court systems, such as denial of service and ransomware attacks on court case management systems, websites, and other critical information technology infrastructure. SJI supports projects that assist courts in preparing for and responding to these attacks, and share lessons learned to courts across the United States.
- *Technology*—Courts must integrate technological advances into daily judicial processes and proceedings. SJI supports projects that institutionalize the innovative technology that has successfully advanced the use of electronic filing and payment systems, online dispute resolution, remote work, and virtual court proceedings. SJI promotes projects that streamline case filing and management processes, thereby reducing time and costs to litigants and the courts; provide online access to courts to litigants so that disputes can be resolved more efficiently; and make structural changes to court services that enable them to evolve into an online environment.
- *Strategic Planning*—Courts must rely on a deliberate process to determine organizational values, mission, vision, goals, and objectives. SJI promotes structured planning processes and organizational assessments to assist courts in setting priorities, allocating resources, and identifying areas for ongoing improvements in efficiency and effectiveness. Strategic planning includes elements of court governance, data collection, management, analysis, sharing, and sustainable court governance models that drive decision-making. Strategic plans and outcomes must be communicated to judges, court staff, justice partners, and the public.
- *Training, Education, and Workforce Development*—State courts require a workforce that is adaptable to public demands for services. SJI supports projects that focus on the tools needed to enable judges, court managers, and staff to be innovative, forward-thinking court leaders.

IV. Grant Types

SJI supports five types of grants: Project, Technical Assistance (TA), Curriculum Adaptation and Training (CAT), Strategic Initiatives Grants (SIG) Program, and the Education Support Program (ESP). A brief description of each type of grant is below.

a. Project Grant

Project Grants are intended to support innovative education and training, research and evaluation, demonstration, and technical assistance projects that can improve the administration of justice in State courts locally or nationwide. State court and national nonprofit applicants may request up to $300,000 for 36 months. Local court applicants may request up to $200,000 for 24 months. Examples of expenses not covered by Project Grants include the salaries, benefits, or travel of full- or part-time court employees. Funding may not be used for the ordinary, routine operations of court systems.

All applicants for Project Grants must contribute a cash match greater than or equal to the SJI award amount. This means that grant awards by SJI must be matched at least dollar for dollar by grant applicants. For example, an applicant seeking a $300,000 Project Grant must provide a cash match of at least $300,000. Applicants may contribute the required cash match directly or in cooperation with third parties. Funding from other Federal departments or agencies may not be used for a cash match.

b. TA Grant

TA Grants are intended to provide State or local courts, or regional court associations, with sufficient support to obtain expert assistance to diagnose a problem, develop a response to that problem, and implement any needed changes. TA Grants may not exceed $75,000 or 12 months in duration. In calculating project duration, applicants are cautioned to fully consider the time required to issue a request for proposals, negotiate a contract with the selected provider, and execute the project. Funds may not be used for salaries, benefits, or travel of full- or part-time court employees.

Applicants for TA Grants are required to contribute a total match (cash and in-kind) of not less than 50 percent of the SJI award amount, of which 20 percent must be cash. For example, an applicant seeking a $75,000 TA Grant must provide a $37,500 match, of which up to $30,000 can be in-kind and not less than $7,500 must be cash. Funding from other Federal departments and agencies may not be used for a cash match.

c. CAT Grant

CAT Grants are intended to: (1) enable courts or national court associations to modify and adapt model curricula, course modules, or conference programs to meet States' or local jurisdictions' educational needs; train instructors to present portions or all of the curricula; and pilot-test them to determine their appropriateness, quality, and effectiveness; or (2) conduct judicial branch education and training programs, led by either expert or in-house personnel, designed to prepare judges and court personnel for innovations, reforms, and/or new technologies recently adopted by grantee courts. CAT Grants may not exceed $40,000 or 12 months in duration. Examples of expenses not covered by CAT Grants include the salaries, benefits, or travel of full- or part-time court employees.

Applicants for CAT Grants are required to contribute a total match (cash and in-kind) of not less than 50 percent of the SJI award amount, of which 20 percent must be cash. For example, an applicant seeking a $40,000 CAT Grant must provide a $20,000 match, of which up to $16,000 can be in-kind and not less than $4,000 must be cash. Funding from other Federal departments and agencies may not be used for a cash match.

d. SIG Program

The SIG Program provides SJI with the flexibility to address national court issues as they occur and develop solutions to those problems. This is an innovative approach where SJI uses its expertise and the expertise and knowledge of its grantees to address key issues facing State courts across the United States.

The funding is used for grants or contractual services and is handled at the discretion of the SJI Board of Directors and staff. SJI requires the submission of a concept paper prior to the full application process. *Only applicants that submit an approved concept paper will be invited to submit a full application for funding. Potential applicants are strongly encouraged to contact SJI prior to submitting a concept paper for guidance on this initial step.*

e. ESP for Judges and Court Managers

The ESP is intended to enhance the skills, knowledge, and abilities of State court judges and court managers by enabling them to attend out-of-State, or to enroll in online educational and training programs sponsored by national and State providers they could not otherwise attend or take online because of limited State, local, and personal budgets. The program covers only the cost of tuition up to a maximum of $1,000 per course.

The ESP is administered by the National Judicial College (NJC) and the National Center for State Courts (NCSC)/Institute for Court Management (ICM), in partnership with SJI. For NJC courses, register online at *https://www.judges.org/courses.* For ICM courses, register online at *https://www.ncsc.org/education-and-careers/icm-courses.* During the respective registration processes, each website will ask whether a scholarship is needed to participate. Follow the online instructions to request tuition assistance.

V. Application and Submission Information

This section describes in detail what an application must include. An applicant should anticipate that if it fails to submit an application that contains all the specified project components, it may negatively affect the review of the application. Applicants must use the SJI GMS to submit all applications and post-award documents. The SJI GMS is accessible at *https://gms.sji.gov.*

a. Application Components

Applicants for SJI grants must submit the following forms and/or documents via the SJI GMS:

1. Application Form (Form A)

The application form requests basic information regarding the proposed project, the applicant, and the total amount of funding requested from SJI. It also requires the signature of an individual authorized to certify on behalf of the applicant that the information contained in the application is true and complete; submission of the application has been authorized by the applicant; and, if funding for the proposed project is approved, the applicant will comply with the requirements and conditions of the award, including the assurances set forth in Form D in section V.A.4, *Assurances (Form D)* of this guideline.

2. Certificate of State Approval (Form B)

An application from a State or local court must include a copy of Form B signed by the State's chief justice or State court administrator. The signature denotes that the proposed project has been approved by the State's highest court or the agency or council it has designated. Further, the signature denotes, if applicable, a cash match reduction has been requested, and that if SJI approves funding for the project, the court or the specified designee will receive, administer, and be accountable for the awarded funds.

3. Budget Form (Form C)

Applicants must provide a detailed budget and a budget narrative providing

an explanation of the basis for the amounts in each budget category. If funds from other sources are required to conduct the project, either as a match or to support other aspects of the project, the source, current status of the request, and anticipated decision date must be provided.

4. Assurances (Form D)

Form D lists the statutory, regulatory, and policy requirements with which recipients of SJI funds must comply.

5. Disclosure of Lobbying Activities (Form E)

Applicants other than units of State or local government are required to disclose whether they, or another entity that is part of the same organization as the applicant, have advocated a position before Congress on any issue, and to identify the specific subjects of their lobbying efforts.

6. Project Abstract

The abstract must highlight the purposes, goals, methods, and anticipated benefits of the proposed project. It must not exceed one single-spaced page and must be uploaded on the ''Attachments'' tab in the SJI GMS.

7. Program Narrative

The program narrative for an application may not exceed 25 double-spaced pages on 8½- by 11-inch paper with 1-inch margins, using a standard 12-point font. The pages must be numbered. This page limit does not include the forms, the abstract, the budget narrative, or any additional attachments. The program narrative must address the following, noting any specific areas to address by grant type:

i. Statement of Need. Applicants must explain the critical need they are facing, and how SJI funds will enable them to meet this critical need. The applicants must also explain why State or local resources are not sufficient to fully support the costs of the project. Applicants must provide a verified source for the data that supports the statement of the problem (*i.e.,* Federal, State, and local databases). The discussion must include specific references to the relevant literature and to the experience in the field. SJI continues to make all grant reports and most grant products available online through the NCSC Library and Digital Archive. Applicants are required to conduct a search of the NCSC Library and Digital Archive on the topic areas they are addressing. This search must include SJI-funded grants and previous projects not supported by SJI. Searches for SJI grant reports and other State court resources begin with the NCSC Library section. Applicants must discuss the results of their research, how they plan to incorporate the previous work into their proposed project, and if the project will differ from prior work.

ii. Project Grants. If the project is to be conducted in any specific location(s), applicants must discuss the particular needs of the project site(s) the project would address and why existing programs, procedures, services, or other resources do not meet those needs. If the project is not site-specific, the applicants must discuss the problems that the proposed project would address, and why existing programs, procedures, services, or other resources cannot adequately resolve those problems. In addition, applicants must describe how, if applicable, the project will be sustained in the future through existing resources.

iii. TA Grants. Applicants must explain why State or local resources are unable to fully support the modification and presentation of the model curriculum. The applicants must also describe the potential for replicating or integrating the adapted curriculum in the future using State or local funds once it has been successfully adapted and tested. In addition, applicants must describe how, if applicable, the project will be sustained in the future through existing resources.

iv. CAT Grants (curriculum adaptation). Applicants must explain why State or local resources are unable to fully support the modification and presentation of the model curriculum. The applicants must also describe the potential for replicating or integrating the adapted curriculum in the future using State or local funds once it has been successfully adapted and tested.

v. CAT Grants (training). Applicants must describe the court reform or initiative prompting the need for training. Applicants must also discuss how the proposed training will help them implement planned changes at the court, and why State or local resources are not sufficient to fully support the costs of the required training.

vi. SIGs. Applicants must detail the origin of the project (*i.e.,* requested by SJI or a request to SJI) and provide a detailed description of the issue of national impact the proposed project will address, including any evaluations, reports, resolutions, or other data to support the need statement.

b. Project Description and Objectives

The applicants must include a clear, concise statement of what the proposed project is intended to accomplish and how those objectives will be met. Applicants must delineate the tasks to be performed in achieving the project objectives and the methods to be used for accomplishing each task.

Applicants must describe how the proposed project addresses one or more Priority Investment Areas. If the project does not address one or more Priority Investment Areas, the applicants must provide an explanation as to the reason.

1. Application Details by Project Type

i. Project Grants. The applicants must include detailed descriptions of tasks, methods, and evaluations. For example:

- *Research and evaluation projects.* The applicants must include the data sources, data collection strategies, variables to be examined, and analytic procedures to be used for conducting the research or evaluation and ensuring the validity and general applicability of the results. For projects involving human subjects, the discussion of methods must address the procedures for obtaining respondents' informed consent, ensuring the respondents' privacy and freedom from risk or harm, and protecting others who are not the subjects of research but would be affected by the research. If the potential exists for risk or harm to human subjects, a discussion must be included that explains the value of the proposed research and the methods to be used to minimize or eliminate such risk. Refer to section VIII.R.3, *Human Subject Protection* of this guideline for additional information.
- *Education and training projects.* The applicants must include the adult education techniques to be used in designing and presenting the program, including the teaching and learning objectives of the educational design, the teaching methods to be used, and the opportunities for structured interaction among the participants. The opportunities applicants must include are: how faculty would be recruited, selected, and trained; the proposed number and length of the conferences, courses, seminars, or workshops to be conducted and the estimated number of persons who would attend them; the materials to be provided and how they would be developed; and the cost to participants.
- *Demonstration projects.* The applicants must include the demonstration sites and the reasons they were selected or, if the sites have not been chosen, how they would be identified; how the applicants would obtain the cooperation of demonstration sites; and how the program or procedures would be implemented and monitored.

• *Technical assistance projects.* The applicants must explain the types of assistance that would be provided, the particular issues and problems for which assistance would be provided, the type of assistance determined, how suitable providers would be selected and briefed, and how reports would be reviewed.

ii. TA Grants. Applicants must identify which organization or individual will be hired to provide the assistance, and how the consultant was selected. The applicants must describe the tasks the consultant will perform, and how the tasks will be accomplished.

If a consultant has not yet been identified, the applicants must describe the procedures and criteria that will be used to select the consultant (applicants are expected to follow their jurisdictions' normal procedures for procuring consultant services).

If the consultant has been identified, the applicants must provide a letter from that individual or organization documenting interest in and availability for the project, as well as the consultant's ability to complete the assignment within the proposed timeframe and for the proposed cost. The consultant must agree to submit a detailed written report to the court and SJI upon completion of the technical assistance. Applicants must then describe the steps that have been or will be taken to facilitate implementation of the consultant's recommendations upon completion of the technical assistance.

The applicants must then address the following questions:

• What specific tasks will the consultant and court staff undertake?

• What is the schedule for completion of each required task and the entire project?

• How will the applicant oversee the project and provide guidance to the consultant, and who at the court or regional court association would be responsible for coordinating all project tasks and submitting Quarterly Progress and Financial Status Reports?

iii. CAT Grants (curriculum adaptation). The applicants must provide the title of the curriculum that will be adapted and identify the entity that originally developed the curriculum. Applicants must allow at least 90 days between the potential award date and the date of the proposed program to allow sufficient time for planning. This period of time should be reflected in the project timeline. The applicants must also address the following questions:

• Why is this education program needed at the present time?

• What are the project's goals?

• What are the learning objectives of the adapted curriculum?

• What program components would be implemented, and what types of modifications, if any, are anticipated in length, format, learning objectives, teaching methods, or content?

• Who would be responsible for adapting the model curriculum?

• Who would the participants be, how many would there be, how would they be recruited, and from where would they come (*e.g.,* from a single local jurisdiction, from across the State, from a multistate region, from across the nation)?

The applicants must also provide the proposed timeline, including the project start and end dates, the date(s) the judicial branch education program will be presented, and the process that will be used to modify and present the program. Applicants must also identify who will serve as faculty, and how they will be selected, in addition to the measures taken to facilitate subsequent presentations of the program.

iv. CAT Grants (training). The applicants must identify the tasks the trainer will be expected to perform, which organization or individual will be hired, and, if in-house personnel are not the trainer, how the trainer will be selected.

If a trainer has not yet been identified, the applicants must describe the procedures and criteria that will be used to select the trainer.

If the trainer has been identified, the applicants must provide a letter from that individual or organization documenting interest in and availability for the project, as well as the trainer's ability to complete the assignment within the proposed timeframe and for the proposed cost.

In addition, the applicants must address the following questions:

• What specific tasks would the trainer and court staff or regional court association members undertake?

• What presentation methods will be used?

• What is the schedule for completion of each required task and the entire project?

• How will the applicant oversee the project and provide guidance to the trainer, and who at the court or affiliated with the regional court association would be responsible for coordinating all project tasks and submitting Quarterly Progress and Financial Status Reports?

• The applicant must explain what steps have been or will be taken to coordinate the implementation of the training. For example, if the support or cooperation of specific court, regional court association officials, committees, other agencies, funding bodies, organizations, or a court other than the applicant will be needed to adopt the reform and initiate the proposed training, how will the applicant secure their involvement in the development and implementation of the training?

v. SIGs. The applicants should expand upon the project description and objectives described in the approved concept paper. Any and all feedback and questions submitted by the SJI Board of Directors and staff during the review of the concept paper should also be incorporated into the project design.

2. Dissemination Plan

The application must: (1) explain how and to whom the products would be disseminated; describe how they would benefit the State courts, including how they could be used by judges and court personnel; (2) identify development, production, and dissemination costs covered by the project budget; and (3) present the basis on which products and services developed or provided under the grant would be offered to the court community and the public at large (*i.e.,* whether products would be distributed at no cost to recipients, or if costs are involved, the reason for charging recipients and the estimated price of the product). Ordinarily, applicants must schedule all product preparation and distribution activities within the project period.

The type of product to be prepared depends on the nature of the project. For example, in most instances, the products of a research, evaluation, or demonstration project must include: (1) an article summarizing the project findings that is publishable in a journal serving the courts community nationally, (2) an executive summary that would be disseminated to the project's primary audience, or (3) both an article and executive summary. Applicants proposing to conduct empirical research or evaluation projects with national import must describe how they would make their data available for secondary analysis after the grant period.

The curricula and other products developed through education and training projects must be designed for use by others and again by the original participants in the course of their duties. Applicants proposing to develop web-based products must provide for sending a notice and description of the document to the appropriate audiences to alert them to the availability of the website or electronic product (*i.e.,* a written report with a reference to the website).

Applicants must submit a final draft of all written grant products to SJI for review and approval at least 30 days before the products are submitted for publication or reproduction. For products in website or multimedia format, applicants must provide for SJI review of the product at the treatment, script, rough-cut, and final stages of development, or their equivalents. No grant funds may be obligated for publication or reproduction of a final grant product without the written approval of SJI. Project products should be submitted to SJI electronically in HTML or PDF format.

Applicants must also include in all project products a prominent acknowledgment that SJI provided support and a disclaimer paragraph such as, ''This [document, film, videotape, etc.] was developed under [grant/cooperative agreement] number SJI–[insert number] from the State Justice Institute. The points of view expressed are those of the [author(s), filmmaker(s), etc.] and do not necessarily represent the official position or policies of the State Justice Institute.'' The ''SJI'' logo must appear on the front cover of a written product or in the opening frames of a website or other multimedia products, unless SJI approves another placement. The SJI logo can be downloaded from SJI's website at the bottom of the ''Grants'' page.

3. Staff Capability and Organizational Capacity

An applicant that is not a State or local court and has not received a grant from SJI within the past 3 years must indicate whether it is either: (1) a national nonprofit organization controlled by, operating in conjunction with, and serving the judicial branches of State governments, or (2) a national nonprofit organization for the education and training of State court judges and support personnel. If the applicant is a nonjudicial unit of Federal, State, or local government, it must explain whether the proposed services could be adequately provided by nongovernmental entities.

Applicants that have not received a grant from SJI within the past 3 years must include a statement describing their capacity to administer grant funds, including the financial systems used to monitor project expenditures (and income, if any), a summary of their past experience in administering grants, and any resources or capabilities they have that would particularly assist in the successful completion of the project.

Unless requested otherwise, an applicant that has received a grant from SJI within the past 3 years must describe only the changes in its organizational capacity, tax status, or financial capability that may affect its capacity to administer a grant. If the applicant is a nonprofit organization (other than a university), it must also provide documentation of its 501(c)(3) tax-exempt status as determined by the Internal Revenue Service and a copy of a current certified audit report. For the purpose of this requirement, ''current'' means no earlier than 2 years prior to the present calendar year.

The applicant must include a summary of key staff members' and consultants' training and experience that qualify them to conduct and manage the proposed project. Resumes of identified staff should be attached to the application. If one or more key staff members and consultants are not known at the time of the application, a description of the criteria that would be used to select persons for these positions should be included. The applicant must also identify the person who would be responsible for managing and reporting on the financial aspects of the proposed project.

4. Evaluation

Projects must include an evaluation plan to determine whether the project met its objectives. The evaluation must be designed to provide an objective and independent assessment of the effectiveness or usefulness of the training or services provided; the impact of the procedures, technology, or services tested; or the validity and applicability of the research conducted. The evaluation plan must be appropriate to the type of project proposed considering the nature, scope, and magnitude of the project.

5. Sustainability

Describe how the project will be sustained after SJI assistance ends. The sustainability plan must describe how current collaborations and evaluations will be used to leverage ongoing resources. SJI encourages applicants to ensure sustainability by coordinating with local, State, and other Federal resources.

c. Budget and Matching State Contribution

Applicants must complete a budget in the SJI GMS and upload a budget narrative. The budget narrative must provide the basis for all project-related costs and the sources of any match, as required. The budget narrative must thoroughly and clearly describe every category of expense listed. SJI expects proposed budgets to be complete, cost effective, and allowable (*i.e.,* reasonable, allocable, and necessary for project activities).

1. Prohibited Uses of SJI Funds. To ensure that funds made available are used to supplement and improve the operation of State courts, rather than to support basic court services, funds shall not be used:

- To supplant State or local funds supporting a program or activity (such as paying the salary of court employees who would be performing their normal duties as part of the project or paying rent for space that is part of the court's normal operations).
- To construct court facilities or structures.
- Solely to purchase equipment.

Examples of *basic court services* include:

- Hiring of personnel
- Purchase and/or maintenance of equipment
- Purchase of software and/or licenses
- Purchase of internet access or service
- Supplies to support the day-to-day operations of courts

The final determination of what constitutes basic court services is made by SJI and is not negotiable.

Meals and refreshments are generally not allowable costs unless the applicant or grantee obtains *prior* written approval from SJI. This applies to all awards, including contracts, grants, and cooperative agreements. In general, SJI may approve such costs only in very rare instances where:

- sustenance is not otherwise available (*e.g.,* in extremely remote areas);
- the size of the event and nearby food and/or beverage vendors would make it impractical to not provide meals and/or refreshments; and/or
- a special presentation at a conference requires a plenary address where there is no other time for sustenance to be obtained.

Trinkets (items such as hats, mugs, portfolios, t-shirts, coins, gift bags, gift cards, etc.) may not be purchased with SJI grant funding.

2. Justification of Personnel Compensation. The applicants must set forth the amount of time the individuals who would staff the proposed project would devote, the annual salary of each of those persons, and the number of workdays per year used to calculate the amount of time or daily rates of those individuals. The applicants must explain any deviations from current rates or established written organizational policies. No grant funds or cash match may be used to pay the salary and related costs for a current or

new employee of a court or other unit of government because such funds would constitute a supplantation of State or local funds in violation of 42 U.S.C. 10706(d)(1); this includes new employees hired specifically for the project. The salary and any related costs for a current or new employee of a court or other unit of government may only be accepted as an in-kind match.

3. Fringe Benefit Computation. For nongovernmental entities, applicants must provide a description of the fringe benefits provided to employees. If percentages are used, the authority for such use should be presented, as well as a description of the elements included in the determination of the percentage rate.

4. Consultant/Contractual Services and Honoraria. The applicants must describe the tasks each consultant would perform, the estimated total amount to be paid to each consultant, the basis for compensation rates (*e.g.,* the number of days multiplied by the daily consultant rates), and the method for selection. Prior written SJI approval is required for any consultant rate in excess of $800 per day; SJI funds may not be used to pay a consultant more than $1,100 per day. Honorarium payments must be justified in the same manner as consultant payments.

5. Travel. Transportation costs and per diem rates must comply with the policies of the applicant organization. If the applicant does not have an established travel policy, then travel rates must be consistent with those established by the Federal Government. The budget narrative must include an explanation of the rate used, including the components of the per diem rate and the basis for the estimated transportation expenses. The purpose of the travel must also be included in the narrative.

6. Equipment. Grant funds may be used to purchase only the equipment necessary to demonstrate a new technological application in a court or that is otherwise essential to accomplishing the objectives of the project. In other words, grant funds cannot be used strictly for the purpose of purchasing equipment. Equipment purchases to support basic court operations will not be approved. Applicants must describe the equipment to be purchased or leased and explain why the acquisition of that equipment is essential to accomplish the project's goals and objectives. The narrative must clearly identify which equipment is to be leased and which is to be purchased. The method of procurement must also be described.

7. Supplies. Applicants must provide a general description of the supplies necessary to accomplish the goals and objectives of the grant. In addition, the applicants must provide the basis for the amount requested for this expenditure category.

8. Construction. Construction expenses are prohibited.

9. Postage. Anticipated postage costs for project-related mailings, including distribution of the final product(s), should be described in the budget narrative. The cost of special mailings, such as for a survey or for announcing a workshop, should be distinguished from routine mailing costs. The bases for all postage estimates should be included in the budget narrative.

10. Printing/Photocopying. Anticipated costs for printing or photocopying project documents, reports, and publications must be included in the budget narrative, along with the bases used to calculate these estimates.

11. Indirect Costs. Indirect costs are only applicable to organizations that are not State courts or government agencies. Recoverable indirect costs are limited to no more than 75 percent of a grantee's direct personnel costs (*i.e.,* salaries plus fringe benefits). Applicants must describe the indirect cost rates applicable to the grant in detail. If costs often included within an indirect cost rate are charged directly (*e.g.,* a percentage of the time of senior managers to supervise project activities), the applicants should specify that these costs are not included within their approved indirect cost rate. If an applicant has an indirect cost rate or allocation plan approved by any Federal granting agency, a copy of the approved rate agreement must be attached to the application.

12. Matching Requirements. SJI grants require a match, which is the portion of project costs not borne by SJI and includes both cash and in-kind matches as outlined in this paragraph. A cash match is the direct outlay of funds by the grantee or a third party to support the project. Other Federal department and agency funding may not be used for a cash match. An in-kind match consists of contributions of time and/or services of current staff members, new employees, space, supplies, etc., made to the project by the grantee or others (*e.g.,* advisory board members) working directly on the project. An in-kind match can also consist of that portion of the grantee's federally approved indirect cost rate that exceeds the limit of permitted charges (75 percent of salaries and benefits).

The grantee is responsible for ensuring that the total amount of the match proposed is contributed. If a proposed contribution is not fully met, SJI may reduce the award amount accordingly, to maintain the ratio originally provided for in the award agreement. The match should be expended at the same rate as SJI funding.

i. Project Grants. Applicants for Project Grants must contribute a cash match greater than or equal to the SJI award amount. This means that grant awards by SJI must be matched at least dollar for dollar by grant applicants. For example, an applicant seeking a $300,000 Project Grant must provide a cash match of at least $300,000. Applicants may contribute the required cash match directly or in cooperation with third parties.

ii. TA Grants. Applicants for TA Grants are required to contribute a total match (cash and in-kind) of not less than 50 percent of the SJI award amount, of which 20 percent must be cash. For example, an applicant seeking a $75,000 TA Grant must provide a $37,500 match, of which up to $30,000 can be in-kind and not less than $7,500 must be cash.

iii. CAT Grants. Applicants for CAT Grants are required to contribute a total match (cash and in-kind) of not less than 50 percent of the SJI award amount, of which 20 percent must be cash. For example, an applicant seeking a $40,000 CAT Grant must provide a $20,000 match, of which up to $16,000 can be in-kind and not less than $4,000 must be cash. Funding from other Federal departments and agencies may not be used for a cash match.

iv. SIGs. State and local courts and non-court units of government must provide a dollar-for-dollar cash match for SIG projects. Matching funds may not be required for SIG projects that are awarded to non-court or nongovernmental entities.

13. Letters of Support. Written assurances of support or cooperation should accompany the application letter if the support or cooperation of agencies, funding bodies, organizations, or courts other than the applicant would be needed in order for the consultant to perform the required tasks. Applicants may also submit memorandums of agreement or understanding, as appropriate.

14. Project Timeline. A project timeline detailing each project objective, activity, expected completion date, and responsible person or organization should be included. The plan should include the starting and completion date for each task; the time commitments to

the project of key staff and their responsibilities regarding each project task; and the procedures that would ensure that all tasks are performed on time, within budget, and at the highest level of quality. In preparing the project timeline, applicants must make certain that all project activities, including publication or reproduction of project products and their initial dissemination, would occur within the proposed project period. The project timeline must also provide for the submission of Quarterly Progress and Financial Status Reports within 30 days after the close of each calendar quarter, as well as submission of all final closeout documents. The project timeline may be included in the program narrative or provided as a separate attachment.

15. Other Attachments. Resumes of key project staff may also be included. Additional background material should be attached only if it is essential to impart a clear understanding of the proposed project. Numerous and lengthy appendices are strongly discouraged.

d. Application Review Information

1. *Selection Criteria.* In addition to the criteria detailed below, SJI will consider whether the applicant is a State or local court, a national court support or education organization, a non-court unit of government, or other type of entity eligible to receive grants under SJI's enabling legislation; the availability of financial assistance from other sources for the project; the diversity of subject matter; geographic diversity; the level and nature of the match that would be provided; reasonableness of the proposed budget; the extent to which the proposed project would also benefit the Federal courts or help State or local courts enforce Federal constitutional and legislative requirements; and the level of appropriations available to SJI in the current year and the amount expected to be available in succeeding fiscal years, when determining which projects to support.

2. Project Grant Applications. Project Grant applications will be rated based on the criteria set forth below:

- Soundness of the methodology.
- Demonstration of need for the project.
- Appropriateness of the proposed evaluation design.
- If applicable, the key findings and recommendations of the most recent evaluation and the proposed responses to those findings and recommendations.
- Applicant's management plan and organizational capabilities.
- Qualifications of the project's staff.
- Products and benefits resulting from the project, including the extent to which the project will have long-term benefits for State courts across the nation.
- Degree to which the findings, procedures, training, technology, or other results of the project can be transferred to other jurisdictions.
- Reasonableness of the proposed budget.
- Demonstration of cooperation and support of other agencies that may be affected by the project.

3. TA Grant Applications. TA Grant applications will be rated based on the following criteria:

- Whether the assistance would address a critical need of the applicant.
- Soundness of the technical assistance approach to the problem.
- Qualifications of the consultant(s) to be hired or the specific criteria that will be used to select the consultant(s).
- Commitment of the court or association to act on the consultant's recommendations.
- Reasonableness of the proposed budget.

4. CAT Grant Applications. CAT Grant applications will be rated based on the following criteria:

- Goals and objectives of the proposed project.
- How the training would address a critical need of the court or association.
- Need for outside funding to support the program.
- Soundness of the approach in achieving the project's educational or training objectives.
- Integration of distance learning and technology in project design and delivery.
- Qualifications of the trainer(s) to be hired or the specific criteria that will be used to select the trainer(s) (training project only).
- Likelihood of effective implementation and integration of the modified curriculum into the State or local jurisdiction's ongoing educational programming (curriculum adaptation project only).
- Commitment of the court or association to the training program (training project only).
- Expressions of interest by judges and/or court personnel, as demonstrated by letters of support.

5. SIG Applications. SIG applications will be rated based on the following criteria:

- Goals and objectives of the proposed project.
- Demonstration of need for the project.
- Degree to which the project addresses a current national court issue.
- Level of innovation in addressing the identified need.
- Potential impact on the court community.
- Qualifications of the consultant(s) engaged to manage the project.

6. Review Process. SJI reviews the application to make sure that the information presented is reasonable, understandable, measurable, and achievable, as well as consistent with this guideline. Applications must meet basic minimum requirements. Although specific requirements may vary by grant type, the following are common requirements applicable to all SJI grant applications:

- Must be submitted by an eligible type of applicant.
- Must request funding within funding constraints of each grant type (if applicable).
- Must be within statutorily allowable expenditures.
- Must include all required forms and documents.
- The SJI Board of Directors reviews all applications and makes final funding decisions. The decision to fund a project is solely that of the SJI Board of Directors.

7. Notification of SJI Board of Directors Decision. The Chairman of the Board signs grant awards on behalf of SJI. SJI will notify applicants regarding the SJI Board of Directors' decisions to award, defer, or deny their respective applications. If requested, SJI conveys the key issues and questions that arose during the review process. A decision by the SJI Board of Directors to deny an application may not be appealed, but it does not prohibit resubmission of a proposal in a subsequent funding cycle.

8. Response to Notification of Award. Grantees have 30 days from the date they were notified about their award to respond to any revisions requested by the SJI Board of Directors. If the requested revisions (or a reasonable schedule for submitting such revisions) have not been submitted to SJI within 30 days after notification, the award may be rescinded, and the application presented to the SJI Board of Directors for reconsideration. Special conditions, in the form of incentives or sanctions, may also be used in other situations.

VI. How To Apply

Applicants must use the SJI GMS to submit all applications and post-award documents. SJI urges applicants to submit applications at least 72 hours prior to the application due date in order to allow time for the applicant to receive an application acceptance message, and to correct in a timely fashion any problems that may arise,

such as missing or incomplete forms. Files must be in .doc, .docx, .xls, .xlsx, .pdf, .jpg, or .png format. Individual file size cannot exceed 5 MB.

a. Submission Steps

Applicants (except for ESP) must register with the SJI GMS to submit applications for funding consideration. Below are the basic steps for submission:

1. Access the SJI GMS and complete the information required to create an account.
2. If you already have an account, log in and create a new application.
3. Complete all required forms and upload all required documents:
- Application Form.
- Certificate of State Approval.
- Budget and Budget Narrative.
- Assurances.
- Disclosure of Lobbying Activities.
- Project Abstract.
- Program Narrative.
- Attachments.
  - Letters of Support.
  - Project Timeline.
  - Resumes.
  - Indirect Cost Approval.
  - Other Attachments.

4. Certify and submit the application to SJI for review.

VII. Post-Award Reporting Requirements

All required reports and documents must be submitted via the SJI GMS.

a. Quarterly Reporting Requirements

Recipients of SJI funds must submit Quarterly Progress and Financial Status Reports within 30 days after the close of each calendar quarter (that is, no later than January 30, April 30, July 30, and October 30).

1. Program Progress Reports. Program Progress Reports must include a narrative description of project activities during the calendar quarter; the relationship between those activities, the task schedule, and objectives set forth in the approved application or an approved adjustment thereto; any significant problem areas that have developed and how they will be resolved; and the activities scheduled during the next reporting period. Failure to comply with the requirements of this provision could result in the termination of a grantee's award.

2. Financial Reporting. A Financial Status Report is required from all grantees for each active quarter on a calendar-quarter basis. This report is due within 30 days after the close of the calendar quarter. It is designed to provide financial information relating to SJI funds, State and local matching shares, project income, and any other sources of funds for the project, as well as information on obligations and outlays.

b. Request for Reimbursement of Funds

Awardees will receive funds on a reimbursable, U.S. Department of the Treasury check-issued or electronic funds transfer (EFT) basis. Upon receipt, review, and approval of a Request for Reimbursement by SJI, payment will be issued directly to the grantee or its designated fiscal agent. Requests for reimbursements, along with the instructions for their preparation, and the SF 3881 Automated Clearing House (ACH/Miscellaneous Payment Enrollment Form for EFT) are available in the SJI GMS.

1. Accounting System. Awardees are responsible for establishing and maintaining an adequate system of accounting and internal controls. Awardees are also responsible for ensuring that an adequate system exists for each of their subgrantees and contractors. An acceptable and adequate accounting system:
- Properly accounts for receipt of funds under each grant awarded and the expenditure of funds for each grant by category of expenditure (including matching contributions and project income).
- Assures that expended funds are applied to the appropriate budget category included within the approved grant.
- Presents and classifies historical costs of the grant as required for budgetary and evaluation purposes.
- Provides cost and property controls to assure optimal use of grant funds.
- Is integrated with a system of internal controls adequate to safeguard the funds and assets covered, check the accuracy and reliability of the accounting data, promote operational efficiency, and assure conformance with any general or special conditions of the grant.
- Meets the prescribed requirements for periodic financial reporting of operations.
- Provides financial data for planning, control, measurement, and evaluation of direct and indirect costs.

c. Final Progress Report

The Final Progress Report must describe the project activities during the final calendar quarter of the project and the close-out period, including to whom project products have been disseminated; provide a summary of activities during the entire project; specify whether all the objectives set forth in the approved application or an approved adjustment have been met and, if any of the objectives have not been met, explain why not; and discuss what, if anything, could have been done differently that might have enhanced the impact of the project or improved its operation. In addition, grantees are required to submit electronic copies of the final products related to the project (*e.g.,* reports, curriculum, etc.). These reporting requirements apply at the conclusion of every grant.

VIII. Compliance Requirements

a. Advocacy

No funds made available by SJI may be used to support or conduct training programs for the purpose of advocating particular nonjudicial public policies or encouraging nonjudicial political activities (42 U.S.C. 10706(b)).

b. Approval of Key Staff

If the qualifications of an employee or consultant assigned to a key project staff position are not adequately described in the application or if there is a change of a person assigned to such a position, the recipient must submit a description of the qualifications of the newly assigned person to SJI. Prior written approval of the qualifications of the new person assigned to a key staff position must be received from SJI before the salary or consulting fee of that person and associated costs may be paid or reimbursed from grant funds.

c. Audit

Recipients of SJI grants must provide for an annual fiscal audit, which includes an opinion on whether the financial statements of the grantee fairly present its financial position and its financial operations in accordance with generally accepted accounting principles. If requested, a copy of the audit report must be made available electronically to SJI.

d. Budget Revisions

Budget revisions among direct cost categories that: (1) transfer grant funds to an unbudgeted cost category, or (2) individually or cumulatively exceed 5 percent of the approved original budget or the most recently approved revised budget require prior SJI approval. Refer to section X, *Grant Adjustments,* of this guideline for additional details about the process for modifying the project budget.

e. Conflict of Interest

Personnel and other officials connected with SJI-funded programs must adhere to the following requirements:

• Officials or employees of a recipient court or organization must not participate personally through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in any proceeding, application, request for a ruling or other determination, contract, grant, cooperative agreement, claim, controversy, or other particular matter in which SJI funds are used, where, to their knowledge, they or their immediate family; partners; organization other than a public agency in which they are serving as officer, director, trustee, partner, or employee; or any person or organization with whom they are negotiating or have any arrangement concerning prospective employment, have a financial interest.

• In the use of SJI project funds, an official or employee of a recipient court or organization must avoid any action which might result in or create the appearance of:

▪ using an official position for private gain; or

▪ affecting adversely the confidence of the public in the integrity of the SJI program.

• Requests for proposals or invitations for bids issued by a recipient of SJI funds or a subgrantee or subcontractor will provide notice to prospective bidders that the contractors who develop or draft specifications, requirements, statements of work, and/or requests for proposals for a proposed procurement will be excluded from bidding on or submitting a proposal to compete for the award of such procurement.

f. Inventions and Patents

If any patentable items, patent rights, processes, or inventions are produced during the course of SJI-sponsored work, such fact must be promptly and fully reported to SJI. Unless there is a prior agreement between the grantee and SJI on the disposition of such items, SJI will determine whether protection of the invention or discovery must be sought.

g. Lobbying

Funds awarded to recipients by SJI must not be used, indirectly or directly, to influence Executive orders or similar promulgations by Federal, State, or local agencies; or to influence the passage or defeat of any legislation by Federal, State, or local legislative bodies (42 U.S.C. 10706(a)).

It is the policy of the SJI Board of Directors to award funds only to support applications submitted by organizations that would carry out the objectives of their applications in an unbiased manner. Consistent with this policy and the provisions of 42 U.S.C. 10706, SJI will not knowingly award a grant to an applicant that has, directly or through an entity that is part of the same organization as the applicant, advocated a position before Congress on the specific subject matter of the application.

h. Matching Requirements

All grant recipients are required to provide a match. A match is the portion of project costs not borne by SJI. A match includes both cash and in-kind contributions. A cash match is the direct outlay of funds by the grantee or a third party to support the project. An in-kind match for State and local courts or other units of government consists of contributions of time and/or services of current staff members, new employees, space, supplies, etc., made to the project by the grantee or others (*e.g.,* advisory board members) working directly on the project. Generally, these same items are considered cash matches for nongovernmental entities. For nongovernmental entities, a federally approved indirect cost rate may be used as an in-kind match for that portion of the rate that exceeds the limit of permitted charges for indirect costs (75 percent of salaries and benefits).

Under normal circumstances, an allowable match may be incurred only during the project period. The amount and nature of the required match depends on the type of grant. Refer to section V.C.12, *Matching Requirements,* of this guideline for details by grant type.

The grantee is responsible for ensuring that the total amount of the match proposed is contributed. If a proposed contribution is not fully met, SJI may reduce the award amount accordingly, to maintain the ratio originally provided for in the award agreement. The match should be expended at the same rate as SJI funding.

The SJI Board of Directors looks favorably upon any unrequired match contributed by applicants when making grant decisions. The match requirement may be waived in exceptionally rare circumstances upon the request of the chief justice of the highest court in the State or the highest ranking official in the requesting organization, and approval by the SJI Board of Directors (42 U.S.C. 10705(d)). The SJI Board of Directors encourages all applicants to provide the maximum amount of cash and in-kind match possible, even if a waiver is approved. The amount and nature of the match are criteria in the grant selection process.

Other Federal department and agency funding may not be used for a cash match.

i. Nondiscrimination

No person may, on the basis of race, sex, national origin, disability, color, or creed, be excluded from participation in, denied the benefits of, or otherwise subjected to discrimination under any program or activity supported by SJI funds. Recipients of SJI funds must take any measures necessary to effectuate this provision immediately.

j. Political Activities

No recipient may contribute or make available SJI funds, program personnel, or equipment to any political party or association or the campaign of any candidate for public or party office. Recipients are also prohibited from using funds in advocating or opposing any ballot measure, initiative, or referendum. Officers and employees of recipients must not intentionally identify SJI or recipients with any partisan or nonpartisan political activity associated with a political party or association or the campaign of any candidate for public or party office (42 U.S.C. 10706(a)).

k. Products

1. Acknowledgment, Logo, and Disclaimer. Recipients of SJI funds must acknowledge prominently on all products developed with grant funds that support was received from SJI. The SJI logo must appear on the front cover of a written product, or in the opening frames of a multimedia product, unless another placement is approved in writing by SJI. This includes final products printed or otherwise reproduced during the grant period, as well as reprintings or reproductions of those materials following the end of the grant period. The SJI logo can be downloaded from SJI's website at the bottom of the ''Grants'' page.

Recipients also must display the following disclaimer on all grant products: ''This [document, film, videotape, etc.] was developed under [grant/cooperative agreement] number SJI-[insert number] from the State Justice Institute. The points of view expressed are those of the [author(s), filmmaker(s), etc.] and do not necessarily represent the official position or policies of the State Justice Institute.''

i. Project Grants. In addition to other required grant products and reports, recipients must provide a one-page executive summary of the project. The summary should include a background on the project, the tasks undertaken, and

the outcome. In addition, the summary should provide the performance metrics that were used during the project, and how performance will be measured in the future.

ii. TA Grants. Grantees must submit a final report that explains how they intend to act on the consultant's recommendations, as well as a copy of the consultant's written report. Both should be submitted in electronic format.

iii. CAT Grants. Grantees must submit an electronic version of the agenda or schedule, an outline of presentations and/or relevant instructor's notes; copies of overhead transparencies, Microsoft PowerPoint presentations, or other visual aids; exercises, case studies, and other background materials; hypotheticals, quizzes, and other materials involving the participants; manuals, handbooks, conference packets, and evaluation forms; and suggestions for replicating the program, including possible faculty or the preferred qualifications or experience of those selected as faculty, developed under the grant after the grant period, along with a final report that includes any evaluation results and explains how the grantee intends to present the educational program in the future, as well as the consultant's or trainer's report. All items should be submitted in electronic format.

2. Charges for Grant-Related Products/Recovery of Costs. SJI's mission is to support improvements in the quality of justice and foster innovative, efficient solutions to common issues faced by all courts. SJI has recognized and established procedures for supporting research and development of grant products (*e.g.,* a report, curriculum, video, software, database, or website) through competitive grant awards based on the merit reviews of proposed projects. To ensure that all grants benefit the entire court community, projects SJI considers worthy of support (in whole or in part) are required to be disseminated widely and to be available for public consumption. This includes open-source software and interfaces. Costs for development, production, and dissemination are allowable as direct costs to SJI.

Applicants must disclose their intent to sell grant-related products in the application. Grantees must obtain SJI's prior written approval of their plans to recover project costs through the sale of grant products. Written requests to recover costs ordinarily should be received during the grant period and should specify the nature and extent of the costs to be recouped, the reason that such costs were not budgeted (if the rationale was not disclosed in the approved application), the number of copies to be sold, the intended audience for the products to be sold, and the proposed sale price. If the product is to be sold for more than $25, the written request should also include a detailed itemization of costs that will be recovered and a certification that the costs were not supported by either SJI grant funds or grantee matching contributions.

In the event that the sale of grant products results in revenues that exceed the costs to develop, produce, and disseminate the product, the revenue must continue to be used for the authorized purposes of the SJI-funded project or other purposes consistent with the State Justice Institute Act that have been approved by SJI.

l. Copyrights

Except as otherwise provided in the terms and conditions of an SJI award, a recipient is free to copyright any books, publications, or other copyrightable materials developed in the course of an SJI-supported project. SJI must reserve a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use, the materials for purposes consistent with the State Justice Institute Act.

m. Due Date

All products and, for TA and CAT Grants, consultant and/or trainer reports are to be completed and distributed not later than the end of the award period, not the 90-day closeout period. The 90-day closeout period is intended only for grantee final reporting and to liquidate obligations.

n. Distribution

In addition to the distribution specified in the grant application, grantees must send an electronic version of all products in HTML or PDF format to SJI.

o. Original Material

All products prepared as the result of SJI-supported projects must be originally developed material unless otherwise specified in the award documents. Material not originally developed that is included in such products must be properly identified, whether the material is in a verbatim or extensive paraphrase format.

p. Prohibition Against Litigation Support

No funds made available by SJI may be used directly or indirectly to support legal assistance for parties in litigation, including cases involving capital punishment.

q. Reporting Requirements

All reports must be submitted via the SJI GMS as detailed below:

1. Quarterly Progress and Financial Status Reports. Recipients of SJI funds must submit Quarterly Progress and Financial Status Reports within 30 days after the close of each calendar quarter (that is, no later than January 30, April 30, July 30, and October 30). The Quarterly Progress Reports must include a narrative description of project activities during the calendar quarter; the relationship between those activities, the task schedule, and objectives set forth in the approved application or an approved adjustment thereto; any significant problem areas that have developed and how they will be resolved; and the activities scheduled during the next reporting period. Failure to comply with the requirements of this provision could result in the termination of a grantee's award.

2. Quarterly Financial Reporting. The Quarterly Financial Report must be submitted in accordance with section VII.A.2, *Financial Reporting,* of this guideline. A Final Progress Report and Financial Status Report must be submitted within 90 days after the end of the grant period.

r. Research

1. Availability of Research Data for Secondary Analysis. Upon request, grantees must make available for secondary analysis backup files containing research and evaluation data collected under an SJI grant and the accompanying code manual. Grantees may recover the actual cost of duplicating and mailing, or otherwise transmitting, the dataset and manual from the person or organization requesting the data. Grantees may provide the requested dataset in the format in which it was created and analyzed.

2. Confidentiality of Information. Except as provided by Federal law other than the State Justice Institute Act, no recipient of financial assistance from SJI may use or reveal any research or statistical information furnished under the Act by any person and identifiable to any specific private person for any purpose other than the purpose for which the information was obtained. Such information and copies thereof will be immune from legal process and must not, without the consent of the person furnishing such information, be admitted as evidence or used for any purpose in any action; suit; or other

judicial, legislative, or administrative proceedings.

3. Human Subject Protection. Human subjects are defined as individuals who are participants in an experimental procedure or who are asked to provide information about themselves, their attitudes, feelings, opinions, and/or experiences through an interview, questionnaire, or other data collection technique. All research involving human subjects must be conducted with the informed consent of those subjects and in a manner that will ensure their privacy and freedom from risk or harm and the protection of persons who are not subjects of the research but would be affected by it—unless such procedures and safeguards would make the research impractical. In such instances, SJI must approve procedures designed by the grantee to provide human subjects with relevant information about the research after their involvement and minimize or eliminate risk or harm to those subjects due to their participation.

4. Prohibited Uses of SJI Funds. To ensure that SJI funds are used to supplement and improve the operation of State courts, rather than to support basic court services, SJI funds must not be used for the following purposes:

- To supplant State or local funds supporting a program or activity (such as paying the salary of court employees who would be performing their normal duties as part of the project or paying rent for space which is part of the court's normal operations).
- To construct court facilities or structures.
- Solely to purchase equipment.

Examples of *basic court services* include:

- Hiring of personnel
- Purchase and/or maintenance of equipment
- Purchase of software and/or licenses
- Purchase of internet access or service
- Supplies to support the day-to-day operations of courts

The final determination of what constitutes basic court services is made by SJI and is not negotiable.

Meals and refreshments are generally not allowable costs unless the applicant or grantee obtains *prior* written approval from SJI. This applies to all awards, including contracts, grants, and cooperative agreements. In general, SJI may approve such costs only in very rare instances where:

- sustenance is not otherwise available (*e.g.,* in extremely remote areas);
- the size of the event and nearby food and/or beverage vendors would make it impractical to not provide meals and/or refreshments; and/or
- a special presentation at a conference requires a plenary address where there is no other time for sustenance to be obtained.

Trinkets (items such as hats, mugs, portfolios, t-shirts, coins, gift bags, gift cards, etc.) may not be purchased with SJI grant funding.

5. Suspension or Termination of Funding. After providing a recipient reasonable notice and opportunity to submit written documentation demonstrating why fund termination or suspension should not occur, SJI may terminate or suspend funding of a project that fails to comply substantially with the Act, the Grant Guideline, or the terms and conditions of the award (42 U.S.C. 10708(a)).

6. Title to Property. At the conclusion of the project, title to all expendable and nonexpendable personal property purchased with SJI funds must vest in the recipient court, organization, or individual that purchased the property if certification is made to and approved by SJI that the property will continue to be used for the authorized purposes of the SJI-funded project or other purposes consistent with the State Justice Institute Act. If such certification is not made or SJI disapproves of such certification, title to all such property with an aggregate or individual value of $1,000 or more must vest in SJI, which will direct the disposition of the property.

IX. Financial Requirements

The purpose of this section is to establish accounting system requirements and offer guidance on procedures to assist all grantees, subgrantees, contractors, and other organizations in:

- Complying with the statutory requirements for the award, disbursement, and accounting of funds.
- Complying with regulatory requirements of SJI for the financial management and disposition of funds.
- Generating financial data to be used in planning, managing, and controlling projects.
- Facilitating an effective audit of funded programs and projects.

a. Supervision and Monitoring Responsibilities

All grantees receiving awards from SJI are responsible for the management and fiscal control of all funds. Responsibilities include accounting for receipts and expenditures, maintaining adequate financial records, and refunding expenditures disallowed by audits. If the project includes subawards, the grantees' responsibilities also include:

1. Reviewing Financial Operations. The grantee or its designee must be familiar with, and periodically monitor, its subgrantee's financial operations, records system, and procedures. Particular attention should be directed to the maintenance of current financial data.

2. Recording Financial Activities. The subgrantee's grant award or contract obligation, as well as cash advances and other financial activities, must be recorded in the financial records of the grantee or its designee in summary form. Subgrantee expenditures must be recorded on the books of the State supreme court or evidenced by report forms duly filed by the subgrantee. Matching contributions provided by subgrantees must likewise be recorded, as should any project income resulting from program operations.

3. Budgeting and Budget Review. The grantee or its designee must ensure that each subgrantee prepares an adequate budget as the basis for its award commitment. The State supreme court must maintain the details of each project budget on file.

4. Accounting for Match. The grantee or its designee will ensure that subgrantees comply with the match requirements specified in this guideline.

5. Audit Requirement. The grantee or its designee is required to ensure that subgrantees meet the necessary audit requirements set forth by SJI.

6. Reporting Irregularities. The grantee, its designees, and its subgrantees are responsible for promptly reporting to SJI the nature and circumstances surrounding any financial irregularities discovered.

b. Accounting System

The grantee is responsible for establishing and maintaining an adequate system of accounting and internal controls, and for ensuring that an adequate system exists for each of its subgrantees and contractors. An acceptable and adequate accounting system:

- Properly accounts for receipt of funds under each grant awarded and the expenditure of funds for each grant by category of expenditure, including matching contributions and project income.
- Assures that expended funds are applied to the appropriate budget category included within the approved grant.
- Presents and classifies historical costs of the grant as required for budgetary and evaluation purposes.

• Provides cost and property controls to assure optimal use of grant funds.
• Is integrated with a system of internal controls adequate to safeguard the funds and assets covered, check the accuracy and reliability of the accounting data, promote operational efficiency, and assure conformance with any general or special conditions of the grant.
• Meets the prescribed requirements for periodic financial reporting of operations.
• Provides financial data for planning, control, measurement, and evaluation of direct and indirect costs.

c. Total Cost Budgeting and Accounting

Accounting for all funds awarded by SJI must be structured and executed on a total-project-cost basis. That is, total project costs, including SJI funds, State and local matching shares, and any other fund sources included in the approved project budget, serve as the foundation for fiscal administration and accounting. Grant applications and financial reports require budget and cost estimates based on total costs.

1. Timing of Matching Contributions. Matching contributions should be applied at the same time as the obligation of SJI funds. Ordinarily, the full matching share must be obligated during the award period; however, with the written permission of SJI, contributions made following approval of the grant by the SJI Board of Directors but before the beginning of the grant may be counted as a match. If a proposed cash or in-kind match is not fully met, SJI may reduce the award amount accordingly to maintain the ratio of grant funds to matching funds stated in the award agreement.

2. Records for Match. All grantees must maintain records that clearly show the source, amount, and timing of all matching contributions. In addition, if a project has included, within its approved budget, contributions that exceed the required matching portion, the grantee must maintain records of those contributions in the same manner as it does SJI funds and required matching shares. For all grants made to State and local courts, the State supreme court has primary responsibility for grantee/subgrantee compliance with the requirements of this section.

3. Maintenance and Retention of Records. All financial records, including supporting documents; statistical records; and all other information pertinent to grants, subgrants, cooperative agreements, or contracts under grants, must be retained by each organization participating in a project for at least 3 years for purposes of examination and audit. State supreme courts may impose record retention and maintenance requirements in addition to those prescribed in this section.

4. Coverage. The retention requirement extends to books of original entry, source documents supporting accounting transactions, the general ledger, subsidiary ledgers, personnel and payroll records, canceled checks, and related documents and records. Source documents include copies of all grant and subgrant awards, applications, and required grantee/subgrantee financial and narrative reports. Personnel and payroll records must include the time and attendance reports for all individuals reimbursed under a grant, subgrant, or contract, whether they are employed full-time or part-time. Time and effort reports are required for consultants.

5. Retention Period. The 3-year retention period starts from the date of the submission of the final expenditure report.

6. Maintenance. Grantees and subgrantees are expected to see that records of different fiscal years are separately identified and maintained so that requested information can be readily located. Grantees and subgrantees are also obligated to protect records adequately against fire or other damage. When records are stored away from the grantee's or subgrantee's principal office, a written index of the location of stored records should be on hand, and ready access should be assured.

7. Access. Grantees and subgrantees must give any authorized representative of SJI access to and the right to examine all records, books, papers, and documents related to an SJI grant.

8. Project-Related Income. Records of the receipt and disposition of project-related income must be maintained by the grantee in the same manner as required for the project funds that gave rise to the income and must be reported to SJI (see section VII.A.2, *Financial Reporting,* of this guideline). The policies governing the disposition of the various types of project-related income are listed below.

i. Interest. A State and any agency or instrumentality of a State, including institutions of higher education and hospitals, will not be held accountable for interest earned on advances of project funds. When funds are awarded to subgrantees through a State, the subgrantees are not held accountable for interest earned on advances of project funds. Local units of government and nonprofit organizations that are grantees must refund any interest earned. Grantees must ensure minimum balances in their respective grant cash accounts.

ii. Royalties. The grantee or subgrantee may retain all royalties received from copyrights or other works developed under projects or from patents and inventions unless the terms and conditions of the grant provide otherwise.

iii. Registration and Tuition Fees. Registration and tuition fees may be considered as a cash match with prior written approval from SJI. Estimates of registration and tuition fees, and any expenses to be offset by the fees, should be included in the application budget forms and narrative.

iv. Income from the Sale of Grant Products. If the sale of products occurs during the project period, the income may be treated as a cash match with the prior written approval of SJI. The costs and income generated by the sales must be reported on the Quarterly Progress and Financial Status Reports and documented in an auditable manner. Whenever possible, the intent to sell a product should be disclosed in the application or reported to SJI in writing once a decision to sell products has been made. The grantee must request approval to recover its product development, reproduction, and dissemination costs (see section VIII.K.2, *Charges for Grant-Related Products/Recovery of Costs,* of this guideline).

v. Other. Other project income will be treated in accordance with disposition instructions set forth in the grant's terms and conditions.

d. Payments and Financial Reporting Requirements

The procedures and regulations set forth below are applicable to all SJI grant funds and grantees.

1. Request for Reimbursement of Funds. Grantees will receive funds on a reimbursable, U.S. Department of the Treasury check-issued or EFT basis. Upon receipt, review, and approval of a Request for Reimbursement (Form R) by SJI, payment will be issued directly to the grantee or its designated fiscal agent. The Form R, along with the instructions for its preparation, and the SF 3881 Automated Clearing House (ACH/Miscellaneous Payment Enrollment Form for EFT), are available for download and submission in the SJI GMS.

2. Financial Reporting

i. General Requirements. To obtain financial information concerning the use of funds, SJI requires that grantees/subgrantees submit timely reports for review.

ii. Due Dates and Contents. A Financial Status Report is required from all grantees for each active quarter on a calendar-quarter basis. This report is due within 30 days after the close of the calendar quarter. It is designed to provide financial information relating to SJI funds, State and local matching shares, project income, and any other sources of funds for the project, as well as information on obligations and outlays. The Financial Status Report (Form F), along with instructions, is accessible in the SJI GMS. If a grantee requests substantial payment for a project prior to the completion of a given quarter, SJI may request a brief summary of the amount requested, by object class, to support the Request for Reimbursement.

iii. Consequences of Noncompliance with Submission Requirement. Failure of the grantee to submit required Progress and Financial Status Reports may result in suspension or termination of grant reimbursement.

e. Allowability of Costs

1. Costs Requiring Prior Approval

i. Pre-Agreement Costs. The written prior approval of SJI is required for costs considered necessary but which occur prior to the start date of the project period.

ii. Equipment. Grant funds may be used to purchase or lease only that equipment essential to accomplishing the goals and objectives of the project. The written prior approval of SJI is required when: (1) the amount of automated data processing equipment to be purchased or leased exceeds $10,000 or (2) the amount of software to be purchased exceeds $3,000.

iii. Consultants. The written prior approval of SJI is required when the rate of compensation to be paid to a consultant exceeds $800 a day. SJI funds may not be used to pay a consultant more than $1,100 per day.

iv. Budget Revisions. Budget revisions among direct-cost categories that: (1) transfer grant funds to an unbudgeted cost category or (2) individually or cumulatively exceed 5 percent of the approved original budget or the most recently approved revised budget require prior SJI approval.

2. Travel Costs. Transportation and per diem rates must comply with the policies of the grantee. If the grantee does not have an established written travel policy, then travel rates must be consistent with those established by the U.S. General Services Administration.

Grant funds may not be used to cover the transportation or per diem costs for a member of a national organization to attend an annual or other regular meeting, or conference of that organization.

3. Indirect Costs. Indirect costs are only applicable to organizations that are not State courts or government agencies. These are costs of an organization that are not readily assignable to a particular project but are necessary to the operation of the organization and the performance of the project. The costs of operating and maintaining facilities, depreciation, and administrative salaries are examples of the types of costs that are usually treated as indirect costs. Although SJI's policy requires all costs to be budgeted directly, it will accept indirect costs if a grantee has an indirect cost rate approved by a Federal agency. However, recoverable indirect costs are limited to no more than 75 percent of a grantee's direct personnel costs (salaries plus fringe benefits).

i. Approved Plan Available

- A copy of an indirect cost rate agreement or allocation plan approved for a grantee during the preceding 2 years by any Federal granting agency on the basis of allocation methods substantially in accord with those set forth in the applicable cost circulars must be submitted to SJI.
- Where flat rates are accepted in lieu of actual, indirect costs, grantees may not also charge expenses normally included in overhead pools (*e.g.,* accounting services, legal services, building occupancy and maintenance, etc.) as direct costs.

f. Audit Requirements

1. Implementation. Grantees must provide for an annual fiscal audit. This requirement also applies to a State or local court receiving a subgrant from the State supreme court. Audits conducted using generally accepted auditing standards in the United States will satisfy the requirement for an annual fiscal audit. The audit must be conducted by an independent Certified Public Accountant, or a State or local agency authorized to audit government agencies. The audit report must be made available to SJI electronically, if requested.

2. Resolution and Clearance of Audit Reports. Timely action on recommendations by responsible management officials is an integral part of the effectiveness of an audit. Each grantee must have policies and procedures for acting on audit recommendations by designating officials responsible for:

- Following up.
- Maintaining a record of the actions taken on recommendations and time schedules.
- Responding to and acting on audit recommendations.
- Submitting periodic reports to SJI on recommendations and actions taken.

3. Consequences of Non-Resolution of Audit Issues. Ordinarily, SJI will not make a subsequent grant award to an applicant that has an unresolved audit report involving SJI awards. Failure of the grantee to resolve audit questions may also result in the suspension or termination of payments for active SJI grants to that organization.

g. Closeout of Grants

1. Grantee Closeout Requirements. Within 90 days after the end date of the grant or any approved extension thereof, the following documents must be submitted to SJI by grantees:

i. Financial Status Report. The final report of expenditures must have no unliquidated obligations and must indicate the exact balance of unobligated funds. Any unobligated or unexpended funds will be de-obligated from the award by SJI. Final payment requests for obligations incurred during the award period must be submitted to SJI prior to the end of the 90-day closeout period.

ii. Final Progress Report. This report should describe the project activities during the final calendar quarter of the project and the closeout period, including to whom project products have been disseminated; provide a summary of activities during the entire project; specify whether all the objectives set forth in the approved application or an approved adjustment have been met and, if any of the objectives have not been met, explain why not; and discuss what, if anything, could have been done differently that might have enhanced the impact of the project or improved its operation. These reporting requirements apply at the conclusion of every grant.

2. Extension of Closeout Period. Upon the written request of the grantee, SJI may extend the closeout period to assure completion of the grantee's closeout requirements. Requests for an extension must be submitted at least 14 days before the end of the closeout period and must explain why the extension is necessary, and what steps will be taken to assure that all the grantee's responsibilities will be met by the end of the extension period. Extensions must be submitted via the SJI GMS as Grant Adjustments.

X. Grant Adjustments

All requests for programmatic or budgetary adjustments requiring SJI approval must be submitted by the project director in a timely manner (ordinarily 30 days prior to the implementation of the adjustment being requested). All requests for changes from the approved application will be carefully reviewed for both consistency with this guideline and the enhancement of grant goals and objectives. Failure to submit adjustments in a timely manner may result in the termination of a grantee's award.

a. Grant Adjustments Requiring Prior Written Approval

The following Grant Adjustments require the prior written approval of SJI:

- Budget revisions among direct cost categories that (1) transfer grant funds to an unbudgeted cost category or (2) individually or cumulatively exceed 5 percent of the approved original budget or the most recently approved revised budget.
- A change in the scope of work to be performed or the objectives of the project.
- A change in the project site.
- A change in the project period, such as an extension of the grant period or extension of the Final Financial Report or Final Progress Report deadline.
- Satisfaction of special conditions, if required.
- A change in or temporary absence of the project director.
- The assignment of an employee or consultant to a key staff position whose qualifications were not described in the application, or a change in a person assigned to a key project staff position.
- A change in or temporary absence of the person responsible for managing and reporting on the grant's finances.
- A change in the name of the grantee organization.
- A transfer or contracting out of grant-supported activities.
- A transfer of the grant to another recipient.
- Pre-agreement costs.
- The purchase of Americans with Disabilities Act (ADA) equipment and software.
- Consultant rates.
- A change in the nature or number of the products to be prepared or the way a product would be distributed.

b. Requests for Grant Adjustments

All grantees must promptly notify SJI, in writing, of events or proposed changes that may require adjustments to the approved project design. In requesting an adjustment, the grantee must set forth the reasons and basis for the proposed adjustment and any other information the program manager determines would help SJI's review. All requests for Grant Adjustments must be submitted via the SJI GMS.

c. Notification of Approval or Disapproval

If the request is approved, the grantee will be sent a Grant Adjustment signed by the SJI Executive Director. If the request is denied, the grantee will be sent a written explanation of the reasons for the denial.

d. Changes in the Scope of the Grant

Major changes in scope, duration, training methodology, or other significant areas must be approved in advance by SJI. A grantee may make minor changes to methodology, approach, or other aspects of the grant to expedite achievement of the grant's objectives with subsequent notification to SJI.

e. Date Changes

A request to change or extend the grant period must be made at least 30 days in advance of the end date of the grant. A revised task plan must accompany a request for an extension of the grant period, along with a revised budget if shifts among budget categories will be needed. A request to change or extend the deadline for the Final Financial Report or Final Progress Report must be made at least 14 days in advance of the report deadline.

f. Temporary Absence of the Project Director

Whenever an absence of the project director is expected to exceed a continuous period of 1 month, the plans for the conduct of the project director's duties during such absence must be approved in advance by SJI. This information must be provided in a letter signed by an authorized representative of the grantee or subgrantee at least 30 days before the departure of the project director or as soon as it is known that the project director will be absent. The grant may be terminated if arrangements are not approved in advance by SJI.

g. Withdrawal of or Change in Project Director

If the project director relinquishes or expects to relinquish active direction of the project, SJI must be notified immediately. In such cases, if the grantee or subgrantee wishes to terminate the project, SJI will forward procedural instructions upon notification of such intent. If the grantee wishes to continue the project under the direction of another individual, a statement of the candidate's qualifications should be sent to SJI for review and approval. The grant may be terminated if the qualifications of the proposed individual are not approved in advance by SJI.

h. Transferring or Contracting Out of Grant-Supported Activities

No principal activity of a grant-supported project may be transferred or contracted out to another organization without specific prior approval by SJI. All such arrangements must be formalized in a contract or other written agreement between the parties involved. Copies of the proposed contract or agreement must be submitted for prior approval to SJI at the earliest possible time. The contract or agreement must state, at a minimum, the activities to be performed, the time schedule, the policies and procedures to be followed, the dollar limitation of the agreement, and the cost principles to be followed in determining what costs, both direct and indirect, will be allowed. The contract or other written agreement must not affect the grantee's overall responsibility for the direction of the project and accountability to SJI.

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Jonathan D. Mattiello,

Executive Director.

[FR Doc. 2022–21814 Filed 10–6–22; 8:45 am]

BILLING CODE 6820–SC–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Extension of Solicitation of Nominations for Membership to the Organization Designation Authorizations for Transport Airplanes Expert Review Panel

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

ACTION: Extension of solicitation of nominations for appointment to the Organization Designation Authorizations (ODA) for Transport Airplanes Expert Review Panel.

SUMMARY: On September 9, 2022, the FAA published in the **Federal Register** a notice to solicit nominations for membership on the ODA for Transport Airplanes Expert Review Panel (''Review Panel''). This notice extends the solicitation period for membership on the Review Panel to provide additional opportunities for interested persons to submit their nomination applications. All nominations previously received pursuant to the September 9, 2022 notice will be duly considered during the extended solicitation period and should not be resubmitted.

DATES: Nominations for membership on the Review Panel published on September 9, 2022 (87 FR 55457) has been extended from October 11, 2022, to October 31, 2022, and must be received no later than 5 p.m. eastern time. Nominations received after the due date may be retained for evaluation of any remaining vacancies after all other nominations received by the due date have been evaluated and considered.

ADDRESSES: Nominations must be submitted electronically (by email) to Johann Hadian at *Johann.Hadian@faa.gov.* The subject line should state, ''ODA Review Panel Nomination.'' The body of the email must contain content or attachments that address all requirements as specified in the below ''Materials to Submit'' section. Incomplete/partial submittals as well as those that exceed the specified document length may not be considered for evaluation.

FOR FURTHER INFORMATION CONTACT: Kevin Dickert, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (781) 238–7763; email *Kevin.Dickert@faa.gov.*

Background

The Review Panel is established pursuant to section 103, ''Expert Review of Organization Designation Authorizations for Transport Airplanes,'' of the Aircraft Certification, Safety, and Accountability Act, Public Law 116–260, Div. V, section 103 (the Act). The objectives of the Review Panel are to review and make recommendations for each holder of an ODA for the design and production of transport airplanes (transport airplanes as defined in section 137(6) of the Act), on the following matters:

a. The extent to which the holder's safety management processes promote or foster a safety culture consistent with the principles of the International Civil Aviation Organization Safety Management Manual, Fourth edition (ICAO Doc. No. 9859) or any similar successor document.

b. The effectiveness of measures instituted by the holder to instill among employees and contractors of such holder that support organization designation authorization functions, a commitment to safety above all other priorities.

c. The holder's capability, based upon the organizational structures, requirements applicable to officers and employees of such holder, and safety culture, of making reasonable and appropriate decisions regarding functions delegated to the holder pursuant to the organization designation authorization.

d. Any other matter determined by the Administrator for which inclusion in the review would be consistent with the public interest in aviation safety.

Description of Duties

a. Carry out the review of ODA holders for the design and production of transport airplanes as identified in the preceding panel objectives.

b. Make recommendations to the Administrator regarding suggested actions to address any deficiencies found after review of the matters listed in the preceding panel objectives.

c. Not later than 270 days after the date of the first meeting of the Review Panel, create a report documenting the findings and resulting recommendations, in accordance with the criteria of section 103(a)(5) of the Act. The report shall be submitted to the Administrator and the Congressional committees of jurisdiction.

Membership

The Administrator shall establish a Review Panel of members from the aviation community. The Review Panel shall consist of 24 members as outlined in section 103(a)(3) of the Act. Review Panel member organizations must include representatives of the following interest in the number prescribed by section 103(a)(3) of the Act: NASA, FAA Aircraft Certification Service, FAA Flight Standards Service, labor unions (airline pilots, transport airplane assembly, FAA engineers, FAA safety inspectors, transport airplane design), independent engineering experts, air carriers, ODA holders, and legal experts.

All members serve at the pleasure of the FAA Administrator and will be appointed for a period of one year. Member employing organizations bears all costs related to its members' participation.

Members must have the ability to support all Review Panel meetings (virtual and face-to-face once travel restrictions lifted).

Each individual member of the Review Panel must execute a Disclosure of Financial Interests agreement with the Administrator as outlined in section 103(a)(6)(B) prior to the first meeting of the Review Panel.

Non-Federal government members of the review panel must execute a Non-Disclosure Agreement with the Administrator, as outlined in section 103(a)(6)(C)(ii), prior to the first meeting of the Review Panel.

Qualifications

Candidates must be in good public standing and meet any specific member qualification requirements specified in the section 103(a)(3) for the membership position being sought.

Candidates should highlight any level of familiarization/experience with the following:

a. Safety management processes and systems;

b. Application of International Civil Aviation Organization Safety Manual, Fourth Edition; and

c. Assessing organizational structure, culture and dynamics.

Nomination Process

The Administrator is seeking individual nominations for membership to the Review Panel. Any interested person may nominate one or more qualified individuals for membership on the Review Panel. Self-nominations are also accepted. Nominations must include, in full, the following materials

to be considered for Review Panel membership. Failure to submit the required information may disqualify a candidate from the review process.

Nominations must include the following materials to be considered for membership.

a. A short biography of the nominee, including professional and academic credentials.

b. A résumé or curriculum vitae, which must include relevant job experience, qualifications, as well as contact information (email, telephone, and mailing address).

c. A one-page statement describing how the candidate will benefit the Review Panel, considering current membership and the candidate's unique perspective that will advance the conversation. This statement must also identify a primary and secondary interest to which the candidate's expertise best aligns.

d. Candidates should identify, within the above materials or separately, their previous experience on Federal Advisory Committees and/or Aviation Rulemaking Committees (if any), their level of knowledge in their above stakeholder groups (if applicable), and the size of their constituency they represent or are able to reach.

e. Up to three letters of recommendation may be submitted, but are not required. Each letter may be no longer than one page.

Evaluations will be based on the materials submitted. An email confirmation from the FAA will be sent upon receipt of all complete nominations that meet the criteria. The FAA will notify those appointed by the Administrator to serve on the panel via email.

Issued in Washington, DC, on October 4, 2022.

Jodi L. Baker,

Deputy Associate Administrator, Aviation Safety.

[FR Doc. 2022–21925 Filed 10–6–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, the California Aqueduct Bridge Rehabilitation and Seismic Retrofit on State Route 166 about 2.6 miles east of Old River Road and 5 miles west of Interstate 5 in the County of Kern, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before February 27, 2022. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Trais Norris, Branch Chief, Southern San Joaquin Valley Management Branch 3, 2015 E Shields Avenue, Suite 100, Fresno, CA 93726, (209) 601–3521, *trais.norris@dot.ca.gov,* Mon.–Fri. 9:00 a.m.–5:00 p.m.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans, have taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: The California Aqueduct Bridge Rehabilitation and Seismic Retrofit proposes to seismically retrofit and rehabilitate California Aqueduct Bridge Number 50–0323 on State Route 166. The project is in Kern County east of Maricopa, 2.6 miles east of Old River Road and 5 miles west of Interstate 5. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (FEA) for the project, approved on August 22, 2022, in the FHWA Finding of No Significant Impact (FONSI) issued on August 22, 2022, and in other documents in the FHWA project records. The FEA, FONSI, and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans FEA and FONSI can be viewed and downloaded from the project website at *https://dot.ca.gov/caltrans-near-me/district-6/district-6-projects/06-0s050.*

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4335].

2. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303].

3. *Wildlife:* Federal Endangered Species Act [16 U.S.C. 1531–1543]; Fish and Wildlife Coordination Act [16 U.S.C. 661–666(C); Migratory Bird Treaty Act [16 U.S.C. 760c–760g].

4. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*].

5. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1344].

6. *Hazardous Waste:* Comprehensive Environmental Response, Compensation and Liability Act [42 U.S.C. 103]; Resource Conservation and Recovery Act of 1976 [42 U.S.C. 6901 *et seq.*].

Authority: 23 U.S.C. 139(l)(1).

Antonio Johnson,

Director, Planning, Environment, and Right of Way, Federal Highway Administration, California Division.

[FR Doc. 2022–21836 Filed 10–6–22; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0048]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Intellistop, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition; denial of exemption.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to deny Intellistop, Inc.'s (Intellistop) application for an exemption to allow motor carriers to operate commercial motor vehicles (CMVs) equipped with Intellistop's module which, when brakes are applied, pulses the required rear clearance, identification, and brake lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds and then returns the lights to a steady-burning state. Intellistop has not shown that an industry-wide exemption would likely

achieve a level of safety equivalent to or greater than the level of safety provided by the regulation.

DATES: This decision is applicable October 7, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Luke W. Loy, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–0676, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

I. Supplememtary Information

Docket: For access to the docket to read background documents, comments submitted, or the notice requesting public comments on the exemption application, go to *www.regulations.gov* at any time or visit Dockets Operations, 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. The on-line Federal document management system is available 24 hours each day, 365 days each year. The docket number is listed at the beginning of this notice.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from certain parts of the FMCSRs if it ''finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent the exemption.'' FMCSA must publish a notice of each exemption request in the **Federal Register** and provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted, and an opportunity for public comment on the request (49 U.S.C. 31315(b)(6)(A); 49 CFR 381.315(a)).

The Agency reviews safety analyses and public comments submitted 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 reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. Granted exemptions may be renewed (49 CFR 381.300(b)).

III. Current Regulatory Requirements

Section 393.25(e) of the Federal Motor Carrier Safety Regulations (FMCSRs) requires all exterior lamps (both required lamps and any additional lamps) be steady-burning, except for turn signal lamps, hazard warning signal lamps, school bus warning lamps, amber warning lamps or flashing warning lamps on tow trucks and CMVs transporting oversized loads, and warning lamps on emergency and service vehicles authorized by State or local authorities. This FMCSR is consistent with the Federal Motor Vehicle Safety Standard (FMVSS) No. 108, ''Lamps, reflective devices, and associated equipment'' (49 CFR 571.108) issued by the U.S. Department of Transportation's National Highway Traffic Safety Administration (NHTSA), which, among other things, requires that brake lamps, whether original or replacement equipment, be steady burning.

IV. Intellistop's Application for Exemption

Intellistop applied for an exemption from 49 CFR 393.25(e) to allow all motor carriers to operate CMVs equipped with Intellistop's module which, when the brakes are applied, pulses the rear clearance, identification, and brake lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds and then maintains the original equipment manufacturer's (OEM) level of illumination for those lamps until the brakes are released and reapplied. Intellistop stated that if the module ever fails, the clearance, identification, and brake lamps will default to normal OEM function and illumination.

Intellistop stated that previous research has demonstrated that the use of pulsating brake-activated lamps increases visibility of vehicles and thus has the ability to reduce rear-end crashes with commercial motor vehicles (CMVs). Intellistop further stated that the use of the Intellistop module would allow motor carriers to maintain operational safety levels and implement more efficient and effective operations.

Intellistop noted that FMCSA has previously granted similar, but not identical, temporary exemptions [1] to the National Tank Truck Carriers Inc. (NTTC) (85 FR 63643, Oct. 8, 2020), Grote Industries, LLC (Grote) (85 FR 78918, Dec. 7, 2020) (Grote), and Groendyke Transport Inc. (Groendyke) (84 FR 17910, April 26, 2019).

In its application, Intellistop also referred to several studies conducted by the National Highway Traffic Safety Administration (NHTSA) on the issues of rear-end crashes, distracted driving, and braking signals. Intellistop stated that the addition of brake-activated pulsating lamp(s) will not have an adverse impact on safety, and that adherence to the terms and conditions of the exemption would likely achieve a level of safety equivalent to or greater than the level of safety achieved without the exemption.

A copy of the application is included in the docket referenced at the beginning of this notice.

V. Public Comments

FMCSA published a notice of the application in the **Federal Register** on June 14, 2021, and asked for public comment (86 FR 31552). The Agency received comments from the Transportation Safety Equipment Institute (TSEI), the National Truck Equipment Association (NTEA), the American Trucking Associations (ATA), Tankstar USA Inc. (Tankstar), the Commercial Vehicle Safety Alliance (CVSA) and 15 other stakeholders and individuals. Sixteen organizations and individuals supported approving the exemption application, three individuals or organizations opposed the exemption application, and one organization was noncommittal but offered comments.

ATA supported granting the exemption. ATA stated that:

> Consistent with DOT's reports and research, National Tank Truck Carriers (NTTC) and Grote Industries have successfully petitioned the agency to recognize the value of enhanced rear signaling (ERS) for improving safe operations when compared with traditional standard brake lamps. ERS can provide functions beyond what traditional commercial motor vehicle (CMV) lighting and reflective devices offer, including: attention to CMVs stopped ahead; awareness of roadside breakdowns; emergency braking; and driver confidence from both vehicles. In addition to these safety benefits, ERS performance is superior to steady burning brake lamps in severe weather conditions, tail light glare and around infrastructure obstacles. ERS also reduces the chances of damage to both vehicles involved in a rear-end crash, which improves commercial operation uptime, CSA scores for the CMV owner, and traffic inconvenience.

Tankstar operates a small group of trucking and bulk transport companies

[1] During the pendency of Intellistop's exemption application FMCSA also granted a similar exemption to Waste Management Inc. (Waste Management) (*See* 87 FR 3166, Jan. 20, 2022).

and supported Intellistop's request. Tankstar said that its companies had experienced a number of rear end collisions. It also noted that the 34 percent reduction in rear end crashes reported by Groendyke while using pulsating brake lamps supported the Intellistop request. Tankstar pointed out that the Intellistop flash rate of 4 times in 2 seconds does not match the higher intensity strobing lamps of emergency vehicle lighting systems, and the application should not be denied on the ground of possible confusion with such vehicles. TankStar stated that it is testing the Intellistop module on a few of its trailers, noting that the testing has been very successful in reducing crashes. Tankstar stated that this type of safety product should have the ability to be retrofitted, so as to impact highway safety immediately, and be affordable.

TSEI urged the Agency to deny the petition and offered the following comment:

> The requirement that stop lamps and marker/clearance lamps be steady burning is longstanding. We do not believe FMCSA should make the leap from pulsating brake-activated warning or auxiliary lamps to pulsating *required* lamps without a thorough consideration of safety data and research[footnote omitted] with the aim of setting standards (including those related to flash patterns) to ensure consistency across all vehicles equipped with such lamps. . . . In our comments to FMCSA related to prior exemption petitions, TSEI acknowledged the safety benefits of brake-activated warning lamps when used in conjunction with steady burning red brake lamps and we have generally supported exemption requests for such lamps. However, we also expressed concerns regarding the proliferation of multiple lamps on the rear of commercial vehicles in the absence of consistent standards related to number, color, intensity, flash patterns, duty cycle, location, and other characteristics.

The CVSA commented that it is opposed to allowing red brake-activated pulsating lamps because pulsating red lamps are typically associated with emergency vehicles. It stated that allowing red pulsating lamps on the rear of commercial motor vehicles may negatively impact the driving public's recognition and response to emergency vehicles. CVSA further noted that many state laws prohibit nonemergency vehicles from having pulsating red lights. CVSA stated that it would support allowing motor carriers to equip commercial motor vehicles with amber brake-activated pulsating lights, but not red brake-activated pulsating lights, because of what it believes are likely unintended safety impacts related to emergency vehicles. A different commenter supported granting Intellistop's application specifically for red pulsing lights, and not amber pulsing lights, based on the commenter's review of studies on the effect of different wavelength lights (*i.e.* different color lights) on human vision and crash data for vehicles currently equipped with different colored flashing lights.

The NTEA was noncommittal as to the exemption. However, NTEA noted, ''In an effort to clarify the distinctions between the FMCSA authority over motor carrier operations and those of NHTSA over the manufacturer of new motor vehicles and the make inoperative prohibitions to used vehicle modifications, we respectfully request that FMCSA include in any notices granting such exemptions a brief description of the difference between FMCSA and NHTSA responsibilities and the limitations to the involved entities and conditions under which they may perform these modifications.''

One individual opposed the petition, noting the potential for driver confusion or distraction, while fourteen stakeholders and individuals submitted brief comments in support of granting the exemption. The commenters who supported the exemption generally asserted that this technology may be able to reduce rear-end crashes and should therefore be allowed, citing various benefits of brake activated pulsating lamps, including (1) enhanced awareness that the vehicle is making a stop, especially at railroad crossings, (2) anecdotal reduction in rear-end crashes within commenter fleets, presumably due to increased reaction time for following drivers, and (3) increased visibility near rail-road crossings and in severe weather conditions. Two commenters noted that flashing lights are used on other vehicles, like utility trucks and emergency responder vehicles, to improve driver awareness of those vehicles and therefore pulsing lights on CMVs would similarly alert nearby drivers to the vehicles. In general, the comments received were conclusory and anecdotal and did not provide specific data or research in support of their position.

VI. Equivalent Level of Safety Analysis

As noted, Intellistop petitions FMCSA to grant motor carriers an exemption from 49 CFR 393.25(e)—which requires certain exterior lamps to be steady burning—in order to permit them use its device. FMCSA may only grant such exemptions if it ''finds such exemption[s] would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent the exemption[s].''

Rear-end crashes generally account for approximately 30 percent of all crashes. They often result from a failure to respond (or delays in responding) to a stopped or decelerating lead vehicle. Data on crashes that occurred between 2010 and 2016 show that large trucks are consistently three times more likely than other vehicles to be struck in the rear in two-vehicle fatal crashes.[2] [3] Accordingly, FMCSA is deeply interested in the development and deployment of technologies that can reduce the frequency, severity, and risk of rear-end crashes.

Both FMCSA and NHTSA have considered alternative rear-signaling systems to reduce the incidence of rear-end crashes. While these efforts concluded that improvements could be realized through certain rear-lighting systems that flash,[4] neither the FMCSRs nor the FMVSSs currently permit the use of pulsating, brake-activated lamps on the rear of CMVs. FMCSA believes that the two agencies' previous research programs demonstrate that rear-signaling systems may be able to ''improve attention getting'' to reduce the frequency and severity of rear-end crashes, though that benefit must be balanced against increased risk of driver distraction and confusion.

While the Agency recognizes the existing data that supports the potential safety value of alternative rear-signaling systems in general, it is also mindful of the data deficiencies in this area. Data deficiencies include the effect on nearby drivers if many vehicles on a roadway are equipped with pulsing brake lights and whether such lighting would serve to improve driver attention or, alternatively, cause confusion or distraction. Commenters also disagree on which color light is most appropriate to pulse on the rear of a vehicle, red or amber, and at this time, FMCSA does not have sufficient data to support one conclusion over the other.

In addition to FMCSA's and NHTSA's research on rear-end crashes into CMVs

[2] U.S. Department of Transportation, National Highway Traffic Safety Administration (2012), Traffic Safety Facts—2010 Data; Large Trucks, Report No. DOT HS 811 628, Washington, DC (June 2012), *available at: https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/811628.*

[3] U.S. Department of Transportation, National Highway Traffic Safety Administration (2018), Traffic Safety Facts—2016 Data; Large Trucks, Report No. DOT HS 812 497, Washington, DC (May 2018), *available at: https://crashstats.nhtsa.dot.gov/Api/Public/Publication/812497#:~:text=Fatalities%20in%20crashes%20involving%20large,to%204%2C317%20fatalities%20in%202016.*

[4] Expanded Research and Development of an Enhanced Rear Signaling System for Commercial Motor Vehicles: Final Report, William A. Schaudt *et al.* (Apr. 2014) (Report No. FMCSA–RRT–13–009).

outlined above, there is also data from other industry applicants whose exemption requests the Agency has previously granted. FMCSA acknowledges that the number of vehicles operating under those exemptions is significant. Intellistop's exemption application, however, is potentially far broader in scope than most previous exemption applications FMCSA has granted, as it would apply to any motor carrier that sought to use Intellistop's equipment and also, importantly, alters the functioning of required lamps.[5] FMCSA is required to monitor implementation of the exemption to ensure compliance with its terms and conditions and ensure that operation under the exemption meets and maintains an equivalent level of safety. Because of the broad scope of Intellistop's application, FMCSA would not be able to sufficiently monitor operations under the exemption.

Importantly, all other pulsing rear-light exemptions that FMCSA has previously granted involved the addition of non-mandatory auxiliary lighting systems, whereas Intellistop seeks permission to alter the functionality of original equipment manufacturers' lamps, which are covered by an existing FMVSS. The Agency believes this is a crucial distinction, and one that TSEI highlighted in its comment. TSEI explained that while it has generally supported other similar exemption applications, in this instance it cautioned against making ''the leap from pulsating brake-activated warning or auxiliary lamps to pulsating *required* lamps.''[6] The Agency, in consultation with NHTSA, has determined that it does not currently have data to support a blanket exemption for industry[7] to alter the performance of a required lamp covered by the FMCSRs and FMVSSs.

Moreover, FMCSA and NHTSA are concerned that additional requests for industry-wide exemption from section 393.25(e) might follow, from other companies seeking to market similar but perhaps slightly varying brake lamp products that modify existing FMVSS brake lights. Industry-wide exemptions are not the norm and FMCSA grants them only on a very limited basis, especially when doing so would involve equipment mandated by an FMVSS. The Agency has no data on the effect that such broad adoption of pulsing brake lamps would have on driver distraction, confusion, and overall safety, particularly if large numbers of trucks quickly became equipped with such devices.

Commenting on this exemption application, TSEI articulated its' long-standing ''concerns regarding the proliferation of multiple lamps on the rear of commercial vehicles in the absence of consistent standards related to number, color, intensity, flash patterns, duty cycle, location, and other characteristics.''[8] FMCSA shares TSEIs concerns regarding the unknown safety effects from a sudden and industry-wide proliferation of a variety of non-conforming lighting.

For these reasons, FMCSA concludes that Intellistop failed to demonstrate that its device is likely to provide the equivalent level of safety as 49 CFR 393.25(e).

VII. Exemption Decision

Given the scope of the exemption sought, to include *all* motor carriers, and the limitations of the research studies completed to date, the Agency believes an exemption to allow the alteration of the performance of an FMVSS-required lighting device (*i.e.,* stop lamps) on all CMVs is not supported at this time.

Applicants requesting an exemption bear the burden of demonstrating that the exemption from existing regulatory requirements will likely provide an equivalent level of safety to the existing regulations. FMCSA has evaluated Intellistop's application and the comments received in support of and opposition to the exemption. FMCSA has also reviewed and analyzed the research cited by Intellistop in support of its application.

Unlike other exemption requests received by the Agency relating to rear lighting, Intellistop's application seeks to alter the performance of the FMVSS-required lighting device on all CMVs rather than adding additional pulsating lights. Intellistop did not provide any specific data relating to the operation of its device. Intellistop did not provide data specific to the use of its module which pulses the existing brake lamps rather than the use of additional lamps as identified in the exemptions to Waste Management, Grote, NTTC, and Groendyke, or regarding the distraction, confusion, or safety effects of large numbers of trucks being so equipped.

Generally, Intellistop relied on studies of other lighting configurations proposing to add additional pulsating lights rather than altering the performance of the existing brake lights. Further, Intellistop did not provide data to demonstrate that the installation of the device would safely interact with the CMV's existing systems or to support its claim that a malfunction of the Intellistop device would result in the brake lights returning to OEM functionality, in conformance with the required FMVSS.

While the technology at issue may have promise, FMCSA believes a blanket exemption for all motor carriers to use Intellistop's product is not supported by the currently available data, is not an appropriate approach, and lacks the necessary monitoring controls to ensure highway safety. Previous research programs demonstrate the potential effectiveness of rear-signaling systems to ''improve attention getting'' to reduce the frequency and severity of rear-end crashes, but that previous research does not address the potential safety benefits or risks of a lighting system that would replace rather than merely supplement a light required by an FMVSS. Thus, at this stage, the record before the Agency does not show that Intellistop's petition for an industry-wide exemption adequately demonstrates the required threshold, of likely to achieve an equivalent level of safety.

FMCSA notes that this decision does not necessarily preclude motor carriers from seeking exemptions from 49 CFR 393.25(e) to purchase, install, and use the Intellistop device subject to the terms and conditions of an exemption if granted by FMCSA, as one of the bases of the Agency's decision here is the broad reach of Intellistop's request. Moreover, receipt and specific consideration by FMCSA of separate applications for exemption from individual motor carriers or motor carrier trade groups (especially those representing a particular class or type of CMV operators) also more closely aligns FMCSA's exemption granting practice with the Motor Vehicle Safety Act administered by NHTSA, which states that, ''[a] manufacturer, distributor, dealer, rental company, or motor vehicle repair business may not knowingly

[5] In contrast, the Groendyke exemption is specific to the individual motor carrier and applies to a single, amber, auxiliary lamp. The NTTC and Waste Management exemptions were both granted to organizations and apply to tens of thousands of vehicles, but again, apply to auxiliary lamps (whether red or amber, single or double mounted). Finally, the Grote exemption does apply to all motor carriers, but only allows flashing of an auxiliary lamp, unlike Intellistop's device that alters the required lamps.

[6] Transportation Safety Equipment Institute, Comment to Docket FMCSA–2021–0048 at 2 (July 14, 2021) (emphasis in original), *available at: https://www.regulations.gov/comment/FMCSA-2021-0048-0020.*

[7] FMCSA seeks to make clear that this decision does not preclude individual MCs from seeking an exemption to use an Intellistop device.

[8] Transportation Safety Equipment Institute, Comment to Docket FMCSA–2021–0048 at 2 (July 14, 2021), *available at: https://www.regulations.gov/comment/FMCSA-2021-0048-0020.*

make inoperative any part of a device or element of design installed on or in a motor vehicle or motor vehicle equipment in compliance with an applicable motor vehicle safety standard prescribed under this chapter,'' other than to make repairs.[9] Here, this would mean that the installation of equipment like that included in Intellistop's petition would likely run afoul of this prohibition if installed by any entity other than the operator or owner. Granting an industry-wide exemption would make it extremely difficult, if not impossible, to monitor the installation of the devices and the ''make inoperative'' provisions of the Safety Act. However, individual exemption applications from motor carriers may more closely align with FMCSA and NHTSA authorities to ensure compliance with all applicable regulations, since the exemption grantee would be easily identifiable, and their compliance with the ''make inoperative'' prohibition and any other related regulations could be checked.

For the above reasons, Intellistop's application seeking an industry-wide exemption for its pulsing brake light module is denied.

Robin Hutcheson,

Administrator.

[FR Doc. 2022–21875 Filed 10–6–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2021–0124]

Privacy Act of 1974; Department of Transportation (DOT), Federal Aviation Administration (FAA), DOT/FAA 852 Complaint Investigations System

AGENCY: Office of the Departmental Chief Information Officer, Office of the Secretary of Transportation, DOT.

ACTION: Notice of a modified Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Transportation (DOT) intends to rename, modify and re-issue a DOT Federal Aviation Administration (FAA) system of records notice entitled, ''DOT/FAA 852 Suspected Unapproved Parts (SUP) Program.'' The name of this System of Records Notice (SORN) is being changed to ''DOT/FAA 852 Complaint Investigations System.'' The modification of this system of records notice (hereafter referred to as ''Notice'') is appropriate because the FAA has aligned the management and oversight of the SUP program with that of other reports of actual or perceived aviation safety-related issues, alleged violations of criminal, civil and administrative laws and regulations, including aircraft noise and whistleblower complaints, and aviation safety related orders under the regulatory oversight of the FAA. The records include the investigative records created as a result of the variety of complaints and issues reported by the public, as well as by FAA employees and contractors. The records of the complaints are covered by the DOT/FAA 845 Administrators Correspondence Control and Hotline Information System (ACCIS), Administrator's Hotline Information System (AHIS) and Consumer Hotline Information System (CHIS) SORN,[1] while the investigative records, if any, created as a result of these complaints received under the DOT/FAA 845 SORN, will be covered by this SORN. These investigations and findings are managed using the same FAA policies, information systems, and common processes.

DATES: Written comments should be submitted on or before November 7, 2022. The Department may publish an amended SORN in light of any comments received. This new system will be effective November 7, 2022.

ADDRESSES: You may submit comments, identified by docket number 2021–0124 by any of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. 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 Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.
- *Instructions:* You must include the agency name and docket number DOT–OST–2021–0124.
- All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in 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 the DOT's complete Privacy Act Statement in the **Federal Register** published on January 17, 2008, (73 FR 3316–3317), or you may visit *http://DocketsInfo.dot.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: For privacy questions, please contact Karyn Gorman, Acting Departmental Chief Privacy Officer, Privacy Office, Department of Transportation, Washington, DC 20590; *privacy@dot.gov;* or 202–366–3140.

SUPPLEMENTARY INFORMATION:

Notice Updates

This Notice update includes both substantive and non-substantive changes to the previously published Notice. The substantive changes include: system name, system location, system manager, authority, purpose, categories of individuals, categories of records, record source categories, routine uses of records maintained in the system, policies and practices for retrieval of records, policies and practices for retention and disposal of records, and record access procedures. The non-substantive changes include policies and practices for storage of records, administrative, technical and physical safeguards, contesting record procedures, notification procedures, and exemptions. Certain updates also include changes to align with the requirements of Office of Management and Budget Memorandum (OMB) A–108 and to ensure consistency with other Notices issued by DOT.

I. Background

In accordance with the Privacy Act of 1974, as amended, the Department of Transportation (DOT) proposes to rename, modify and re-issue a DOT system of records notice to be titled, ''Department of Transportation, Federal Aviation Administration, DOT/FAA 852 Complaint Investigations System,'' to reflect the change in the purpose and scope of the system of records.

The Notice currently provides a collection point and tracking for

[9] 49 U.S.C. 30112(b). *See also* NHTSA Interpretation Letter from Steve Wood to Wolfred Freeman (approx. 1989), *available at: https://www.nhtsa.gov/interpretations/aiam4661* (explaining that the Safety Act ''prohibits modifications by persons other than the owner of the vehicle if they render inoperative, in whole or in part, equipment that is installed pursuant to a safety standard.'')

[1] Please check the DOT Privacy Act System of Records Notices page (Privacy Act System of Records Notices | U.S. Department of Transportation) for the most recent published version.

complaints around suspected unapproved parts. Given the alignment of management and oversight of the investigative records of the SUP program with that of reports of actual or perceived aviation safety-related issues and alleged violations of criminal, civil and administrative laws and regulations, it is necessary to update this Notice with the investigative records pertaining to other types of complaints of alleged aviation safety-related issues and wrongdoings by individuals and entities. These investigative records pertain to whistleblower complaints and other aviation safety-related issues, such as aircraft noise concerns, and allegations by the FAA's Office of Aviation Safety (AVS) employees and are being added to this system in order to consolidate maintenance of the investigative records by the FAA. These investigations and findings are also managed using the same FAA policies, information systems, and common processes. AVS employees utilize an internal system to report their issues whereas all others, including members of the public, use external facing websites to submit their whistleblower and other aviation safety-related complaints. The information systems used to receive and maintain the complaints are covered by the DOT/FAA 845 Administrators Correspondence Control and Hotline Information System (ACCIS), Administrator's Hotline Information System (AHIS) and Consumer Hotline Information System (CHIS) SORN. The records in this updated Notice specifically include the investigative results, findings, resolutions, supporting documentation and other related records accumulated for the purpose of addressing the complaints submitted to the FAA. Investigative records may include, but are not limited to, certain personal information such as name, address, phone number, email address, aircraft registration number, and airman certificate number of the reporting individual or subject of alleged violations.

The following substantive changes have been made to the Notice:

1. *System Name and Number:* This Notice updates the system name to DOT/FAA 852 ''Complaint Investigations System'' to better reflect the expanded purpose and scope of the system of records created as part of the investigation of complaints under this Notice.

2. *System Location:* This Notice updates the system location to include the multiple system locations for the various investigative records added to this Notice. The additional system locations include the FAA Headquarters locations, the William J. Hughes Technical Center (WJHTC) in Atlantic City, New Jersey, and the facility at 3701 MacIntosh Drive, Warrenton, Virginia. The investigation and resolution records of complaints, submitted by AVS employees prior to April 2021, are located at the Mike Monroney Aeronautical Center (MMAC) in Oklahoma City, Oklahoma, and the complaint records submitted subsequent to April 2021 are located at the MITRE offices at 7525 Colshire Drive, McLean, Virginia. The previously referenced locations of the SUP program office in Dulles, Virginia, various regional and directorate offices and civil aviation security offices, are being removed, as this information was superseded due to integration of these records into a different information technology system.

3. *System Manager:* This Notice updates the system manager information to reflect the inclusion of records maintained at the WJHTC in Atlantic City, New Jersey, the FAA headquarters locations, the facility at Warrenton, Virginia, the MMAC in Oklahoma City, Oklahoma (pre-April 2021) and the MITRE offices in McLean, Virginia (April 2021 onward). Additionally, contact information for the system manager in each location is included in this update. The reference in the previous Notice to the SUP system manager in Dulles, Virginia, is being removed, as this information was superseded due to integration of these records into a different information technology system.

4. *Authority:* This Notice updates the authorities to include the following: 44 U.S.C. 3101, which applies to records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency that are maintained by heads of agencies, such as the Administrator and Noise Ombudsman; 49 U.S.C. 42121, which applies to discrimination against airline employees reporting safety concerns/violations; and 49 U.S.C. 40101, and Sections 341, 510, and 1210 of the Federal Aviation Reauthorization Act of 1996, as well as Section 180 of the FAA Reauthorization Act of 2018, and 49 U.S.C. 106(t),), which apply to reporting of other safety issues. The previously referenced authority of 49 U.S.C. 44701 covering the SUP program, including discussion on safety, eliminating accidents, minimum safety standards, and identification of registered aircraft, will remain because these records are still included in this system of records. Section 44701 also applies to AVS personnel complaint reports and other hotline records.

5. *Purpose:* This Notice updates the purpose of this System as covering the records pertaining to the investigations, and findings and resolution of complaints, reports of unsafe or unauthorized aviation activities concerning the perceived or actual violations of FAA regulation, order, or other provisions of Federal law related to aviation safety or practices, including whistleblower and noise complaints. The updated purpose applies to all investigative records, when applicable, including the SUP program referenced in the previous Notice. The previous purpose to provide a primary collection point of SUP records and issues and provide technical support to the FAA and industry on SUP; maintain a parts reporting information system for tracking SUP investigations and analysis of data; provide program oversight; and review of SUP related enforcement actions and audits, will be superseded with updated language given the alignment of SUP investigative records with that of other FAA hotline complaint records.

6. *Categories of Individuals:* This Notice updates the categories of individuals to include complainants, such as members of the public, FAA employees and contractors, and other individuals alleged to have been involved in the reported alleged violations or other aviation safety concerns. This expands the previously referenced individuals who call in to report the manufacture, sale or use of suspected unapproved parts. Additionally, the previous reference to ''company representatives of air carriers, repair stations, mechanics, manufacturers, suppliers, brokers, or individuals who are otherwise directly or indirectly involved in suspected unapproved parts investigations'' will be superseded by the more general categories of individuals mentioned here.

7. *Categories of Records:* This Notice updates the categories of records with the list of personal information contained in these records that includes: names of complainants and other individuals involved with the alleged violations, contact information (phone number, address, email address), geolocation of noise, airmen/mechanic/air carrier certificate number, aircraft registration number, aircraft tail number, and report/case tracking number (to include, but not limited to, reference number, case number, record number, and control number). The previously referenced records such as

investigatory materials, investigation results, individuals' roles in investigations and information on any enforcement actions, alert or notification actions, will continue to be maintained in the system.

8. *Records Source:* The Notice updates the records source categories to reference categories of sources instead of a list of individuals. This section will state that records related to investigation and resolution of alleged violations are received from complainants, including members of the public, FAA employees and contractors, and other federal agencies. The previously referenced list of individuals, including air carriers, repair stations, aircraft owners/operators, manufacturers, suppliers, brokers, mechanics, pilots, FAA, and DOT officials, providing information on SUP records will be superseded by the more general language mentioned here.

9. *Routine uses:* This Notice updates the routine uses to include DOT's general routine uses applicable to this Notice as they were previously only incorporated by reference. OMB Memorandum A–108 recommends that agencies include all routine uses in one notice rather than incorporating general routine uses by reference. Therefore, the Department is replacing the statement in DOT/FAA 852 that referenced the ''Statement of General Routine Uses'' with all of the general routine uses that apply to this system of records. This Notice modifies an existing system-specific routine use and adds two new system-specific routine uses that are compatible with the purpose of the system of records. The routine uses include:

a. To the Federal Bureau of Investigation, U.S. Customs Service, and the Department of Defense, the initial SUP complaints received by FAA, for their use in any civil/criminal investigations when an FAA suspected unapproved parts case is initiated. The language in this routine use was modified and the term ''Defense Criminal Investigative Services'' was replaced with the broader title of ''Department of Defense'';

b. Routine use 2(a) and (b) apply only to records pertaining to investigations into noise complaints, and do not apply to information contained in files related to other types of investigations described in this notice. Pursuant to routine use (2), the FAA may disclose:

i. To airport sponsors, federal agencies and departments when necessary to resolve noise complaints of their manned and unmanned aircraft, and other operators of aerial landing and takeoff sites, records relating to noise complaints stemming from their flight operations and to ensure consistency between the FAA and these entities on noise complaints;

ii. To manned and unmanned aircraft operators when necessary to resolve a complaint pertaining to the operator, or when necessary to ensure consistency between the FAA and the operator in responding to noise complaints. Records disclosed pursuant to this routine use are limited to the following information: geolocation only to the extent necessary to identify the general location of the noise complaint; time and date of complaint; and summary reports of the complaint or inquiry and related investigation. Complainant names and contact information will not be disclosed pursuant to this routine use; and

c. To officials of labor organizations recognized under 5 U.S.C. chapter 71, when relevant and necessary to their duties of exclusive representation concerning AVS's Voluntary Safety Reporting Program. In this case, the FAA analysts work in conjunction with the labor organizations in conducting the investigations of actual or alleged violations reported by AVS employees.

10. *Records Retrieval:* This Notice updates records retrieval to indicate that all records that can be retrieved by report/case tracking number (to include, but not limited to, reference number, case number, record number, and control number). Additionally, FAA hotline complaint investigative records can be retrieved by the individual's name (including complainant name and subject of complaint) while noise specific investigative records can be retrieved by individual's name, email address and event address (street/city/state).

11. *Records Retention:* This Notice updates the records retention and disposal to reflect records retention timeframes for the investigative records for new types of complaints covered by this system of records. FAA complaint and whistleblower investigative records are to be maintained in accordance with DAA–0237–2019–0012 with cut off after cases are closed and destruction 3 years after cut off, and the SUP records maintained in accordance with DAA–0237–2019–0010 with cut off at the end of the calendar year in which cases are closed and destruction 8 years after cut off. The FAA is adding a new section to DAA–0237–2019–0012 to request destruction of noise specific investigative records to be 10 years after cut off. These records will be treated as permanent records until the temporary record is approved by the National Archives and Records Administration (NARA). Finally, records on AVS employee reporting on aviation safety matters (collected pre-April 2021) are maintained in accordance with DAA–0237–2019–0012 with destruction 3 years after cut off, with records collected in the replacement information technology system (April 2021 onward) to be treated as permanent records until NARA approves the new records retention request, DAA–0237–2020–0028, for 15 years. Due to an administrative error at the time, the retention timeframe for SUP records in the previously published Notice was referenced as 5 years but is updated to 8 years in this Notice.

12. *Records Access:* This Notice updates the record access procedures to reflect that signatures on signed requests for records must either be notarized or accompanied by a statement made under penalty of perjury in compliance with 28 U.S.C. 1746.

The following non-substantive changes have been made to improve the transparency and readability of the Notice:

13. *Records Storage:* This Notice updates records storage procedures to generalize the language and not focus on SUP records only.

14. *Administrative, Technical, and Physical Safeguards:* This Notice updates the administrative, technical, and physical safeguards to generalize the language.

15. *Contesting Records:* This Notice updates the contesting records procedures to refer the individual to the record access procedures section.

16. *Notifications:* This Notice updates the notification procedures to refer the individual to the record access procedures section.

17. *Exemption:* This Notice continues to claim the current exemption as this updated system of records contains the original SUP investigative records and adds investigative records from complaints that also require this exemption.

II. Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the Federal Government collects, maintains, and uses personally identifiable information (PII) in a System of Records. A ''System of Records'' is a group of any records under the control of a Federal agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a System of Records Notice (SORN) identifying and describing each System of Records the agency maintains, including the purposes for which the agency uses PII

in the system, the routine uses for which the agency discloses such information outside the agency, and how individuals to whom a Privacy Act record pertains can exercise their rights under the Privacy Act (*e.g.,* to determine if the system contains information about them and to contest inaccurate information). In accordance with 5 U.S.C. 552a(r), DOT has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

Department of Transportation (DOT)/ Federal Aviation Administration (FAA) 852—Complaint Investigations System.

SECURITY CLASSIFICATION:

Unclassified, sensitive.

SYSTEM LOCATION:

The system locations are as follow:

a. Hotline complaint investigative records, including SUP and whistleblower records: Office of Audit and Evaluation, Reporting and Data Analysis Branch, AAE–300, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; and, AIT Infrastructure and Operations, Data Center Services, AIF–300, Federal Aviation Administration, William J. Hughes Technical Center, Atlantic City, New Jersey 08405.

b. AVS employee reporting investigative records: Operations Services Division AIF–300, Federal Aviation Administration, Mike Monroney Aeronautical Center (MMAC), 6500 South Macarthur Boulevard, Oklahoma City, Oklahoma 73169 (pre-April 2021); and MITRE Corporation, 7525 Colshire Drive, McLean, Virginia 22102 (April 2021 onward).

c. Noise specific investigative records: ATO System Operations, NAS Data Integration and Services, AJR–G2, Federal Aviation Administration, 3701 MacIntosh Dr, Warrenton, Virginia 20187.

SYSTEM MANAGER(S):

The system managers are as follows:

a. Hotline complaint investigative records, including SUP and whistleblower records: Director, Office of Audit and Evaluation (AAE–1), Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, *https://www.faa.gov/about/office_org/headquarters_offices/aae/.*

b. AVS employee reporting investigative records: Manager, Flight Standards Service, Quality Control and Investigations Branch (AFB–440A), Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591 (pre-April 2021); and Executive Director, Office of Quality, Integration and Executive Services (AQS–1), Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, *9-avs-vsrp@faa.gov* (April 2021 onward); *and*

c. Noise specific investigative records: IT Program Manager, System Data and Infrastructure (AJR–G2), Federal Aviation Administration, 3701 MacIntosh Dr, Warrenton, Virginia 20187, *https://noise.faa.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 106(t), 3101, 40101, 42121, 44701; Sections 341, 510, 1210, Federal Aviation Reauthorization Act of 1996; Section 180, FAA Reauthorization Act of 2018.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system of records is to cover the investigations, findings and resolution of complaints, and reports of unsafe or unauthorized aviation activities concerning the perceived or actual violations of FAA regulation, order, or other provision of Federal law related to aviation safety or practices, including whistleblower and noise complaints.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system of records consist of complainants, including members of the public, FAA employees and contractors, and individuals who are the subject of such violations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records maintained in this system include files specific to reports of alleged violations, investigatory materials, investigation results, individuals' roles in investigations and information on any enforcement actions, alert or notification actions. Individual records may include names of complainants, contact information (phone number, address, email address), geolocation of noise, aircraft registration number, airman/mechanic/air carrier certificate number, aircraft tail number, and report/case tracking number (to include, but not limited to, reference number, case number, record number, and control number).

RECORD SOURCE CATEGORIES:

Reports of alleged violations and other aviation related concerns and safety-related issues, such as noise complaints, are received from complainants, including members of the public, FAA employees and contractors, and other federal agencies.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to other disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOT as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

System Specific Routine Uses

1. To the Federal Bureau of Investigation, U.S. Customs Service, and the Department of Defense, the initial SUP complaints received by FAA, for their use in any civil/criminal investigations when an FAA suspected unapproved parts case is initiated.

2. Routine use (2)(a) and (b) apply only to records pertaining to investigations into noise complaints, and do not apply to information contained in files related to other types of investigations described in this notice. Pursuant to routine use (2), the FAA may disclose:

a. To airport sponsors, federal agencies and departments operating manned and unmanned aircraft outside FAA's regulatory jurisdiction, and other operators of aerial landing and takeoff sites, records relating to noise complaints stemming from their operations to ensure consistency between the FAA and these entities on noise complaints; and

b. To man and unmanned aircraft operators when necessary to resolve a complaint pertaining to the operator, or when necessary to ensure consistency between the FAA and the operator in responding to noise complaints. Records disclosed pursuant to this routine use are limited to the following information: geolocation only to the extent necessary to identify the general location of the noise complaint; time and date of complaint; and summary reports of the complaint or inquiry and related investigation. Complainant names and contact information will not be disclosed pursuant to this routine use

3. To officials of labor organizations recognized under 5 U.S.C. chapter 71, access to all information when relevant and necessary to their duties of exclusive representation concerning AVS's Voluntary Safety Reporting Program.

Departmental General Routine Uses

4. In the event that a system of records maintained by DOT to carry out its functions indicates a violation or potential violation of law, whether civil,

criminal or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto.

5. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a DOT decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

6. A record from this system of records may be disclosed, as a routine use, to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

7a. Routine Use for Disclosure for Use in Litigation. It shall be a routine use of the records in this system of records to disclose them to the Department of Justice or other Federal agency conducting litigation when (a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof (including a member of the Coast Guard), in his/her official capacity, or (c) Any employee of DOT or any agency thereof (including a member of the Coast Guard), in his/her individual capacity where the Department of Justice has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that litigation is likely to affect the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or other Federal agency conducting the litigation is deemed by DOT to be relevant and necessary in the litigation, provided, however, that in each case, DOT determines that disclosure of the records in the litigation is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

7b. Routine Use for Agency Disclosure in Other Proceedings. It shall be a routine use of records in this system to disclose them in proceedings before any court or adjudicative or administrative body before which DOT or any agency thereof, appears, when (a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof (including a member of the Coast Guard) in his/her official capacity, or (c) Any employee of DOT or any agency thereof (including a member of the Coast Guard) in his/her individual capacity where DOT has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that the proceeding is likely to affect the United States, is a party to the proceeding or has an interest in such proceeding, and DOT determines that use of such records is relevant and necessary in the proceeding, provided, however, that in each case, DOT determines that disclosure of the records in the proceeding is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

8. The information contained in this system of records will be disclosed to the Office of Management and Budget, OMB in connection with the review of private relief legislation as set forth in OMB Circular No. A–19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

9. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual. In such cases, however, the Congressional office does not have greater rights to records than the individual. Thus, the disclosure may be withheld from delivery to the individual where the file contains investigative or actual information or other materials which are being used, or are expected to be used, to support prosecution or fines against the individual for alleged violations of a statute, or of regulations of the Department based on statutory authority. No such limitations apply to records requested for Congressional oversight or legislative purposes; release is authorized under 49 CFR 10.35(9).

10. One or more records from a system of records may be disclosed routinely to the National Archives and Records Administration in records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

11. Routine Use for disclosure to the Coast Guard and to Transportation Security Administration. A record from this system of records may be disclosed as a routine use to the Coast Guard and to the Transportation Security Administration if information from this system was shared with either agency when that agency was a component of the Department of Transportation before its transfer to the Department of Homeland Security and such disclosure is necessary to accomplish a DOT, TSA, or Coast Guard function related to this system of records.

12. DOT may make available to another agency or instrumentality of any government jurisdiction, including State and local governments, listings of names from any system of records in DOT for use in law enforcement activities, either civil or criminal, or to expose fraudulent claims, regardless of the stated purpose for the collection of the information in the system of records. These enforcement activities are generally referred to as matching programs because two lists of names are checked for match using automated assistance. This routine use is advisory in nature and does not offer unrestricted access to systems of records for such law enforcement and related antifraud activities. Each request will be considered on the basis of its purpose, merits, cost effectiveness and alternatives using Instructions on reporting computer matching programs to the Office of Management and Budget, OMB, Congress, and the public, published by the Director, OMB, dated September 20, 1989.

13. It shall be a routine use of the information in any DOT system of records to provide to the Attorney General of the United States, or his/her designee, information indicating that a person meets any of the disqualifications for receipt, possession, shipment, or transport of a firearm under the Brady Handgun Violence Prevention Act. In case of a dispute concerning the validity of the information provided by DOT to the Attorney General, or his/her designee, it shall be a routine use of the information in any DOT system of records to make any disclosures of such information to the National Background Information Check System, established by the Brady Handgun Violence Prevention Act, as may be necessary to resolve such dispute.

14a. To appropriate agencies, entities, and persons when (1) DOT suspects or has confirmed that there has been a breach of the system of records; (2) DOT has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOT (including its information systems, programs, and operations), the Federal

Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOT's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

14b. To another Federal agency or Federal entity, when DOT determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

15. DOT may disclose records from this system, as a routine use, to the Office of Government Information Services for the purpose of (a) resolving disputes between FOIA requesters and Federal agencies and (b) reviewing agencies' policies, procedures, and compliance in order to recommend policy changes to Congress and the President.

16. DOT may disclose records from this system, as a routine use, to contractors and their agents, experts, consultants, and others performing or working on a contract, service, cooperative agreement, or other assignment for DOT, when necessary to accomplish an agency function related to this system of records.

17. DOT may disclose records from this system, as a routine use, to an agency, organization, or individual for the purpose of performing audit or oversight operations related to this system of records, but only such records as are necessary and relevant to the audit or oversight activity. This routine use does not apply to intra-agency sharing authorized under Section (b)(1) of the Privacy Act.

18. DOT may disclose from this system, as a routine use, records consisting of, or relating to, terrorism information (6 U.S.C. 485(a)(5)), homeland security information (6 U.S.C. 482(f)(1)), or Law enforcement information (Guideline 2 Report attached to White House Memorandum, ''Information Sharing Environment, November 22, 2006) to a Federal, State, local, tribal, territorial, foreign government and/or multinational agency, either in response to its request or upon the initiative of the Component, for purposes of sharing such information as is necessary and relevant for the agencies to detect, prevent, disrupt, preempt, and mitigate the effects of terrorist activities against the territory, people, and interests of the United States of America, as contemplated by the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108–458) and Executive Order 13388 (October 25, 2005).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in electronic databases and/or hard copy files.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

All investigative records can be retrieved by report/case tracking number (to include, but not limited to, reference number, case number, record number, and control number). FAA Hotline complaint investigative records can be retrieved by individual's name (including complainant name and subject of complaint), and noise specific investigative records can be retrieved by individual's name, email address and event address (street/city/state).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

FAA will maintain hotline complaint investigative records, including whistleblower records, in accordance with DAA–0237–2019–0012 with cut off after cases are closed and destruction 3 years after cut off, SUP investigative records in accordance with DAA–0237–2019–0010 with cut off at the end of the calendar year in which cases are closed and destruction 8 years after cut off, and AVS employee safety reporting investigative records in accordance with DAA–0237–2019–0012 with destruction 3 years after cut off (pre-April 2021). The new retention schedule, DAA–0237–2020–0028, for the AVS employee safety reporting investigative records (April 2021 onward) in the replacement information technology system is still pending at NARA, and the FAA is adding a new section to DAA–0237–2019–0012 to request destruction of noise specific investigative records to be 10 years after cut off. The noise specific and new AVS employee safety reporting investigative records will be treated as permanent records until the temporary record is approved by NARA.

ADMINISTRATIVE, TECHNICAL AND PHYSICAL SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DOT automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of whether this system of records contains information about them may contact the System Manager at the address provided in the section ''System Manager''. When seeking records about yourself from this system of records or any other Departmental system of records, the request must conform to the Privacy Act regulations set forth in 49 CFR part 10. You must sign your request and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

CONTESTING RECORDS PROCEDURES:

See ''Redress Access Procedures'' above.

NOTIFICATION PROCEDURES:

See ''Redress Access Procedures'' above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

This system of records is exempted from certain provisions of the Privacy Act. The purpose of the exemptions is to protect investigatory materials compiled for non-criminal law enforcement purposes. The exemptions claimed for this system are pursuant to 5 U.S.C. 552a(k)(2).

HISTORY:

A full notice of this system of records, DOT/FAA 852, was published in the **Federal Register** on December 29, 2000 (65 FR 83124).

Issued in Washington, DC.

Karyn Gorman,

Acting Departmental Chief Privacy Officer.

[FR Doc. 2022–21927 Filed 10–6–22; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No.: OST–2022–0106]

Notice of Proposed Temporary Waiver of Buy America Requirements for the Strengthening Mobility and Revolutionizing Transportation (SMART) Grants Program

ACTION: Notice; request for comments.

SUMMARY: In order to deliver projects and meaningful results while ensuring robust adoption of Buy America standards, DOT is proposing to establish a temporary public interest waiver for projects funded under the new Strengthening Mobility and Revolutionizing Transportation (SMART) Grants Program. The waiver only applies to awards made within the first year (FY 2022) of funding for the new program, for which there may be limited cases where the Buy America requirements would apply for planning and prototyping activities. Given that this program is in its first year and DOT has not yet received applications, the waiver is intended to ensure that applicants consider the broadest possible range of technologies and solutions in their proposals for funding in FY 2022. Recipients of FY 2022 funds for Stage 1 activities are to collect data that will help inform the application of Buy America requirements to the funding of implementation activities under the program and identify any current gaps in the domestic availability of products that could potentially be filled by American suppliers.

DATES: Comments must be received by October 21, 2022.

ADDRESSES: Please submit your comments to the U.S. Government electronic docket site at *http://www.regulations.gov/,* Docket: OST–2022–0106.

Note: All submissions received, including any personal information therein, will be posted without change or alteration to *http://www.regulations.gov.* For more information, you may review DOT's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477).

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Darren Timothy, DOT Office of the Assistant Secretary for Transportation Policy, at *darren.timothy@dot.gov* or at 202–366–4051. For legal questions, please contact Michael A. Smith, DOT Office of the General Counsel, 202–366–2917, or via email at *michael.a.smith@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

On November 15, 2021, President Biden signed the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act, Public Law 117–58. Section 25005 of the BIL authorized the Department of Transportation (DOT) to establish the SMART Grants Program, and Div. J of the BIL appropriated $500 million for that purpose for fiscal year 2022 through 2026, of which $100 million is available for fiscal year 2022. The purpose of the SMART Grants Program is to conduct demonstration projects focused on advanced smart city or community technologies and systems in a variety of communities to improve transportation efficiency and safety. Eligible project activities under the program include Coordinated Automation; Connected Vehicles; Intelligent, Sensor-based Infrastructure; Systems Integration; Commerce Delivery and Logistics; Leveraging Use of Innovative Aviation Technology; Smart Grid; and Smart Technology Traffic Signals.

The SMART Grants Program anticipates providing two types of funding. The first is Stage 1 Planning and Prototyping Grants (Stage 1 grants) which will support recipients' efforts in refining and prototyping their proposed projects. At the conclusion of Stage 1, recipients should have the information to either create a fully realized implementation plan with robust performance metrics or to make an informed decision not to proceed with the concept.

Eligible entities will be required to receive Stage 1 grants in order to be considered for selection for the second type of funding: Stage 2 Implementation Grants (Stage 2 grants). Stage 2 implementation projects should result in a scaled-up demonstration of the concept, integrating it with the existing transportation system and refining the concept such that it could be replicated by others. In FY 2022, DOT is only soliciting applications for Stage 1 grants. DOT anticipates that it will solicit applications for both Stage 1 and Stage 2 grants in FY 2023.

In January 2021, President Biden issued *Executive Order (E.O.) 14005,* titled ''Ensuring the Future is Made in All of America by All of America's Workers,'' launching a whole-of-government initiative to strengthen Made in America standards. The E.O. states that the United States Government ''should, consistent with applicable law, use terms and conditions of Federal financial assistance awards and Federal procurements to maximize the use of goods, products, and materials produced in, and services offered in, the United States.'' DOT is committed to ensuring strong and effective Buy America implementation consistent with E.O. 14005, and has a long track record of successfully applying Made in America standards to support American workers and businesses through its more than $70 billion in grant programs, and $700 million in direct purchases in FY2020.

The BIL also includes the Build America, Buy America Act (''the Act''). Public Law 117–58, div. G 70901–52, which greatly strengthens Made in America standards by expanding the coverage and application of Buy America preferences in Federal financial assistance programs for infrastructure. The Act requires that the head of each covered Federal agency shall ensure that ''none of the funds made available for a Federal financial assistance program for infrastructure . . . may be obligated for a project unless all of the iron, steel, manufactured products, and construction materials used in the project are produced in the United States.'' BIL § 70914(a).

On April 18, 2022, OMB issued memorandum *M–22–11,* ''Initial Implementation Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure'' (''Implementation Guidance''). The Implementation Guidance states that, for purposes of applying the Act's domestic preference requirements, ''the term 'infrastructure' includes, at a minimum, the structures, facilities, and equipment for, in the United States, roads, highways, and bridges; public transportation'' and other public infrastructure. The Implementation Guidance also states that ''Federal agencies should interpret the term 'infrastructure' broadly and consider the definition provided above as illustrative and not exhaustive. When determining if a particular construction project of a type not listed in the definition above constitutes ''infrastructure,'' agencies should consider whether the project will serve a public function.'' Implementation Guidance at p. 4.

Section 70914(b) of the Act allows the head of a Federal agency to waive the application of a Buy America preference under an infrastructure program under certain limited circumstances, including on the basis of public interest; nonavailability of domestically produced materials or products; or unreasonable cost. The Implementation Guidance notes that a ''waiver in the

public interest may be appropriate where an agency determines that other important policy goals cannot be achieved consistent with the Buy America requirements established by the Act.'' Implementation Guidance at p. 10. The guidance also recognizes several instances in which Federal agencies may consider issuing a public interest waiver.

Proposed Waiver and Request for Comments

With the goal of advancing crucial infrastructure projects in a timely manner while implementing the new Buy America requirements, DOT is considering using its authority under Section 70914(b)(1) of the Act to provide a temporary waiver of the Buy America requirement for projects funded under the SMART grants program, on the basis that applying the domestic content preference for these materials would be inconsistent with the public interest. The temporary waiver would apply only to projects' Stage 1 planning and prototyping activities awarded pursuant to the *FY 2022 Notice of Funding Opportunity* for the program. The Department requests comment on whether such a waiver would be warranted. The proposed waiver would not apply to any Stage 1 or Stage 2 activities funded by the SMART Grants program in subsequent fiscal years.

As noted above, in FY 2022, SMART Grants funding will only be awarded for Stage 1 Planning and Prototyping grants. While those activities will largely involve project pre-development activities that would not be subject to Buy America requirements, they may also include the permanent installation of transportation-related technologies and equipment on public roads or public transportation systems, in which case they would be considered infrastructure that is subject to the domestic preference requirements of the Act.

The purpose of this waiver is to ensure that applicants for Stage 1 funding in FY 2022 consider the broadest possible range of technologies and solutions in their proposals. During and following Stage 1, recipients will report on their projects and results, which will be shared with the broader transportation sector to document lessons learned and identify any barriers or technical limitations on further development and deployment of those solutions, as well as those technologies that might show promise. Those purposes are best served by ensuring that a variety of technological applications can be explored in this first stage. The waiver will also ensure that recipients of FY 2022 funding are able to obligate those funds in a timely manner and commence the critical activities envisioned by Congress in its creation of this Federal assistance program.

The data collected by recipients of FY 2022 Stage 1 grant funding will also assist DOT in better understanding the nature of the types of structures and equipment that may be deployed in Stage 2 Implementation, which will assist the Department in determining how the Act's domestic preference requirements for infrastructure should be applied. Recipients will also collect and report data on the manufacturing sources of that equipment, which will help DOT and the industry identify both potential domestic suppliers for these technologies and any gaps in availability from U.S.-based sources that would provide a market opportunity for any suppliers able to meet the domestic preference requirements of the Act for iron and steel, manufactured products, and/or construction materials.

If this general applicability waiver is not issued, recipients of FY 2022 SMART Grants funding would be expected to comply with the Act in implementing their Stage 1 planning and prototyping projects. This could lead some potential applicants to limit the range of potential eligible projects that they might consider seeking funding for in FY 2022 due to an inability to determine a priori whether products procured under those projects might be subject to and compliant with the Buy America requirements of the Act, which would thus reduce the program's potential to foster innovative concepts in its inaugural year. In contrast, under the proposed waiver, applicants will be able to propose more diverse innovative concepts.

The OMB Implementation Guidance also provides that, before granting a waiver in the public interest, to the extent permitted by law, agencies shall assess whether a significant portion of any cost advantage of a foreign-sourced product is ''the result of the use of dumped steel, iron, or manufactured products or the use of injuriously subsidized steel, iron, or manufactured products.'' Implementation Guidance at p. 12. E.O. 14005 at Section 5 includes a similar requirement for ''steel, iron, or manufactured goods.'' However, because the public interest waiver that DOT is proposing in this notice is not based on consideration of the cost advantage of any foreign-sourced steel, iron, or manufactured product content, there is not a specific cost advantage for DOT to consider.

DOT will consider all comments received in the 15-day comment period during its consideration of the proposed waiver, as required by section 70914(c)(2) of the Act. Comments received after this period, but before any notice of a decision whether to grant a waiver is published in the **Federal Register**, will be considered to the extent practicable.

Issued in Washington, DC.

Polly E. Trottenberg,

Deputy Secretary.

[FR Doc. 2022–21848 Filed 10–6–22; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Recordkeeping Requirements for Securities Transactions

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning its information collection titled, ''Recordkeeping Requirements for Securities Transactions.''

DATES: You should submit comments by December 6, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0142, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–

0142'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet.

• *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' drop down menu, and click on ''Information Collection Review.'' From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0142'' or ''Recordkeeping Requirements for Securities Transactions.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.

• For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Mary H. Gottlieb, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests and/or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 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, the OCC is publishing notice of the renewal of this collection of information.

Title: Recordkeeping Requirements for Securities Transactions.

OMB Number: 1557–0142.

Abstract: The information collection requirements in 12 CFR parts 12 and 151 are designed to ensure that national banks and Federal savings associations comply with securities laws and to improve the protections afforded to persons who purchase and sell securities through these financial institutions. Parts 12 and 151 establish recordkeeping and confirmation requirements applicable to certain securities transactions effected by national banks or Federal savings associations for customers. The transaction confirmation information required by these regulations ensures that customers receive a record of each securities transaction and that financial institutions and the OCC have the records necessary to monitor compliance with securities laws and regulations. The OCC uses the required information in the course of its examinations to evaluate, among other things, an institution's compliance with the antifraud provisions of the Federal securities laws.

The information collection requirements contained in 12 CFR parts 12 and 151 are as follows:

• Twelve CFR 12.3 requires a national bank effecting securities transactions for customers to maintain certain records for at least three years. The records required by this section must clearly and accurately reflect the information required and provide an adequate basis for the audit of the information.

• Twelve CFR 151.50 requires a Federal savings association effecting securities transactions for customers to maintain certain records for at least three years. Twelve CFR 151.60 provides that the records required by 12 CFR 151.50 must clearly and accurately reflect the information required and provide an adequate basis for audit of the information.

• Twelve CFR 12.4 requires a national bank to give or send to the customer a written notification of the transaction at or before completion of the securities transaction or, if using a confirmation from a registered broker/dealer, to send a copy of that confirmation within one business day from the bank's receipt of the confirmation from the broker dealer. Section 12.4 also establishes minimum disclosures needed for a customer's securities transactions.

• Twelve CFR 151.70 establishes the types of notice a Federal savings association must provide when effecting a securities transaction for a customer. Twelve CFR 151.80 establishes when a Federal savings association must provide notice if the Federal savings association is complying with section 151.70 by using a broker-dealer confirmation, and also requires the Federal savings association to provide a statement of the source and amount of any remuneration it will receive in connection with the transaction, unless it has determined remuneration in a written agreement with the customer. Twelve CFR 151.90 establishes when a Federal savings association must provide notice if complying with section 151.70 by providing written notice and establishes the minimum disclosures that must be included in that notice. Twelve CFR 151.90 requires a Federal savings association to provide its customers with a written notice of each securities transaction if it is not following the procedures in 12 CFR 151.80. The Federal savings association must give or send the notice to the customer at or before the completion of the securities transaction.

• Twelve CFR 12.5(a), (b), (c), and (e) describe notification procedures that a national bank may elect to use, as an alternative to complying with section 12.4, to notify customers of transactions in which the bank does not exercise investment discretion, trust transactions, agency transactions, and certain periodic plan transactions.

• Twelve CFR 151.100 describes notification procedures that a Federal savings association may use, as an alternative to complying with 12 CFR 151.70, for an account in which the savings association does not exercise investment discretion, certain accounts for which it exercises investment discretion in other than an agency capacity, trust transactions, agency transactions, certain periodic plan transactions, collective investment fund transactions, and money market funds.

• Twelve CFR 12.7(a)(1) through (a)(3) require national banks to maintain and adhere to policies and procedures that assign responsibility for supervision of employees who perform securities trading functions, provide for the fair and equitable allocation of securities and prices to accounts for certain types of orders, and provide for

crossing of buy and sell orders on a fair and equitable basis.

• Twelve CFR 151.140 requires Federal savings associations to adopt written policies and procedures dealing with the functions involved in effecting securities transactions on behalf of customers. These policies and procedures must assign responsibility for the supervision of employees who perform securities trading functions, provide for the fair and equitable allocation of securities prices to accounts for certain types of orders, and provide for crossing of buy and sell orders on a fair and equitable basis.

• Twelve CFR 12.7(a)(4) requires certain national bank officers and employees involved in the securities trading process to report to the bank all personal transactions in securities made by them or on their behalf in which they have a beneficial interest.

• Twelve CFR 151.150 requires certain Federal savings association officers and employees to report personal transactions they make or that are made on their behalf in which they have a beneficial interest.

• Twelve CFR 12.8 requires a national bank seeking a waiver of one or more of the requirements of sections 12.2 through 12.7 to file a written request for waiver with the OCC.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 307.

Estimated Frequency of Response: On occasion.

Estimated Total Annual Burden: 1,501.5 Hours.

Comments submitted in response to this notice will be summarized and 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 OCC, including whether the information has practical utility;

(b) The accuracy of the OCC'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 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.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–21902 Filed 10–6–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Revision of Information Collection Request Submitted for Public Comment; Comment Request for Form 8933

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning Form 8933, Carbon Dioxide Sequestration Credit.

DATES: Written comments should be received on or before December 6, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Please include, ''OMB Number: 1545–2132—Public Comment Request Notice'' in the Subject line.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Carbon Dioxide Sequestration Credit.

OMB Number: 1545–2132.

Form Number: 8933.

Abstract: Use Form 8933 to claim the carbon oxide sequestration credit. The credit is allowed for qualified carbon oxide that is captured and disposed of or captured, used, and disposed of by the taxpayer in secure geological storage. Only carbon oxide captured and disposed of or used within the United States or a U.S. possession is taken into account when figuring the credit.

Current Actions: Form 8933 has been updated and revised to reflect new provisions under Public Law 117–169, section 13104.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Individuals or households, and Farms.

Estimated Number of Respondents: 250.

Estimated Time per Respondent: 17 hours 31 min.

Estimated Total Annual Burden Hours: 4,380.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: October 4, 2022.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2022–21887 Filed 10–6–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Interest Rate Paid on Cash Deposited To Secure U.S. Immigration and Customs Enforcement Immigration Bonds

AGENCY: Departmental Offices, Treasury.

ACTION: Notice.

SUMMARY: For the period beginning October 1, 2022, and ending on December 31, 2022, the U.S. Immigration and Customs Enforcement Immigration Bond interest rate is 2.74 per centum per annum.

DATES: Rates are applicable October 1, 2022 to December 31, 2022.

ADDRESSES: Comments or inquiries may be mailed to Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106–1328.

You can download this notice at the following internet addresses: *http://www.treasury.gov* or *http://www.federalregister.gov*.

FOR FURTHER INFORMATION CONTACT: Ryan Hanna, Manager, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Service, Parkersburg, West Virginia 261006–1328 (304) 480–5120; Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106–1328, (304) 480–5117.

SUPPLEMENTARY INFORMATION: Federal law requires that interest payments on cash deposited to secure immigration bonds shall be ''at a rate determined by the Secretary of the Treasury, except that in no case shall the interest rate exceed 3 per centum per annum.'' 8 U.S.C. 1363(a). Related Federal regulations state that ''Interest on cash deposited to secure immigration bonds will be at the rate as determined by the Secretary of the Treasury, but in no case will exceed 3 per centum per annum or be less than zero.'' 8 CFR 293.2. Treasury has determined that interest on the bonds will vary quarterly and will accrue during each calendar quarter at a rate equal to the lesser of the average of the bond equivalent rates on 91-day Treasury bills auctioned during the preceding calendar quarter, or 3 per centum per annum, but in no case less than zero. [FR Doc. 2015–18545]. In addition to this Notice, Treasury posts the current quarterly rate in Table 2b—Interest Rates for Specific Legislation on the TreasuryDirect website.

The Deputy Assistant Secretary for Public Finance, Gary Grippo, having reviewed and approved this document, is delegating the authority to electronically sign this document to Heidi Cohen, Federal Register Liaison for the Department, for purposes of publication in the **Federal Register**.

Heidi Cohen,

Federal Register Liaison.

[FR Doc. 2022–21825 Filed 10–6–22; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Notice of Funding Availability for the Direct Component and the Centers of Excellence Research Grants Program of the RESTORE Act

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Treasury Office of Gulf Coast Restoration announces three Notice of Funding Opportunities for the Direct Component and Centers of Excellence Research Grants Program of the Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies of the Gulf Coast States Act of 2012 (RESTORE Act).

DATES: Applications will be accepted on a rolling basis as long as funds are available in an Applicant's allocation. This funding opportunity announcement will close on October 31, 2023. This funding opportunity announcement will either be extended, or a new funding opportunity announcement may be posted in 2023 as determined necessary by the U.S. Department of the Treasury.

ADDRESSES: For additional information regarding this notice, please contact Bridget Cotti-Rausch, Policy Analyst, Office of Gulf Coast Restoration at telephone number: 202–923–0467.

SUPPLEMENTARY INFORMATION: The Council is authorized to award grants pursuant to the Direct Component and Centers of Excellence Research Grants Program of the Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies of the Gulf Coast States Act of 2012 (RESTORE Act), Public Law 112–141, 1602, 126 Stat. 588 (2012). Treasury announces two Direct Component Notice of Funding Opportunities (NOAs) and one Centers of Excellence Research Grants Program NOA. The NOAs provide guidance to eligible entities on the steps necessary to submit grant applications for individual projects and programs. The full text of the FOAs can be found on Treasury's Direct Component website (*https://home.treasury.gov/policy-issues/financial-markets-financial-institutions-and-fiscal-service/restore-act/direct-component/direct-component-resources*) and Treasury's Centers of Excellence Research Program website (*https://home.treasury.gov/policy-issues/financial-markets-financial-institutions-and-fiscal-service/restore-act/centers-of-excellence-research-grants-program/centers-of-excellence-coe-resources*).

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2022–21827 Filed 10–6–22; 8:45 am]

BILLING CODE 4810–AK–P

DEPARTMENT OF THE TREASURY

Periodic Meeting of the U.S. Department of the Treasury Tribal Advisory Committee

AGENCY: Department of the Treasury.

ACTION: Notice of meeting.

SUMMARY: This notice announces that the Department of the Treasury Tribal Advisory Committee (TTAC) will convene a public meeting from 1:00 p.m.–4:00 p.m. Eastern Time on Wednesday, October 26, 2022 (Public Meeting). The Public Meeting will be held in person at the Treasury Building in Washington, DC and is open to the public.

DATES: The Public Meeting will be held on Wednesday, October 26, 2022, from 1:00 p.m.–4:00 p.m. Eastern Time. Registration for the Public Meeting will close at 5:00 p.m. Eastern Time on Friday, October 21, 2022.

ADDRESSES: Due to security requirements, only registered attendees will be permitted entry into the Treasury Building. Please register for the Public Meeting by visiting: *https://events.treasury.gov/s/event-template/a2mt0000001LvGlAAK.* When registering you will be asked to state your name, title, and organizational affiliation and whether you wish to make public comments. Registration for the Public Meeting will close at 5:00 p.m. Eastern Time on Friday, October

21, 2022. Those wishing to make public comments should register no later than three business days before the Public Meeting. Written comments must be received 15 calendar days before the Public Meeting in order to be considered during the meeting. Written comments can be emailed to *TTAC@treasury.gov.* If you have questions regarding the Public Meeting please email *TTAC@treasury.gov.*

If you require a reasonable accommodation, please contact the Departmental Offices Reasonable Accommodations Coordinator at *ReasonableAccommodationRequests@treasury.gov.* If requesting a sign language interpreter, please make sure your request to the Reasonable Accommodations Coordinator is made at least (5) five days prior to the event if at all possible.

FOR FURTHER INFORMATION CONTACT: Krishna P. Vallabhaneni, Designated Federal Officer, by emailing *TTAC@treasury.gov* or by calling (202) 622–2000 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 3 of the Tribal General Welfare Exclusion Act of 2014, Public Law 113–68, 128 Stat. 1883, enacted on September 26, 2014 (TGWEA), directs the Secretary of the Treasury (Secretary) to establish a seven member Tribal Advisory Committee to advise the Secretary on matters related to the taxation of Indians, the training of Internal Revenue Service field agents, and the provision of training and technical assistance to Native American financial officers.

Pursuant to section 3 of the TGWEA and in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 1 *et seq.,* the TTAC was established on February 10, 2015, as the ''U.S. Department of the Treasury Tribal Advisory Committee.'' The TTAC's Charter provides that it shall operate under the provisions of the FACA and shall advise and report to the Secretary on:

(1) Matters related to the taxation of Indians;

(2) The establishment of training and education for internal revenue field agents who administer and enforce internal revenue laws with respect to Indian tribes of Federal Indian law and the Federal Government's unique legal treaty and trust relationship with Indian tribal governments; and

(3) The establishment of training of such internal revenue field agents, and provisions of training and technical assistance to tribal financial officers, about implementation of the TGWEA and any amendments.

Ninth Periodic Meeting

In accordance with section 10(a)(2) of the FACA and implementing regulations at 41 CFR 102–3.150, Krishna P. Vallabhaneni, the Designated Federal Officer of the TTAC, has ordered publication of this notice to inform the public that the TTAC will convene its ninth periodic meeting on Wednesday, October 26, 2022, from 1:00 p.m.–4:00 p.m. Eastern Time.

Summary of Agenda and Topics To Be Discussed

During this meeting, the TTAC members will provide updates on the work of the TTAC's three subcommittees, hear comments from the public, and take other actions necessary to fulfill the TTAC's mandate.

Public Comments

Members of the public wishing to comment on the business of the TTAC are invited to submit written comments by emailing *TTAC@treasury.gov.* Comments are requested no later than 15 calendar days before the Public Meeting in order to be considered by the TTAC.

The Department of the Treasury will post all comments received on its website (*https://www.treasury.gov/resource-center/economic-policy/tribal-policy/Pages/Tribal-Policy.aspx*) without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. The Department of the Treasury will also make these comments available for public inspection and copying in the Department of the Treasury's Library, 720 Madison Place NW, Room 1020, Washington, DC 20220, on official business days between the hours of 10:00 a.m. and 5:00 p.m. Eastern Time. You can make an appointment to inspect statements by telephoning (202) 622–2000. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

Dated: October 4, 2022.

Krishna P. Vallabhaneni,

Tax Legislative Counsel and Designated Federal Officer.

[FR Doc. 2022–21906 Filed 10–6–22; 8:45 am]

BILLING CODE 4810–AK–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0198]

Agency Information Collection Activity: Application for Annual Clothing Allowance

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration (VHA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before December 6, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Janel Keyes, Office of Regulations, Appeals, and Policy (10BRAP), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Janel.Keyes@va.gov.* Please refer to ''OMB Control No. 2900–0198'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0198'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Application for Annual Clothing Allowance, VA Form 10–8678.

OMB Control Number: 2900–0198.

Type of Review: Reinstatement of a previously approved collection.

Abstract: The Department of Veterans Affairs (VA) through its Veterans Health Administration (VHA) administers an integrated program of benefits and services, established by law for veterans, service personnel, and their dependents and/or beneficiaries. Information is requested by this form under the authority of 38 U.S.C., Section 1162, Clothing Allowance, which provides authority for the Secretary to pay a clothing allowance to veterans who, because of a service-connected disability, wear or use a prosthetic or orthopedic appliance (including a wheelchair) which tends to wear out or tear clothing or uses medication that causes irreparable damage to the outer garments. Entitlement to this benefit is granted by 38 CFR 3.810, Clothing Allowance, upon application by the eligible individual. VA Form 10–8678 is used to collect the necessary information to determine if the veteran has established entitlement to a clothing allowance payment.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,120 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 6,720.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–21822 Filed 10–6–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 87 Friday,
No. 194 October 7, 2022

Part II

Department of Transportation

48 CFR Chapter 12
Streamline and Update the Department of Transportation Acquisition Regulation (TAR Case 2020–001); Final Rule

DEPARTMENT OF TRANSPORTATION

48 CFR Chapter 12

RIN 2105–AE26

Streamline and Update the Department of Transportation Acquisition Regulation (TAR Case 2020–001)

AGENCY: Department of Transportation.

ACTION: Final rule.

SUMMARY: The Department of Transportation (DOT) is issuing a final rule amending the Transportation Acquisition Regulation (TAR). Under this initiative, all parts of the regulation were reviewed to streamline the regulation, to revise or remove policy that has been superseded by changes in the Federal Acquisition Regulation (FAR), to remove procedural guidance that is internal to DOT and move it to the Transportation Acquisition Manual (TAM) as appropriate, and to incorporate new regulations or policies required to implement or supplement the FAR to execute DOT's unique mission and responsibilities. The TAM will incorporate portions of the internal procedural guidance removed from the TAR, as well as other internal agency acquisition policy. This rulemaking revises the entire TAR.

DATES: This rule is effective on November 7, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. LaWanda Morton-Chunn, Procurement Analyst, Acquisition Policy, Oversight & Business Strategies (M–61), Office of the Senior Procurement Executive (OSPE), Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 366–2267. This is not a toll-free telephone number. Please refer to TAR Case 2020–001 in any written communications.

SUPPLEMENTARY INFORMATION:

Background

DOT published a proposed rule in the **Federal Register** at 86 FR 69452 on December 7, 2021, to amend the TAR to implement and/or supplement the FAR. Please refer to the proposed rule for a discussion of the reasons why DOT proposed the changes to the TAR described in that rule document. DOT provided a 60-day comment period for the public to respond to the proposed rule and submit comments. The public comment period closed on February 7, 2022. DOT received no public comments on the proposed rule.

The TAR has been substantially revised and streamlined to update references to obsolete policies, procedures, and organizations, and to incorporate electronic links to key references. Revisions to the TAR were necessary to incorporate additional policies, solicitation provisions, or contract clauses that implement and supplement the FAR to satisfy DOT mission needs, and to incorporate changes in dollar and approval thresholds, definitions, and DOT position titles and offices.

This rule adopts as a final rule the proposed rule published in the **Federal Register** on December 7, 2021, except for technical non-substantive changes to update terminology in accordance with FAR final rules and other minor administrative amendments as shown in the paragraphs that follow. This rule establishes a 2022 baseline edition of the TAR.

Technical Non-Substantive Changes to the Rule

This rule makes the non-substantive changes to the proposed rule described in the following paragraphs to provide clarity, eliminate confusion, and ensure compliance with the Federal Acquisition Regulation (FAR). Specifically, DOT is revising the term ''commercial items'' to reflect either ''commercial products and commercial services'' or ''commercial products or commercial services'' in alignment with FAR final rule, *Federal Acquisition Regulation: Revision of Definition of* ''*Commercial Item*'', RIN 9000–AN76, effective December 6, 2021 (86 FR 61017). There are 28 mentions of the legacy term ''commercial items'' that were identified in the TAR proposed rule amendatory language in various TAR parts, subparts, and sections, to include titles as well as the underlying text. The legacy term ''commercial items'' was also referenced in two FAR clause references where the FAR title has also been revised because of the referenced FAR final rule.

The TAR is also updating terminology under TAR part 1239, Acquisition of Information Technology, and subpart 1239.2, to reflect a FAR change in terminology from ''Electronic and Information Technology'' to ''Information and Communication Technology.'' This includes a change in the heading of subpart 1239.2 to correspond with the new FAR subpart heading.

Accordingly, DOT is revising the TAR final rule to reflect the updated terminology in accordance with the FAR final rules as reflected in the amendatory text as follows (items number 1–14 below):

1. Under 48 CFR chapter 12, Transportation Acquisition Regulation, Table of Contents, the title for TAR part 12, Acquisition of Commercial Items, DOT is revising the title from ''Acquisition of Commercial Items,'' to ''Acquisition of Commercial Products and Commercial Services''.

2. Under TAR part 12, Acquisition of Commercial Items, DOT is revising the title from ''Acquisition of Commercial Items,'' to ''Acquisition of Commercial Products and Commercial Services''.

3. Under TAR part 12, in the Table of Contents, subpart 1213.3, DOT is revising the heading for subpart 1212.3 from ''Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Items'' to read ''Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services.''

4. Under TAR part 12, in the Table of Contents, section 1212.301, Solicitation provisions and contract clauses for the acquisition of commercial items, DOT is revising the heading to read ''Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.''

5. At subpart 1212.3 DOT is revising the heading from ''Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Items'' to read ''Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services.''

6. At section 1212.301, DOT is revising the heading from ''Solicitation provisions and contract clauses for the acquisition of commercial items'' to read ''Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.''

7. Under section 1212.301, at paragraph (f), DOT is revising ''commercial items'' to read ''commercial products or commercial services.''

8. Under section 1239.7003, Contract clauses, in paragraphs (a), (b), and (c), where DOT sets forth the prescription to contract clauses 1252.239–72, Compliance with Safeguarding DOT Sensitive Data Controls; 1252.239–73, Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information; and 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting, respectively, DOT is revising the phrase ''commercial items'' in each prescription to read ''commercial products and commercial services.'' Additionally, in paragraph (b), in the prescription for clause 1252.239–73, Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information,

DOT is adding the word ''commercial'' before ''services'' in the last sentence.

9. Under section 1239.7204, Contract clauses, in each of the prescriptions in paragraphs (a) through (m), for clauses 1252.239–76, Cloud Computing Services; 1252.239–77, Data Jurisdiction; 1252.239–78, Validated Cryptography for Secure Communications; 1252.239–79, Authentication, Data Integrity, and Non-Repudiation; 1252.239–80, Audit Record Retention for Cloud Service Providers; 1252.239–81, Cloud Identification and Authentication (Organizational Users) Multi-Factor Authentication; 1252.239–82, Identification and Authentication (Non-Organizational Users); 1252.239–83, Incident Reporting Timeframes; 1252.239–84, Media Transport; 1252.239–85, Personnel Screening—Background Investigations; 1252.239–86, Boundary Protection—Trusted internet Connections; 1252.239–87, Protection of Information at Rest; and 1252.239–88, Security Alerts, Advisories, and Directives, respectively, DOT is revising the phrase ''commercial items'' in each prescription to read ''commercial products and commercial services.''

10. Under section 1252.232–71, Limitation of Government's Obligation, paragraph (b), where it discusses incrementally funding Contract Line Items Numbers (CLIN(s)), DOT is revising the heading of the referenced FAR clause 52.214–4, ''Commercial Terms and Conditions—Commercial Items,'' to read ''Commercial Terms and Conditions—Commercial Products and Commercial Services.'' And in paragraph (e), where it discusses the termination provisions and references FAR clause 52.212–4, the heading is also revised to reflect the new updated FAR heading of ''Commercial Terms and Conditions—Commercial Products and Commercial Services.''

11. Under section 1252.239–73, Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information, in paragraph (c), Subcontract flowdown requirement, of the clause, DOT is revising the phrase ''commercial items'' to read ''commercial products or commercial services.''

12. Under section 1252.239–74, Safeguarding DOT Sensitive Data, and Cyber Incident Reporting, in paragraph (o)(1) of the clause, DOT is revising the phrase ''commercial items'' to read ''commercial products or commercial services.''

13. Under section 1252.239–76, Cloud Computing Services, in paragraph (j), Subcontract flowdown requirement, DOT is revising the phrase ''commercial items'' to read ''commercial products or commercial services.'' Additionally, DOT is revising the TAR final rule to revise the use of the terminology from ''electronic and information technology (EIT)'' to the FAR updated usage of ''Information and Communication Technology'' as shown below in item number 14.

14. The following technical/administrative non-substantive revisions to TAR subpart 1239.2 were made to reflect updated FAR terminology:

a. Heading of subpart 1232.9 is revised from ''Electronic and Information Technology'' to read ''Information and Communication Technology.''

b. Under section 1239.201, Scope of subpart, the first sentence referring to ''EIT'' is removed and ''Information and Communication Technology (ICT)'' is used instead. The FAR was updated to reflect ''Information and Communication Technology'' and the TAR final rule incorporates this new term and usage as well.

c. Under section 1239.203, Applicability, the phrase, ''Solicitations for information technology (information and communication technology) or IT-related supplies and services may require submission of a Section 508 Checklist . . .'' is revised to read ''Solicitations for information and communication technology supplies and services may require submission of a section 508 Checklist . . .'' to align with the FAR usage of the updated terminology.

d. Under section 1252.239–93, Information and Communication Technology Accessibility, paragraph (a), Definition, is removed in its entirety. The term ''Electronic and Information Technology (EIT)'' supplies and services is no longer necessary because the FAR is updated to reflect the usage of the phrase ''Information and Communication Technology'' and the TAR final rule incorporates this new usage as well.

15. Additionally, the following minor administrative corrections were made to reflect appropriate citation references in accordance with the U.S. Government Publishing Office (GPO) Style Manual and the FAR Drafting Guide:

a. Under section 1201.104, paragraph (a), the reference to ''Chapter 12'' is revised to read ''chapter 12.''

b. Under section 1224.103, the reference ''49 CFR part 10'' is revised to read ''49 CFR part 10.''

c. Under section 1224.203, the reference ''49 CFR part 7'' is revised to read ''49 CFR part 7.''

d. Under section 1239.7402, paragraph (a), the reference to ''36 CFR Chapter XII Subchapter B'' is revised to read ''36 CFR chapter XII, subchapter B.''

e. Under section 1252.239–75, DOT Protection of Information About Individuals, PII, and Privacy Risk Management Requirements, paragraph (c)(1), the reference to ''49 CFR part 10'' is revised to read ''49 CFR part 10.''

f. Under section 1252.239–91, Records Management, paragraph (b), the reference to ''36 CFR Chapter XII Subchapter B'' is revised to read ''36 CFR chapter XII, subchapter B''.

16. DOT also makes the following general non-substantive technical and administrative updates to correct grammar or other sentence formatting and structure, as well as to provide clarity to current DOT policies and procedures:

a. Under section 1201.102–70, paragraph (a), the second sentence is revised to read ''. . . and to ensure that the process embodies fairness . . .'' in lieu of ''to embody fairness . . .''.

b. Under section 1201.105–2, Arrangement of regulations, in the illustrations at paragraphs (c)(3)(iv) and (v), the TAR citations are corrected to reflect the example citation of TAR 1201.105–2.

c. Under section 1201.301, Policy, paragraph (a)(1)(ii), the title ''Senior Executive'' is revised to read ''Senior Procurement Executive.''

d. Under section 1201.301–70, Amendment of the Transportation Acquisition Regulation, paragraph (a), we added a phrase at the end of the email address to provide clarity that proposed changes ''must include the following elements'' referring to paragraphs (a)(1) through (4).

e. Under section 1201.301–71, Effective dates for Transportation Acquisition Circulars (TACs), in paragraph (a), the word, ''or'' is added between ''effective upon receipt'' or ''upon a specified date,'' to ensure proper sentence construction.

f. Under section 1203.204, Treatment of violations, ''DOT'' is substituted for the referenced ''Government'' legal counsel in paragraphs (a) and (c) to specify DOT legal counsel will provide advice to heads of contracting activities.

g. Under section 1203.301, General, ''DOT'' is substituted for the referenced ''Government'' legal counsel in paragraph (b).

h. Under section 1203.405, Misrepresentations or violations of the Covenant Against Contingent Fees, ''DOT'' is substituted for the referenced ''Government'' legal counsel in paragraph (a).

i. In section 1204.804–570, Supporting closeout documents, the sentence is reconstructed to move the parenthetical reference referring to paragraphs (a)(1) through (4) later in the sentence.

j. In section 1204.1301, Policy, the phrase ''or NIST issued successor publications'' is removed as unnecessary.

k. Under section 1209.403, Definitions, minor revisions are made for clarity—

(i) Under the definition ''DOT Order 4200.5G'' the phrase ''or its successor'' is removed as unnecessary.

(ii) Under the definition ''Senior Accountable Official (SAO) for Suspension and Debarment,'' the term ''departmental'' is removed, and the phrase ''for the Department of Transportation'' is added to the second sentence.

(iii) Under the definition ''Suspension and Debarment Coordinator (SDC),'' the term ''Suspending and Debarring Official (SDO)'' is spelled out to ensure clarity.

(iv) Under the definition ''Suspending and Debarring Official (SDO),'' administrative edits to remove the spelled-out term for the Office of the Secretary of Transportation is removed, and a website address for where a list of DOT Operating Administration (OA)-appointed SDOs is provided.

l. In section 1209.405, Effect of listing, in paragraph (e)(2), the phrase ''that a compelling reason exists'' is revised to ''of compelling reasons to''. And in paragraph (e)(3), the phrase ''that a compelling reason exists'' is revised to ''of compelling reasons''.

m. In section 1209.406–1, General, paragraph (c), the word ''each'' is inserted before ''OA-appointed SDO . . .''.

n. In section 1209.406–3, Procedures, paragraph (d)(2), a comma after ''The SDO reviews submittals'' is removed, and the word ''and'' is inserted.

o. In section 1209.407–3, Procedures, paragraph (d), in the second sentence a comma after ''The SDO reviews submittals'' is removed and the word ''and'' is inserted.

p. Under part 1213, Simplified Acquisition Procedures, in section 1213.7000, Applicability, in paragraph (a) the word ''also'' is removed before the phrase ''applies to Standard Form (SF) 182, . . .''.

q. Under part 1219, Small Business Programs, in section 1219.7000, General, the link has been updated to a more direct link to DOT's mentor-protégé program material on the Office of Small and Disadvantaged Business Utilization (OSDBU) website.

r. Under part 1223, Environment, Energy and Water Efficiency, Renewable Energy Technologies, Occupational Safety, and Drug-Free Workplace, in section 1223.7000, Contract clauses, paragraph (c), the sentence is reconstructed to make the prescription clear by moving the condition to the front of the sentence that the clause prescribed shall be inserted ''in all solicitations and contracts exceeding the simplified acquisition threshold, . . .''.

s. Under part 1232, Contract Financing, in section 1232.770–4, Policy, paragraph (a)(1), the word ''or'' is added in the second sentence after ''DOT''. And in paragraph (a)(6), the word ''an'' is added before ''individual''.

t. In section 1232.7003, Payment system registration, the two sentences that comprised the proposed text of the section are removed as they may duplicate some of the language as stated in section 1232.7002(a). The section heading is retained to reflect the coverage in the underlying subsections.

u. In section 1235.010–70, Scientific and technical reports—acquisition, publication and dissemination, we are removing the section in its entirety as it is unnecessary. The FAR adequately covers content in this area, though DOT may consider adopting an agency-specific policy.

v. In section 1235.070, Research misconduct, in paragraph (a), we have included a link to the cited DOT Deputy Secretary Memorandum, Implementation of Departmental Scientific Integrity Policy, April 10, 2012, and have removed a reference to an outdated policy document. Note that DOT intends to update its scientific integrity policies and the TAR as necessary consistent with the Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking (Jan. 27, 2021).

w. Under part 1237, Service Contracting, in section 1237.110–70, Contract clauses, in paragraph (a), the word ''and,'' is added after ''Government facilities''.

17. General non-substantive technical updates to the proposed rule pertaining to part 1239, Acquisition of Information Technology. The following non-substantive minor administrative corrections were made to correct grammar or other sentence formatting and structure, as well as to provide clarity to current DOT policies and procedures:

a. In section 1239.000, Scope of part, DOT is removing the phrase ''information technology-related services and'' after the word ''including'' as it is duplicative to the earlier part of the sentence.

b. In section 1239.101–70–3, Policy, the section is revised slightly to clarify it by adding ''products or services supporting the'' before the word ''development'' and the word ''software'' after DOT.

c. In section 1239.7001, Definitions, under the definition for ''DOT sensitive data'' the word ''as'' is removed after ''unclassified information''.

d. In section 1239.7203, DOT FedRAMP specific requirements, paragraph (b), Digital signature cryptography—(authentication, data integrity, and non-repudiation), DOT has added ''(1–4)'' after the phrase, ''contracting officers shall specify what level'' to denote those FIPS 140–2 (1–4) levels referenced in paragraph (a). In paragraph (d), Cloud identification and authentication (organizational users) multi-factor authentication, the phrase ''or successor publications'' is removed after the FIPS 201–2, Personal Identity Verification (PIV) of Federal Employees and Contractors reference as it is unnecessary to include the phrase. In paragraph (e), the phrase ''are required to'' is removed as it is redundant. In paragraph (i), the word ''who'' is inserted in the first sentence before the phrase ''shall undergo required DOT background investigations . . .'' to correct grammar.

e. In section 1239.7204, Contract clauses, in paragraph (h), the prescription for clause 1252.239–83 is revised be removing the words ''all services'' before the phrase ''solicitations and contracts,'' and the word ''and'' is removed before ''for information technology services . . .'' as both are unnecessary. In paragraph (k), the word ''all'' is removed before ''solicitation and contracts,'' as unnecessary.

f. In section 1239.7302, Policy, the word ''will'' is removed as unnecessary.

g. In section 1239.7400, Scope of subpart, the last word in the section ''exists'' is revised to ''exist.''

h. In section 1239.7402, Policy, paragraph (a)(1), the phrase ''the Federal Records Act'' is removed as an incorrect title reference, and the word ''and'' is added in the citation references. In paragraph (a)(2), the phrase ''the Federal Records Act'' is removed as an incorrect title reference, and the phrase ''records management laws and'' is inserted after ''relevant'' and the words ''statute or'' is removed, and an ''s'' is added to regulations, and the comma is removed after ''regulation'' so the latter part of the sentence now reads: ''. . . only as permitted by relevant records management laws and regulations . . .''.

In paragraph (a)(3), the citation for 36 CFR part 1230 is corrected by adding the word ''part'' as shown. In paragraph (a)(4), the phrase '', is properly protected'' is removed at the end of the first sentence.

i. In section 1239.7403, Contract clause, the word ''or'' is removed before the word ''disseminate'' so the end of the sentence now reads: ''. . . associates collect, access, maintain, use, disseminate or otherwise handle Federal records.''

18. Additional general non-substantive technical updates to the proposed rule that follow part 1239 follow. These also include the following non-substantive minor administrative corrections to correct grammar or other sentence formatting and structure, as well as to provide clarity to current DOT policies and procedures:

a. Under part 1242, Contract Administration and Audit Services, in section 1242.302, Contract administration functions, paragraph (a), the word ''either'' is removed before ''the cognizant government auditing agency,'' as unnecessary. In paragraph (a)(13), the acronym ''OA'' is moved after ''cognizant'' in the second sentence.

b. Under part 1246, Quality Assurance, in section 1246.101–70, Additional definitions, under the definition ''Major acquisition'' the word ''also'' is removed before ''for information technology or information technology related acquisitions, . . .'' as unnecessary.

c. In section 1246.706–70, Warranty terms and conditions—requirements, in paragraph (a)(9), the word ''and'' is added after ''(*e.g.,* delivery, acceptance, in-service date)'', the word ''ending'' is revised to read ''end'', the word ''period'' is added after ''warranty'', and the word ''specify'' is added before ''circumstances'' in order to provide better clarity to the flow of the sentence and meaning. In paragraph (b)(1), the word ''that'' is substituted for ''which.'' In paragraph (b)(3), at the beginning of the sentence the word ''The'' is removed and replaced with ''A'' so it reads ''A warranty provided . . .''.

d. Under part 1247, Transportation, in section 1247.506, Procedures, the long run-on sentence is broken up by adding a period after ''are not available'' and the words ''MARAD can also'' is added to start the next sentence, and the words ''and they can'' are removed.

19. Finally, in parts 1252 and 1253 these technical non-substantive revisions are reflected in the following provisions, clauses, or form prescription published in the proposed rule. These also include the following non-substantive minor administrative corrections to correct grammar or other sentence formatting and structure, as well as to provide clarity to current DOT policies and procedures:

a. In section 1252.204–70, Contractor Personnel Security and Agency Access, under paragraph (a), Definitions, the following definitions had minor administrative or grammatical updates: ''Contractor employee'' and ''Identification card (or ''ID Card'').'' In paragraph (b), the words ''each level'' was added so the text before the list of levels now reads ''and each level includes the prior levels''. In paragraph (f), Background investigation and adjudication, ''PIV–1'' is corrected to reflect ''PIV–I''.

b. In section 1252.209–71, Limitation of Future Contracting, in paragraph (c)(2), the word ''remains'' is revised to use ''remain'' in the phrase ''. . . if these data remain proprietary or confidential, . . .''.

c. In section 1252.217–72, Performance, in paragraph (d), the words ''or not'' are removed before ''the Contractor''.

d. In section 1252.217–73, Inspection and Manner of Doing Work, paragraph (e)(9), the singular word ''valve'' is revised to reflect ''valves.''

e. In section 1252.217–76, Liability and Insurance, paragraph (b)(3)(i)(C) is revised to add ''regardless of'' before ''whether'' and to remove ''or not'' after ''whether'' in both instances. In paragraph (c)(2), in the last sentence the word ''does'' is deleted, and the singular word ''apply'' is revised to ''applies''. This corrects the grammar and readability of the sentence. In paragraph (f)(3), the word ''in'' is removed before ''the conduct of suits'' in the first sentence so the end of the sentence now reads: ''. . . attendance of witnesses, and the conduct of suits.''

f. In section 1252.222–72, Contractor Cooperation in Equal Employment Opportunity and Anti-Harassment Investigations, in paragraph (a), Definitions, under the definition ''Good faith cooperation,'' paragraph (3), the words ''the course of'' are deleted before ''EEO'', and in paragraph (5) under that definition, the term ''the Merit Systems Protection Board'' is spelled out. In paragraph (b), the term ''Equal Employment Opportunity'' is removed and the acronym ''EEO'' remains.

g. In section 1252.223–73, Seat Belt Use Policies and Programs, we are removing a reference to a public-private partnership organization promoting traffic safety. DOT retains a reference to a DOT traffic safety website.

h. In section 1252.228–70, Loss of or Damage to Leased Aircraft, the phrase ''as it wishes'' is removed and the phrase ''in its discretion'' is used in its place as more appropriate terminology.

i. In section 1252.232–70, Electronic Submission of Payment Requests, paragraph (c), the words ''For vendors'' is removed in the third sentence and replaced with ''Vendors'' and the words ''they will be'' are also removed and replace with ''are'' so the sentence reads more clearly now as ''Vendors submitting invoices are required . . .''. In paragraph (d), the phrase at the beginning of the sentence ''In order to'' is removed and replaced with ''To'' so the start of the sentence now reads ''To receive payment . . .''. And in paragraph (g), the last sentence removes ''has been'' after ''DELPHI'' and adds the word ''is'' so it now reads at the beginning of the sentence, ''If DELPHI is succeeded by later technology . . .''.

j. In section 1252.235–70, Research Misconduct, in paragraph (c)(2), the word ''or'' is removed before ''knowingly'' so it now reads: ''The misconduct must have been committed intentionally, knowingly, or recklessly; and . . .''. In paragraph (f)(3)(i), the text is removed in its entirety as duplicative of a similarly worded paragraph in (h) and thus unnecessary; the clarifying sentence is moved to paragraph (h). The text in paragraph (f)(3)(ii) is moved up into paragraph (f)(3) and the designation of (ii) is removed as unnecessary.

k. In section 1252.235–71, Technology Transfer, in paragraph (a)(5), the word ''of'' is removed before ''interest'' and the word ''interest'' is revised to ''interested'' so it now reads as follows at the end of the sentence, ''stakeholders most likely to be interested in the commercialization of the research outputs;''. In paragraph (a)(7), the Contracting Officer fill-in is moved to the end of the sentence.

l. In section 1252.237–70, Qualifications of Contractor Employees, in paragraph (a) the first sentence is revised to add ''is proprietary data or'' before ''if subject to unauthorized access,'' and is removed from later in the sentence for clarity. In paragraph (b), the word ''or'' is inserted before ''sensitive information or resources''. And in paragraph (c), the word ''of'' is inserted before ''those employees.''

m. In section 1252.239–70, Security Requirements for Unclassified Information Technology Resources, paragraph (b), in the last sentence, the word ''and'' is removed after ''. . . in accordance with Federal and DOT policies and procedures,'' and the word '',which'' is added after ''as amended during the terms of this contract,'' and word ''and'' is removed before ''include''.

n. In section 1252.239–72, Compliance with Safeguarding DOT Sensitive Data Controls, paragraph (c), DOT added the reference to ''Revision 2'' to the NIST 800–171 reference and title and updated a new direct link to the cited publication at *nist.gov.* We also added in the Revision 2 (Rev. 2) reference in the clause at paragraphs (d) and (e).

o. In section 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting, we revised the wording in paragraph (a) under the definition for ''Adequate security'' to remove ''balance and'' before the phrase ''are commensurate'', to remove ''impact and'' before ''consequences'', to add the words ''and probability'' after ''consequences'', and to delete the word ''the'' before ''loss, misuse''. In paragraphs (b)(2)(i) through (iv), references are updated and an updated link is provided. In paragraph (b)(2)(v), the word ''to'' is removed before ''have an alternate'' so the end of the sentence now reads ''. . . to be nonapplicable, or have an alternative, but equally effective, security measure that may be implemented in its place.'' In paragraph (b)(2)(vi), the words ''the Contractor'' is added after ''Contracting Officer when'' to clarify who is doing the requesting and ''requesting'' is revised to ''request''. The end of the sentence now reads as follows: ''. . . a copy of that approval shall be provided to the Contracting Officer when the Contractor requests its recognition under this contract.'' In paragraph (c)(1)(i), the word ''that'' is removed after ''DOT sensitive data'' in the second sentence, and the words ''whether the incident'' is added and ''affect'' is revised to ''affects'' so the end of the last/second sentence now reads: ''. . . in order to identify compromised DOT sensitive data or whether the incident affects the Contractor's ability to provide operationally critical support; and . . .''. And in paragraph (o), Subcontract flowdown requirements, the reference to NIST SP 800–171 is updated to add ''Rev. 2.''

p. In section 1252.239–75, DOT Protection of Information About Individuals, PII, and Privacy Risk Management Requirements, paragraph (n), Subcontract flowdown requirements, paragraph (n)(1), the word ''its'' is removed before ''provisions relating to'' and the word ''and'' is deleted before ''Breach Notification''.

q. In section 1252.239–76, Cloud Computing Services, paragraph (b)(4), the reference to NIST Special Publication 800–53 is updated to reflect ''Revision 5.'' In paragraph (b)(6)(ii), the phrase ''DOT Order'' is revised to add an ''s'' and to add ''containing'' immediately afterward so it now reads: ''. . . FedRAMP and DOT Orders containing cybersecurity and privacy policies.'' In paragraph (g), an ''s'' is added to ''discover'' and ''isolate'' so the beginning of the sentence now reads ''The Contractor or subcontractor(s) that discovers and isolates malicious software. . . .''.

r. In section 1252.239–77, Data Jurisdiction, in the first sentence the words ''in which'' are added after ''all data centers'' and the word ''that'' is deleted before ''the data'' so the beginning of the sentence now reads ''The Contractor shall identify all data centers in which the data at rest or data backup will reside, . . .''.

s. In section 1252.239–81, Cloud Identification and Authentication (Organizational Users) Multi-Factor Authentication, at the end of the last sentence the phrase ''or NIST successor publications'' is removed as unnecessary.

t. In section 1252.239–84, Media Transport, paragraph (a)(1) is reconstructed to remove ''that is transported outside of controlled areas'' after ''that require protection'' and a revised phrase of ''when transported outside of controlled areas;'' is added at the end of the sentence. In paragraph (b), the phrase ''must ensure accountability'' is removed at the end of the first sentence as it is redundant to a similar phrase earlier in the sentence.

u. In section 1252.239–85, Personnel Screening—Background Investigations, an updated active link is provided to a website containing the referenced Office of Management and Budget (OMB) memorandum.

v. In section 1252.239–88, Security Alerts, Advisories, and Directives, the words ''who are'' are added before ''assigned system administration, . . .'' and the word ''who'' is added after the words, ''and/or security responsibilities and who are . . .''.

w. In section 1252.239–89, Technology Modernization, the word ''or'' is added before ''strengthen the cyber security posture'' in the second sentence.

x. In section 1252.239–91, Records Management, paragraph (b)(1), the words ''the Federal Records Act'' is removed as an incorrect title reference, and the word ''and'' is inserted in the citation reference chapters for 44 U.S.C. And in paragraph (b)(2), the words ''other'' is inserted before ''relevant statute'' at the end of the paragraph, ''s'' is added to ''statute'' and ''regulation'' so it now reads at the end of the last sentence: ''. . . ''other relevant statutes or regulations, . . .''. And in paragraph (d), the word ''The'' is added to start the sentence before ''Contractor'' in the second and third sentence.

y. In sections 1252.239–92, Information and Communication Technology Accessibility Notice, and 1252.239–93, Information and Communication Technology Accessibility, an updated link to the *www.section508.gov* site is provided in each.

z. Under part 1253, Forms, in section 1253.204–70, Administrative matters—agency specified forms, paragraph (b), DOT is providing the link to the DOT website where forms may be obtained and removing reference to an appendix as the forms controlled by DOT are provided at the linked website.

These minor technical nonsubstantive revisions will ensure DOT's updated regulation is clear and contains the most recent citations, references, links, and current procedures.

The Department emphasizes that, in addition to the changes finalized in this rulemaking, it continues to track a number of new FAR case proposed and final rules, as well as Executive orders (E.O.s) and directives that the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) are reviewing for potential impact to the FAR system. The Executive orders include E.O. 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' (86 FR 7009; Jan. 25, 2021), E.O. 14005, ''Ensuring the Future is Made in All of American by All of America's Workers'' (86 FR 7475; Jan. 28, 2021), and E.O. 14008, ''Tackling the Climate Crisis at Home and Abroad'' (86 FR 7619; Feb. 1, 2021). If and when FAR cases and proposed rules are drafted and FAR final rules are published, DOT intends to examine each of these for impact to the TAR and any updates that may be required to maintain the TAR. DOT is institutionalizing an ongoing, sustained TAR refreshment process, so that as FAR proposed and final rules, E.O.s, and other directives are issued, DOT will initiate new TAR cases to bring the regulation in alignment and to avoid duplication, as necessary. DOT will examine any FAR final rules that become effective and will take into consideration such FAR changes, as appropriate, in subsequent rulemakings. When needed, DOT will also consider use of an advanced notice of public rulemaking (ANPRM) to obtain public input as the agency implements rulemaking to address new and emerging issues that may be identified by the Councils or by DOT as a result of E.O.s and other directives. DOT will

use this public input to inform how DOT implements such guidance in the TAR.

Regulatory Reviews

Executive Order 12866 and 13563

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages, distributive impacts, and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Office of Information and Regulatory Affairs has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action, and has determined that this rule is not a significant regulatory action under E.O. 12866.

Paperwork Reduction Act

This final rule includes provisions constituting new collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that require approval by the Office of Management and Budget (OMB). Accordingly, under 44 U.S.C. 3507(d), DOT submitted the information collections to OMB for review and approval. No comments were received on the proposed collections of information. If OMB does not approve the collections of information as requested, DOT will immediately remove the provisions containing a collection of information or take such other action as directed by OMB.

Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information that does not display a valid OMB control number.

Regulatory Flexibility Act

DOT expects that the overall impact of the rule would benefit small businesses because the updated TAR, among other things, revised outdated information, removed extraneous procedural information that applies only to DOT's internal operating procedures, and removed policy or procedures duplicative of FAR requirements. Any additional costs associated with the rule, such as costs to implement the substantive new and revised requirements concerning information technology security provisions of the Federal Information Security Management Act of 2002 (FISMA) (Title III of the E-Government Act of 2002 (E-Gov Act)) can be factored into the contract price. On this basis, the Secretary hereby certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of sections 603 and 604 do not apply.

While based on the foregoing, DOT has determined that the agency is not required to prepare a Final Regulatory Flexibility Analysis (FRFA), DOT has prepared a FRFA that is summarized here. No comments were received by the agency on the proposed rule or on the summary of the Initial Regulatory Flexibility Analysis.

Final Regulatory Flexibility Analysis

This Final Regulatory Flexibility Analysis has been prepared consistent with 5 U.S.C. 604.

1. Statement of the Need for, and the Objectives of, the Rule

DOT is issuing a final rule amending the Transportation Acquisition Regulation (TAR) to implement updates to the TAR, remove extraneous procedural information that applies only to DOT's internal operating procedures, and remove policy or procedures duplicative of FAR requirements. The rule also includes substantive new and revised requirements concerning information technology (IT) security provisions of the Federal Information Security Management Act of 2002 (FISMA) (Title III of the E-Government Act of 2002 (E-Gov Act)). FISMA requires agencies to identify and provide information security protections commensurate with security risks to Federal information collected or maintained for the agency and information systems used or operated on behalf of an agency by a contractor. The Federal Acquisition Regulatory Council (FAR Council) contemplated in their previous FAR rules on IT that subsequent supplemental policymaking at the agency level may have some impact on small business entities, because FISMA requires that agencies establish IT security policies commensurate with agency risk and potential for harm and that meet certain minimum requirements. The impact on small entities was understood to be variable depending on the agency implementation. Based on a review of the potential impact on small business entities, DOT has determined that the requirements specified in the rule are inherent to successful performance on any Federal contract.

In addition to updating the TAR to remove outdated information, remove extraneous procedural information that applies only to DOT's internal operating procedures, and to remove policy or procedures duplicative of FAR requirements, the rule implements the IT security provisions of the FISMA. Section 301 of FISMA (44 U.S.C. 3544) requires that contractors be held accountable to the same security standards as Government employees when collecting or maintaining information or using or operating information systems on behalf of an agency. Security is to be considered during all phases of the acquisition life cycle. FISMA requires that agencies establish IT security policies commensurate with agency risk and potential for harm and that meet certain minimum requirements. Agencies are further required, through the Chief Information Officer (CIO) or equivalent, to assure compliance with agency security policies. The law requires that contractors and Federal employees be subjected to the same requirements in accessing Federal IT systems and data.

2. Statement of the Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis, a Statement of the Assessment of the Agency of Such Issues, and a Statement of any Changes Made to the Rule as a Result of Such Comments

There were no public comments on the proposed rule, and there were no significant issues or comments raised by the public in response to the initial regulatory flexibility analysis.

3. The Response of the Agency to any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration in Response to the Proposed Rule, and a Detailed Statement of any Change Made to the Proposed Rule in the Final Rule as a Result of the Comments

No comments were filed in response to the proposed rule.

4. Description of and, Where Feasible, Estimate of the Number of Small Entities to Which the Rule Will Apply

To estimate the number of small businesses who could potentially be impacted by the rule, DOT identified contract award actions across key North American Industry Classification

System (NAICS) codes that could be affected for three fiscal years—FY 2017, 2018, and 2019 as set forth in the table below. DOT focused on businesses that could be impacted by the revisions to part 1239, Acquisition of Information Technology, because of the potential costs resulting from the associated Paperwork Reduction Act information collection burdens, the cost of which may be assessed by businesses and included in any proposed price for performance under any awarded contract.

NAICS	NAICS description	FY 2017	FY 2018	FY 2019	Total	Average
518210	Data Processing, Hosting, and Related Services.	172	177	238	587	196
541199	All Other Legal Services	9	12	15	36	12
541511	Custom Computer Programming Services.	896	1,964	870	3,730	1,243
541512	Computer Systems Design Services	754	942	1,036	2,732	911
541513	Computer Facilities Management Services.	385	358	329	1,072	357
541519	Other Computer Related Services	1,270	1,440	1,355	4,065	1,355
541618	Other Management Consulting Services.	86	53	40	179	60
541990	All Other Professional, Scientific, and Tech. Svcs..	947	1,002	848	2,797	932
561110	Office Administrative Services	373	352	279	1,004	335
561499	All Other Business Support Services	20	20	25	65	22
561621	Security Systems Services	187	142	146	475	158
	Total	5,099	6,462	5,181	16,742	5,581

As shown, DOT awarded over 16,742 contracts for IT or IT-related services during FY 2017 through FY 2019. To estimate the number of small businesses potentially impacted by the rule, DOT notes that in FY 2019, the department achieved a 37.12% goal of overall awards to all small business concerns across all NAICS and all operating administrations. Using this figure to project the potential impact to small business entities who may be affected by the rule, the Department estimates that these businesses could be awarded 10%–25% of such work, or up to 4,186 contracts awarded to small businesses.

DOT received no comments from the public based on these estimates. To ensure our original estimates remain roughly the same, we pulled additional data for FY 2020 and FY 2021. Because DOT recognizes that the ongoing COVID–19 pandemic during that period may skew that data and its overall utility, we retain the data estimates from FY 2017–FY 2019 as shown above, and provide the updated information experienced in FY 2020 and FY 2021 below:

NAICS	NAICS description	FY 2020	FY 2021	Total	Average
518210	Data Processing, Hosting, and Related Services	336	525	861	431
541199	All Other Legal Services	19	21	40	20
541511	Custom Computer Programming Services	769	750	1519	760
541512	Computer Systems Design Services	998	1092	2,090	1045
541513	Computer Facilities Management Services	334	248	582	291
541519	Other Computer Related Services	1280	1181	2461	1231
541618	Other Management Consulting Services	49	35	84	42
541990	All Other Professional, Scientific, and Tech. Svcs.	1247	1263	2510	1255
561110	Office Administrative Services	251	183	434	217
561499	All Other Business Support Services	31	34	65	33
561621	Security Systems Services	231	135	366	183
	Total	5,545	5,467	11,012	5,508

The data from FY 2020 and FY 2021 reveal that small businesses that might potentially be impacted by the rule actually decreased. DOT awarded over 16,742 contracts for IT or IT-related services during FY 2017 through FY 2019, but for FY 2020 and FY 2021, the same number of IT or IT-related services equated to 11,012. To estimate the number of small businesses potentially impacted by the rule, DOT notes that in FY 2020, the department achieved a 34.05% goal of overall awards to all small business concerns across all NAICS and all operating administrations. The decrease in small business contract awards could be attributed to nationwide economic disruptions particularly to small businesses during the beginning of the COVID–19 pandemic. Using this updated figure to project the potential impact to small business entities who may be affected by the final rule, the Department estimates that these businesses could be awarded 10%—25% of such work, or up to 2,753 contracts awarded to small businesses and thus the impact to such businesses is decreased.

5. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including An Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

The revised recordkeeping and reporting requirements and estimated impacts were described in the Paperwork Reduction Act (PRA) section of the proposed rule and associated supporting statements are on file with the Office of Information and Regulatory

Affairs, the Office of Management and Budget. Those requirements and estimated impacts are incorporated into this FRFA by reference.

6. Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule

DOT considered whether any other alternatives would reduce the impact on small businesses but concluded that the rule is necessary for consistency with the FAR, for FISMA compliance, and to ensure the information security and integrity of DOT information and information systems. Many of the provisions of the rule are intended to align with the FAR, update outdated procedures, remove internal operational procedures thus streamlining regulation, which could also potentially reduce the impact on small entities complying with the TAR.

Section 610 Review

As noted in the Department's portion of the Spring 2022 Unified Agenda, this final rule satisfies the Department's periodic review requirement pursuant to the Regulatory Flexibility Act, 5 U.S.C. 610.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (UMRA) requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. DOT has determined that this final rule would have no such effect on State, local, and tribal governments or on the private sector. Therefore, the analytical requirements of UMRA do not apply.

Congressional Review Act

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

List of Subjects

48 CFR Part 1201

Government procurement, Reporting and recordkeeping requirements.

48 CFR Part 1203

Conflict of interest, Government procurement.

48 CFR Parts 1202, 1204, 1205, 1206, 1207, 1209, 1211, 1212, 1213, 1215, 1216, 1217, 1223, 1224, 1233, 1236, 1237, 1239, 1252, and 1253

Government procurement.

48 CFR Part 1219

Government procurement, Small businesses.

48 CFR Part 1222

Government procurement, Labor.

48 CFR Part 1227

Copyright, Government procurement, Inventions and patents.

48 CFR Part 1228

Government procurement, Insurance, Surety bonds.

48 CFR Parts 1231, 1232, and 1242

Accounting, Government procurement.

48 CFR Part 1235

Government procurement, Research.

48 CFR Part 1246

Government procurement, Warranties.

48 CFR Part 1247

Government procurement, Transportation.

Signed on or around September 2, 2022.

Polly E. Trottenberg,

Deputy Secretary, Department of Transportation.

■ For the reasons set out in the preamble, DOT amends title 48 of the Code of Federal Regulations by revising chapter 12 to read as follows:

CHAPTER 12—DEPARTMENT OF TRANSPORTATION

SUBCHAPTER A—GENERAL

SUBCHAPTER B—ACQUISITION PLANNING

SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

SUBCHAPTER D—SOCIOECONOMIC PROGRAMS

SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS

SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

SUBCHAPTER G—CONTRACT MANAGEMENT

SUBCHAPTER H—CLAUSES AND FORMS

Subchapter A—General

PART 1200 [RESERVED]

PART 1201—FEDERAL ACQUISITION REGULATIONS SYSTEM

Subpart 1201.1—Purpose, Authority, Issuance

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1201.1—Purpose, Authority, Issuance

1201.101 Purpose.

The Department of Transportation (DOT), Transportation Acquisition Regulation (TAR), establishes uniform acquisition policies and procedures that implement and supplement the Federal Acquisition Regulation (FAR). The TAR provides regulatory or policy instruction when coverage is needed for DOT-specific subject matter not covered in the FAR. The TAR also includes policy statements that DOT considers important to both internal and external TAR audiences. The Transportation Acquisition Manual (TAM) contains internal operating procedures, providing supplementary guidance and instructions for carrying out FAR and TAR requirements.

1201.102–70 DOT statement of guiding principles for the Department of Transportation Acquisition System.

(a) *Vision.* The TAR applies to all Department acquisitions unless otherwise excluded by statute. DOT strives to make its acquisition process effective, efficient, and transparent, and to ensure that the process embodies fairness and Governmentwide best practices.

(b) *Mission.* The TAR is a key component of DOT's acquisition process and is designed to provide clear and current regulatory and policy oversight to supplement or support implementation of the FAR.

(c) *Role of the Office of the Senior Procurement Executive.* The Office of the Senior Procurement Executive (OSPE) applies leadership and best-in-industry acquisition practices to establish acquisition policies and procedures. The OSPE supports the DOT's mission by providing timely, effective, and ethical business policies, practices, products, innovative programs, strategies, and services.

1201.104 Applicability.

(a) Applicable statutes, the FAR, 48 CFR chapter 1, and the TAR, in this chapter, apply to all acquisitions within the Department unless otherwise specifically excluded by statute, the FAR, or the TAR.

(b) The following order of precedence applies to resolve any question of applicability concerning an acquisition regulation or a procedure found within the TAR, or the TAM which comprises the Department's internal operating procedures and guidance—

(1) U.S. Statutes;
(2) The FAR;
(3) The TAR;
(4) DOT Orders; and
(5) The TAM.

(c) The Maritime Administration may depart from the requirements of the FAR and TAR as authorized by 40 U.S.C. 113(e)(15), but shall adhere to those regulations to the maximum extent practicable. Deviations from the FAR or TAR requirements shall be documented according to Maritime Administration procedures or in each contract file, as appropriate.

(d) The FAR, TAR, and TAM do not apply to the Federal Aviation Administration as provided by 49 U.S.C. 40110(d).

(e) For purposes of the FAR, TAR, and TAM, the Office of the Assistant Secretary for Research and Technology shall have the same authority as an Operating Administration as defined in 1202.1, and the Assistant Secretary for Research and Technology shall have the same authority as a Head of the Operating Administration as defined in 1202.1.

1201.105 Issuance.

1201.105–1 Publication and code arrangement.

(a) The TAR is published or available in—

(1) The **Federal Register**;
(2) Cumulative form in the CFR; and
(3) Online via the internet at *https://www.acquisition.gov/tar.*

(b) The TAR is issued as this chapter.

1201.105–2 Arrangement of regulations.

(a) *General.* The TAR, which encompasses both Department and Operating Administration (OA)/Office of the Assistant Secretary for Research and Technology (OST–R)-specific guidance (*see* subpart 1201.3), conforms with the arrangement and numbering system prescribed by FAR 1.104. Guidance that is OA-specific contains the OA's acronym directly after the heading.

(b) *Numbering*—(1) *Department-wide guidance.* (i) The numbering illustrations at FAR 1.105–2(b) apply to the TAR.

(ii) Coverage within the TAR is identified by the prefix ''12'' followed by the complete TAR citation. For example, 1201.201–1(b).

(iii) Coverage in the TAR that supplements the FAR will use part, subpart, section, and subsection numbers ending in ''70'' through ''89'' (*e.g.,* 1201.301–70). A series of numbers beginning with ''70'' is used for provisions and clauses.

(iv) Coverage in the TAR, other than that identified with a ''70'' or higher number, that implements the FAR uses the identical number sequence and caption of the FAR segment being implemented, which may be to the paragraph level. Paragraph numbers and letters are not always shown sequentially, but may be shown by the specific FAR paragraph implemented. For example, TAR 1201.201–1 contains only paragraph (b) because only this paragraph, correlated with the FAR, is implemented in the TAR.

(2) *Operating Administration-unique guidance.* Supplementary material for which there is no counterpart in the FAR or TAR shall be identified using chapter, part, subpart, section, or subsection numbers of ''90'' and higher.

(c) *References and citations.* The Department of Transportation Acquisition Regulation may be referred to as the TAR. Cross reference to the FAR in the TAR will be cited by ''FAR'' followed by the FAR numbered citation, and cross reference to the TAM in the

TAR will be cited by ''TAM'' followed by the TAM numbered citations. References to specific citations within the TAR will be referenced by the numbered citation only, *e.g.,* 1201.105–3.

(3) Using the TAR coverage at 1201.105–2(b) as a typical illustration, reference to the—

(i) Part would be ''TAR part 1201'' outside the TAR and ''part 1201'' within the TAR.

(ii) Subpart would be ''TAR subpart 1201.1'' outside the TAR and ''subpart 1201.1'' within the TAR.

(iii) Section would be ''TAR 1201.105'' outside the TAR and ''1201.105'' within the TAR.

(iv) Subsection would be ''TAR 1201.105–2'' outside the TAR and ''1201.105–2'' within the TAR.

(v) Paragraph would be ''TAR 1201.105–2(b)'' outside the TAR and ''1201.105–2(b)'' within the TAR.

1201.105–3 Copies.

(a) Copies of the TAR as published in **Federal Register** and as set forth in the CFR may be purchased from the Government Publishing Office (GPO), U.S. Government Online Bookstore on the internet at *https://bookstore.gpo.gov/.*

(b) The TAR and Transportation Acquisition Circulars (TACs) are available on the internet at *https://www.acquisition.gov.*

1201.106 OMB approval under the Paperwork Reduction Act.

The information collection and recordkeeping requirements contained in the TAR have been approved by the Office of Management and Budget (OMB). Details concerning any TAR-related OMB approved control numbers are specified in the TAM.

Subpart 1201.2—Administration

1201.201 Maintenance of the FAR.

1201.201–1 The two councils.

(b) The Senior Procurement Executive is responsible for providing a DOT representative to the Civilian Agency Acquisition Council (CAAC).

Subpart 1201.3—Agency Acquisition Regulations

1201.301 Policy.

(a)(1) *Acquisition regulations*—(i) *Department-wide acquisition regulations.* The Department of Transportation's (DOT's) Senior Procurement Executive (SPE) is the individual having authority to issue or authorize the issuance of agency regulations that implement or supplement the FAR to include agency-unique policies, procedures, contract clauses, solicitation provisions, and forms that govern the contracting process. This authority is re-delegated from the Assistant Secretary for Administration to the SPE.

(ii) *Operating Administration (OA) acquisition regulations.* OA supplemental acquisition regulations proposed to be inserted in the TAR as a TAR supplement regulation shall be reviewed and approved by the SPE. If approved by the SPE, the Office of the Senior Procurement Executive will prepare the rule for publication in the **Federal Register** in accordance with FAR 1.501. OA regulations may be more restrictive or require higher approval levels than those required by the TAR unless otherwise specified.

(2) *Acquisition procedures.* The SPE issues or authorizes the issuance of internal agency guidance at any organizational level. DOT internal operating procedures are contained in the TAM. OA procedures necessary to implement or supplement the FAR, TAR, or TAM may be issued by the head of the contracting activity (HCA), who may delegate this authority to any organizational level deemed appropriate. OA procedures may be more restrictive or require higher approval levels than those permitted by the TAM unless otherwise specified.

(b) The authority of the agency head under FAR 1.301(b) to establish procedures to ensure that agency acquisition regulations are published for comment in the **Federal Register** in conformance with the procedures in FAR subpart 1.5 is delegated to the Office of the General Counsel, Assistant General Counsel for Regulation.

1201.301–70 Amendment of the Transportation Acquisition Regulation.

(a) Changes to the TAR may be the result of recommendations from internal DOT personnel, other Government agencies, or the public. Proposed changes shall be submitted in the following format to the Office of the Senior Procurement Executive (OSPE), 1200 New Jersey Avenue, SE, Washington, DC 20590 or *DOTAcquisitionPolicy@dot.gov* and must include the following elements:

(1) *Problem.* Succinctly state the problems created by current TAR language and describe the factual or legal reasons necessitating regulatory change.

(2) *Recommendation.* Identify the recommended change by using the current language (if applicable) and striking through the proposed deleted words with a horizontal line. Insert proposed language in bold and brackets. If the change is extensive, reflect proposed deleted language in strikethrough and proposed new or revised language with complete paragraphs in bold and brackets.

(3) *Discussion.* Explain why the change is necessary and how it will solve the problem. Address any cost or administrative impact on Government activities, offerors, and contractors, to include potential impact to small businesses. Provide any other information and documents, such as statutes, legal decisions, regulations, and reports, that may be helpful.

(4) *Point of contact.* Provide a point of contact who can answer questions regarding the recommendation.

(b) The TAR is maintained by the SPE through the TAR/TAM change process. This process consists of input from various DOT elements including representatives from DOT OAs specifically designated to formulate Departmental acquisition policies and procedures.

(c) Transportation Acquisition Circulars (TACs) (*see* 1201.301–72) will be used to publish the TAR throughout DOT.

1201.301–71 Effective dates for Transportation Acquisition Circulars (TACs).

(a) *Effective dates set forth in TACs.* Unless otherwise stated in the body of TACs, statements to the effect that the policy or procedures are ''effective upon receipt,'' or ''upon a specified date,'' or that changes set forth in the document are ''to be used upon receipt,'' mean that any new or revised provisions, clauses, procedures, or forms must be included in solicitations, contracts, or modifications issued thereafter.

(b) *Effective dates for in-process acquisitions.* Unless expressly directed by statute or regulation, solicitations in process or negotiations that are completed when a TAC is issued are not required to include or insert new requirements, forms, clauses, or provisions, as may be set forth in a TAC. However, the chief of the contracting office must determine that it is in the best interest of the Government to exclude the new information and the determination and findings must be included in the contract file.

1201.301–72 Transportation Acquisition Circular numbering.

Transportation Acquisition Circulars (TACs) will be numbered consecutively on a fiscal year basis beginning with number ''01'' prefixed by the last two digits of the fiscal year (*e.g.,* TACs 21–01 and 21–02 indicate the first two TACs issued in fiscal year 2021).

1201.304 Agency control and compliance procedures.

(a) DOT shall control the proliferation of acquisition regulations and any revisions thereto (except as noted in paragraph (b) of this section) by using an internal TAR change process.

(b) Specific OA-unique regulations will not be processed through the TAR/TAM change process but shall be reviewed by OA legal counsel and submitted to the OSPE for review and approval. (*See* 1252.101 for additional instructions pertaining to provisions and clauses.)

Subpart 1201.470—Deviations From the FAR and TAR

1201.403 Individual deviations.

The head of the contracting activity (HCA), or designee with a rank that is no lower than that of a Senior Executive Service (SES) official, may authorize individual deviations to the FAR and TAR, unless FAR 1.405(e) applies.

1201.404 Class deviations.

The SPE may authorize and approve class deviations from the FAR and TAR, unless FAR 1.405(e) applies.

Subpart 1201.6—Career Development, Contracting Authority, and Responsibilities

1201.602 Contracting officers.

1201.602–2 Responsibilities.

(d) Each DOT OA is responsible for establishing Contracting Officer's Representative (COR) nomination and appointment procedures consistent with the DOT Acquisition Workforce Career Development Program.

1201.602–3 Ratification of unauthorized commitments.

(b) *Policy.* DOT policy requires that all procurement decisions shall be made only by Government officials having authority to carry out such acquisitions. Procurement decisions made by other than authorized personnel are contrary to Departmental policy and may be considered matters of serious misconduct on the part of the employee making an unauthorized commitment. Disciplinary action against an employee who makes an unauthorized commitment may be considered.

1201.603 Selection, appointment, and termination of appointment for contracting officers.

1201.603–1 General.

Each DOT OA is responsible for appointing its contracting officers. Each HCA shall appoint one Chief of the Contracting Office (COCO) for each OA. Individuals designated as COCOs are considered contracting officers and shall be appointed by their respective HCA. The HCA may select, appoint, and terminate the appointment of contracting officers. The HCA may re-delegate this authority to a level no lower than that of the COCO.

1201.604 Contracting Officer's Representative (COR).

1201.604–70 Contract clause.

The contracting officer shall insert the clause at 1252.201–70, Contracting Officer's Representative, in solicitations and contracts that are identified as other than firm-fixed-price, and for firm-fixed-price solicitations and contracts when appointment of a contracting officer's representative is anticipated.

PART 1202—DEFINITIONS OF WORDS AND TERMS

Subpart 1202.1—Definitions

Subpart 1202.70—Abbreviations

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1202.1—Definitions

1202.101 Definitions.

Agency Advocate for Competition means the Deputy Assistant Secretary for Administration.

Agency, Federal agency, or *Executive agency,* as used in the TAR, means the Department of Transportation (DOT).

Chief Financial Officer (CFO) is the principal fiscal advisor to the Secretary of DOT responsible for providing leadership, advice, and guidance in the development, implementation, and administration of DOT's budget, financial management, and performance management.

Chief Information Officer is the principal information technology (IT), cyber security, privacy, and records management advisor to the Secretary, and is the final authority on these matters within the Department.

Chief of the Contracting Office (COCO) means the individual(s) responsible for managing the contracting office(s) within an Operating Administration.

Contracting activity includes all the contracting offices within an Operating Administration and is the same as the term ''procuring activity.''

Contracting officer means an individual authorized by virtue of their position or by appointment to perform the functions assigned by the Federal Acquisition Regulation (FAR), the Transportation Acquisition Regulation (TAR), and Transportation Acquisition Manual (TAM).

Department of Transportation (DOT) means, when referring to the various suborganizations and components of DOT, all of the Operating Administrations, as defined in the TAR/TAM, included within DOT.

Head of the agency or *Agency head* for Departmental procurement means the Deputy Secretary except for acquisition actions that, by the terms of a statute or delegation, must be done specifically by the Secretary of Transportation.

Head of the contracting activity (HCA) means the individual responsible for managing the contracting offices within an Operating Administration who is a member of the Senior Executive Service except for the HCA within the Great Lakes St. Lawrence Seaway Development Corporation (GLS), which shall be an individual no lower than one level above the COCO. The term HCA is the same as the term ''head of the procuring activity.''

Head of the Operating Administration (HOA) means the individual appointed by the President to manage the DOT operating administration.

Operating Administration (OA) means the following components of DOT—

(1) Federal Aviation Administration (FAA) (FAA is exempt from FAR, TAR, and TAM pursuant to the Department of Transportation and Related Agencies Appropriations Act, 1996 (Pub. L. 104–50));

(2) Federal Highway Administration (FHWA);

(3) Federal Motor Carrier Safety Administration (FMCSA);

(4) Federal Railroad Administration (FRA);

(5) Federal Transit Administration (FTA);

(6) Maritime Administration (MARAD);

(7) National Highway Traffic Safety Administration (NHTSA);

(8) Office of the Secretary of Transportation (OST);

(9) Pipeline and Hazardous Materials Safety Administration (PHMSA);

(10) Great Lakes St. Lawrence Seaway Development Corporation (GLS); and

(11) Office of the Assistant Secretary for Research and Technology (OST–R).

Small Business Specialist (SBS) means the individual appointed by each HCA to assist the Director, Office of Small and Disadvantaged Business Utilization in carrying out the purpose of the Small Business Act.

Senior Procurement Executive (*SPE*) means the Director of the Office of the Senior Procurement Executive.

Subpart 1202.70—Abbreviations

1202.7000 General.

The following abbreviations or acronyms may be used throughout the TAR and the agency's associated internal policies and procedures in the TAM—

TABLE 1 TO 1202.7000—ABBREVIATIONS AND ACRONYMS

CFO	Chief Financial Officer.
CIO	Chief Information Officer.
COCO	Chief of the Contracting Office.
COR	Contracting Officer's Representative.
D&F	Determination and Findings.
FOIA	Freedom of Information Act.
HCA	Head of the Contracting Activity.
HOA	Head of the Operating Administration.
J&A	Justification and Approval.
OA	Operating Administration.
OIG	Office of the Inspector General.
OSDBU	Office of Small and Disadvantaged Business Utilization.
PCR	Procurement Center Representative.
RFP	Request for Proposal.
SBA	Small Business Administration.
SBS	Small Business Specialist.
SPE	Senior Procurement Executive.

PART 1203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1203.1—Safeguards

1203.101–3 Agency regulations.

(a) Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR part 2635, and the Supplemental Standards of Ethical Conduct for Employees of the Department of Transportation, 5 CFR part 6001, apply to all DOT employees.

Subpart 1203.2—Contractor Gratuities to Government Personnel

1203.203 Reporting suspected violations of the Gratuities clause.

(a) Suspected violations of the Gratuities clause shall be reported to the contracting officer responsible for the acquisition (or the Chief of the Contracting Office (COCO) if the contracting officer is suspected of the violation). The contracting officer (or COCO) shall obtain from the person reporting the violation, and any witnesses to the violation, the following information—

(1) The date, time, and place of the suspected violation;

(2) The name and title (if known) of the individual(s) involved in the violation; and

(3) The details of the violation (*e.g.,* the gratuity offered or intended) to obtain a contract or favorable treatment under a contract.

(b) The person reporting the violation and witnesses (if any) should be requested to sign and date the information certifying that the information furnished is true and correct. The COCO shall report suspected violations to the Office of the Inspector General (OIG), 1200 New Jersey Avenue SE, Washington, DC 20590, with a copy to General Counsel and the OA's Chief Counsel.

1203.204 Treatment of violations.

(a) The HCA is authorized to determine whether a Gratuities clause violation has occurred. If the HCA has been personally and substantially involved in the procurement, DOT legal counsel advice should be sought to determine if a substitute for the HCA should be designated.

(b) The COCO shall ensure that the contractor is afforded the hearing procedures required by FAR 3.204(b). Government legal counsel should be consulted regarding the appropriateness of the hearing procedures.

(c) If the HCA determines that the alleged gratuities violation occurred during the ''conduct of an agency procurement'', the COCO shall consult with DOT legal counsel regarding the approach for appropriate processing of either the Procurement Integrity Act violation and/or the Gratuities violation.

Subpart 1203.3—Reports of Suspected Antitrust Violations

1203.301 General.

(b) The same procedures contained in 1203.203 shall be followed for suspected antitrust violations, except reports of suspected antitrust violations shall be coordinated with DOT legal counsel for referral to the Department of Justice, if deemed appropriate.

1203.303 Reporting suspected antitrust violations.

(b) The same procedures contained in 1203.203 shall be followed for suspected antitrust violations, except reports of suspected antitrust violations shall be coordinated with legal counsel for referral to the Department of Justice, if deemed appropriate.

Subpart 1203.4—Contingent Fees

1203.405 Misrepresentations or violations of the Covenant Against Contingent Fees.

(a) The same procedures contained in 1203.203 shall be followed for reporting the attempted or actual exercise of improper influence, misrepresentation of a contingent fee arrangement, or other violation of the Covenant Against Contingent Fees (*see* FAR 52.203–5), except reports of misrepresentation or violations of the Covenant Against Contingent Fees shall be coordinated with DOT legal counsel for referral to the Department of Justice, if deemed appropriate.

Subpart 1203.5—Other Improper Business Practices

1203.502–2 Subcontractor kickbacks.

(g) The same procedures contained in 1203.203 shall be followed for reporting a violation of 41 U.S.C. chapter 87, Kickbacks.

Subpart 1203.7—Voiding and Rescinding Contracts

1203.703 Authority.

(a) The head of the contracting activity (HCA) is authorized by the Secretary of Transportation to declare void and rescind contracts and other transactions listed in Public Law 87–849 (18 U.S.C. 218), in which there has been a final conviction for bribery, conflict of interest, or any other violation of 18 U.S.C. 201–224.

(b) The Head of the Operating Administration (HOA) is authorized to make determinations, in accordance with FAR 3.703(b)(2).

Subpart 1203.9—Whistleblower Protections for Contractor Employees

1203.906 Remedies.

(a) The HCA is authorized to make determinations and take actions under FAR 3.906(a).

(b) The HCA is authorized to take actions under FAR 3.906(b).

PART 1204—ADMINISTRATIVE AND INFORMATION MATTERS

Subpart 1204.1—Contract Execution

Sec.
1204.103 Contract clause.

Subpart 1204.5—Electronic Commerce in Contracting

1204.502 Policy.

Subpart 1204.8—Government Contract Files

1204.801 General.
1204.804 Closeout of contract files.
1204.804–5 Procedures for closing out contract files.
1204.804–570 Supporting closeout documents.

Subpart 1204.9—Taxpayer Identification Number Information

1204.903 Reporting contract information to the IRS.

Subpart 1204.13—Personal Identity Verification

1204.1301 Policy.
1204.1303 Contract clause.

Subpart 1204.17—Service Contracts Inventory

1204.1703 Reporting requirements.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1204.1—Contract Execution

1204.103 Contract clause.

The contracting officer shall insert the clause at FAR 52.204–1, Approval of Contract, filled in as appropriate, in solicitations and contracts when approval to award the resulting contract must be obtained from an official at a level above the contracting officer.

Subpart 1204.5—Electronic Commerce in Contracting

1204.502 Policy.

(c) DOT's preferred policy is to use electronic signatures, records and communication methods in lieu of paper transactions whenever practicable. Before using electronic commerce, the HOA and OA shall ensure that the OA systems are capable of ensuring authentication and confidentiality commensurate with the risk of unauthorized access to or modification of the information.

Subpart 1204.8—Government Contract Files

1204.801 General.

(a) The COCO is designated as the head of each office performing contracting and contract administration functions. The Chief Financial Officer (CFO) of the OA is designated as the head of the office performing paying functions.

1204.804 Closeout of contract files.

1204.804–5 Procedures for closing out contract files.

1204.804–570 Supporting closeout documents.

(a) When applicable and prior to contract closeout, the contracting officer shall obtain the listed DOT and Department of Defense (DOD) forms (*see* paragraphs (a)(1) through (4) of this section) from the contractor to facilitate contract closeout. See part 1253 for links to forms.

(1) Form DOT F 4220.4, Contractor's Release, *see* FAR 52.216–7;

(2) Form DOT F 4220.45, Contractor's Assignment of Refunds, Rebates, Credits and Other Amounts, *see* FAR 52.216–7;

(3) Form DOT F 4220.46, Cumulative Claim and Reconciliation Statement, *see* FAR 4.804–5(a)(13); and

(4) Department of Defense (DD) Form 882, Report of Inventions and Subcontracts, *see* FAR 52.227–14.

(b) The forms listed in paragraph (a) of this section are used primarily for the closeout of cost-reimbursement, time-and-materials, and labor-hour contracts. However, the forms may also be used for closeout of other contract types or when necessary to protect the Government's interest.

Subpart 1204.9—Taxpayer Identification Number Information

1204.903 Reporting contract information to the IRS.

(a) The SPE is authorized to report certain information, including Taxpayer Identification Number (TIN) data, to the Internal Revenue Service (IRS).

Subpart 1204.13—Personal Identity Verification

1204.1301 Policy.

(a) DOT follows National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS) Publication (PUB) Number 201–2, Personal Identity Verification (PIV) of Federal Employees and Contractors, and OMB implementation guidance for personal identity verification, for all affected contractor and subcontractor personnel when contract performance requires contractors to have routine physical access to a federally-controlled facility and/or routine physical and logical access to a federally-controlled information system.

(c) OAs must designate an official responsible for verifying contractor employees' personal identity.

1204.1303 Contract clause.

The contracting officer shall insert the clause at 1252.204–70, Contractor Personnel Security and Agency Access, in solicitations and contracts (including task orders, if appropriate), exceeding the micro-purchase threshold, when contract performance requires contractors to have routine physical access to a federally-controlled facility and/or routine physical and logical access to a Departmental/federally-controlled information system.

Subpart 1204.17—Service Contracts Inventory

1204.1703 Reporting requirements.

(b)(2) The OSPE is responsible for compiling and submitting the DOT annual inventory to OMB and for posting and publishing the inventory consistent with FAR 4.1703(b)(2).

Subchapter B—Acquisition Planning

PART 1205—PUBLICIZING CONTRACT ACTIONS

Subpart 1205.1—Dissemination of Information

Sec.
1205.101 Methods of disseminating information.

Subpart 1205.4—Release of Information

1205.402 General public.
1205.403 Requests from Members of Congress.

Subpart 1205.6—Publicizing Multi-Agency Use Contracts

1205.601 Governmentwide database of contracts.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1205.1—Dissemination of Information

1205.101 Methods of disseminating information.

(a) The DOT Office of Small and Disadvantaged Business Utilization, 1200 New Jersey Avenue SE, Washington, DC 20590 publishes a Procurement Forecast of planned procurements each fiscal year on their website at *https://www.transportation.gov/osdbu/procurement-forecast/summary/.*

Subpart 1205.4—Release of Information

1205.402 General public.

(a) Upon request, and consistent with DOT Freedom of Information Act rules and regulations in 49 CFR part 7 and 1224.203, DOT will furnish the general public with the following information on proposed contracts and contract awards—

(1) After the opening of sealed bids, names of firms that submitted bids; and

(2) After contract award, the names of firms that submitted proposals.

(b) DOT will process requests for other specific information in accordance with the DOT Freedom of Information Act rules and regulations in 49 CFR part 7 and 1224.203.

1205.403 Requests from Members of Congress.

The HCA is authorized to approve the release of certain contract information to Members of Congress under FAR 5.403.

Subpart 1205.6—Publicizing Multi-Agency Use Contracts

1205.601 Governmentwide database of contracts.

(b) The OA HCA is responsible for complying with the requirements of FAR 5.601(b).

PART 1206—COMPETITION REQUIREMENTS

Subpart 1206.2—Full and Open Competition After Exclusion of Sources

Sec.
1206.202 Establishing or maintaining alternative sources.

Subpart 1206.3—Other Than Full and Open Competition

1206.302 Circumstances permitting other than full and open competition.
1206.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements.
1206.302–7 Public interest.

Subpart 1206.5—Advocates for Competition

1206.501 Requirement.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1206.2—Full and Open Competition After Exclusion of Sources

1206.202 Establishing or maintaining alternative sources.

(a) The head of the contracting activity (HCA) is delegated authority to exclude a particular source from a contract action in order to establish or maintain an alternative source under the conditions listed in FAR 6.202(a).

(b) The HCA is also delegated authority to approve a Determination and Findings (D&F) in support of a contract action awarded under the authority of FAR 6.202(a).

Subpart 1206.3—Other Than Full and Open Competition

1206.302 Circumstances permitting other than full and open competition.

1206.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements.

(b)(4) The HCA is authorized to determine that only specified makes and models of technical equipment and parts will satisfy the agency's needs under FAR 6.302–1(b)(4).

1206.302–7 Public interest.

(a)(2) The authority under FAR 6.302–7 whereby full and open competition need not be provided for when determined that it is not in the public interest in a particular acquisition is reserved by the Secretary and may not be delegated. A written determination made and signed by the Secretary shall be included in the contract file.

(c)(3) The contracting officer shall prepare a justification to support the determination under FAR 6.302–7(c)(3).

Subpart 1206.5—Advocates for Competition

1206.501 Requirement.

The DOT Agency Advocate for Competition is the Deputy Assistant Secretary for Administration.

PART 1207—ACQUISITION PLANNING

Subpart 1207.3—Contractor Versus Government Performance

Sec.
1207.305 Solicitation provisions and contract clause.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1207.3—Contractor Versus Government Performance

1207.305 Solicitation provisions and contract clause.

The contracting officer may insert clause 1252.237–73, Key Personnel, in solicitations and contracts when the acquisition is conducted pursuant to OMB Circular A–76 and meets the clause prescription requirements at 1237.110–70(b).

PART 1209—CONTRACTOR QUALIFICATIONS

Subpart 1209.4—Debarment, Suspension, and Ineligibility

Sec.
1209.400 Scope of subpart.
1209.403 Definitions.
1209.405 Effect of listing.
1209.405–1 Continuation of current contracts.
1209.405–2 Restrictions on subcontracting.
1209.406 Debarment.
1209.406–1 General.
1209.406–3 Procedures.
1209.406–4 Period of debarment.
1209.407 Suspension.
1209.407–1 General.
1209.407–3 Procedures.
1209.470 Fact-finding procedures.
1209.471 Appeals.

Subpart 1209.5—Organizational and Consultant Conflicts of Interest

1209.507 Solicitation provisions and contract clause.
1209.507–270 Contract clauses.

Subpart 1209.6—Contractor Team Arrangements

1209.602 General.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1209.4—Debarment, Suspension, and Ineligibility

1209.400 Scope of subpart.

This subpart provides DOT's policy and procedures for the debarment and suspension of contractors.

1209.403 Definitions.

As used in this subpart—

DOT Order 4200.5G means the DOT order establishing DOT's internal procedures for Suspension and Debarment, and Ineligibility Policies.

Senior Accountable Official (SAO) for Suspension and Debarment means the Senior Procurement Executive (SPE), as delegated by the Secretary of DOT, for all suspensions and debarments within DOT. The SAO sets forth standards for suspension and debarment policies and procedures for the Department of Transportation, excluding the Office of Inspector General (OIG).

Suspension and Debarment Coordinator (SDC) means the program manager for the Suspension and Debarment Program at each OA and Office of the Secretary of Transportation. The SDC advises the Suspending and Debarring Official (SDO). The SDC coordinates all materials for presentation to the SDO for proposed suspension or debarment activities, enters information regarding any administrative agreement into the Federal Awardee Performance and Integrity Information System (FAPIIS), and enters information regarding suspensions and debarments into *SAM.gov.*

Suspending and Debarring Official (SDO) means the individual designated responsibility as authorized by the Secretary of DOT to impose procurement suspensions and debarments, exclusions, and other related matters pursuant to FAR part 9. Each OA and the OST has separately appointed SDOs. The SPE serves as the SDO for OST. A list of the OA-appointed SDOs is maintained on the OSPE website at *https://www.transportation.gov/assistant-secretary-administration/procurement/suspension-and-debarment.*

1209.405 Effect of listing.

(a) The SDO is authorized to make a written determination of compelling reasons to solicit offers from, award contracts to, or consent to subcontract with contractors debarred, suspended, or proposed for debarment and that has an active exclusion record in the System for Award Management (SAM) in accordance with FAR 9.405.

(e)(2) The SDO is authorized to make a written determination of compelling reasons to consider a bid or offer from a contractor whose name or company is included on the listing.

(3) The SDO is authorized to make a written determination of compelling reasons for a contracting officer to consider proposals, quotations, or offers received from any listed contractor that have an active exclusion record in SAM, and that such proposals, quotations, or offers may be evaluated for award or included in the competitive range, and, if applicable, discussions conducted with a listed offeror as set forth in FAR 9.405(e)(3).

1209.405–1 Continuation of current contracts.

(a) Notwithstanding the suspension, proposed debarment, or debarment of a contractor, contracting officers may continue contracts or subcontracts in existence at the time the contractor was suspended, proposed for debarment, or debarred, if authorized by the SDO and the SDO makes a written determination, consistent with the procedures described in FAR 9.405–1(a) setting forth the compelling reasons for continuing such contract(s) and placing order(s).

(b) The SDO is delegated the authority on behalf of the Secretary of DOT to make the written determination required under FAR 9.405–1(b).

1209.405–2 Restrictions on subcontracting.

(a) The SDO is delegated the authority on behalf of the Secretary of DOT to authorize contracting officers to consent to subcontracts with contractors debarred, suspended, or proposed for debarment as required by FAR 9.405–2(a).

1209.406 Debarment.

1209.406–1 General.

(c) The OST Suspending and Debarring Official (SDO) and each OA-appointed SDO (*see* 1209.403) is authorized to continue business dealings between the agency and a contractor that is debarred or proposed for debarment under FAR 9.406–1(c), except under FAR 23.506(e) if the SDO has made a written determination of compelling reasons justifying the continued business dealings.

(d)(1) The SDO's authority includes debarments from contracts for the purchase of Federal personal property pursuant to the Federal Management Regulation at 41 CFR 102–117.295 (*see* FAR 9.406–1(d)(1) through (2)).

1209.406–3 Procedures.

Contracting officers and contracting activities shall comply with DOT Order 4200.5G, Suspension and Debarment, and Ineligibility Policies, and this subpart to include the following procedures—

(a) *Investigation and referral.* Any individual may submit a referral to debar an individual or contractor to the cognizant SDO (the debarring official) (*see* 1209.403). The referral for debarment shall be supported with evidence of a cause for debarment listed in FAR 9.406–2 and this subpart. The contracting officer shall promptly report a proposed debarment action directly to the SDO. Upon review by the SDO, if the matter involves possible criminal or fraudulent activities, the SDO shall also refer the matter to the DOT Office of Inspector General to ensure coordination of appropriate activity. The report shall contain the following information:

(1) The DOT official OA code to identify the OA taking action is as follows: DOT (general) (DOT–OST); Federal Aviation Administration (DOT–FAA); Federal Highway Administration (DOT–FHWA); Federal Motor Carrier Safety Administration (DOT–FMCSA); Federal Railroad Administration (DOT–FRA); Federal Transit Administration (DOT–FTA); Maritime Administration (DOT–MARAD); National Highway Traffic Safety Administration (DOT–NHTSA); Pipeline and Hazardous Materials Safety Administration (DOT–PHMSA); Office of the Assistant Secretary for Research and Technology (OST–R); and Great Lakes St. Lawrence Development Corporation (GLS).

(2) Name, address, and telephone number for the point of contact for the activity making the report.

(3) Name and address of the contractor.

(4) Names and addresses of the members of the board, principal officers, partners, owners, and managers.

(5) Names and addresses of all known affiliates, subsidiaries, or parent firms, and the nature of the business relationship.

(6) For each contract affected by the conduct being reported—

(i) The contract number;

(ii) Description of supplies or services;

(iii) The amount;

(iv) The percentage of completion;

(v) The amount paid to the contractor;

(vi) Whether the contract is assigned under the Assignment of Claims Act and, if so, to whom; and

(vii) The amount due to the contractor.

(7) For any other contracts outstanding with the contractor or any of its affiliates—

(i) The contract number(s);

(ii) The amount(s);

(iii) The amounts paid to the contractor;

(iv) Whether the contract(s) is assigned under the Assignment of Claims Act and, if so, to whom; and

(v) The amount(s) due the contractor.

(8) A complete summary of all pertinent evidence and the status of any legal proceedings involving the contractor.

(9) An estimate of any damages sustained by the Government as a result of the contractor's action (explain how the estimate was calculated).

(10) The comments and recommendations of the contracting officer and each higher-level contracting review authority regarding—

(i) Whether to suspend or debar the contractor;

(ii) Whether to apply limitations to the suspension or debarment;

(iii) The period of any recommended debarment; and

(iv) Whether to continue any current contracts with the contractor (explain why a recommendation regarding current contract is not included).

(11) When appropriate, as an enclosure to the report—

(i) A copy or extracts of each pertinent contract;

(ii) Witness statements or affidavits;

(iii) Copies of investigative reports;

(iv) Certified copies of indictments, judgments, and sentencing actions; and

(v) Any other appropriate exhibits or documents.

(b) *Decisionmaking process.* When the SDO finds preponderance of the evidence for a cause for debarment, as listed in FAR 9.406–2 or this subpart, the contracting officer in conjunction with the SDC shall prepare a recommendation and draft notice of proposed debarment for the SDO's consideration. The contractor (and any specifically named affiliates) are provided an opportunity to submit, in person, in writing, or through a representative, information and argument in opposition to the proposed debarment as set forth in paragraph (d) of this section.

(c) *Notice of proposal to debar.* DOT shall send the notice of proposed debarment to the last known address of the individual or contractor, the individual or contractor's counsel, or agent for service of process, by certified mail, return receipt requested, or any other means that allows for confirmation of delivery to include by mail, to the last known street address, to the last known facsimile numbers, or to the last known email address. In the case of a contractor, DOT may send the notice of proposed debarment to the contractor, any partner, principal, officer, director, owner or co-owner, or joint venture; to the contractor's identified counsel for purposes of administrative proceedings; or to the contractor's agent for the service of process. If sent by email, it shall be sent to the last known email addresses for all three, if known. Additionally, for each specifically named affiliate, the notice shall be sent to the affiliate itself, the affiliate's identified counsel for purposes of the administrative proceedings, or the affiliate's agency for service of process. If sent by email, it shall be sent to the last known email addresses for all three, if known. The SDO shall also ensure that the appropriate parties are listed as excluded in the System for Award Management (SAM) in accordance with FAR 9.404.

(d) *Debarring official's decision.* (1) If DOT does not receive a reply from the contractor within 30 calendar days after sending the notice of proposed debarment, the SDC shall prepare a recommendation in conjunction with the cognizant contracting officer, and refer the case to the SDO for a decision on whether to debar based on the information available. If DOT receives a reply from the contractor within 30 calendar days after sending the notice of proposed debarment, the SDC in conjunction with the cognizant contracting officer shall consider the information in the reply before the SDC makes their recommendation to the SDO.

(2) The SDO reviews submittals and case documents, and acts in accordance with DOT Order 4200.5G and the General DOT Guidelines for Suspension and Debarment, paragraph 12c.

(i) The SDO, upon the request of the contractor proposed for debarment, shall, as soon as practicable, allow the contractor an opportunity to appear before the SDO to present information or argument, in person or through a representative. The contractor may supplement the oral presentation with written information and argument. This information submitted by a contractor proposed for debarment is known as a Presentation of Matters in Opposition as set forth in DOT Order 4200.5G. DOT shall conduct the proceeding in an informal manner and without requirement for a transcript. The SDO may use flexible procedures to allow a contractor to present matters in opposition via telephone or internet. If so, the debarring official should change the notice in paragraph (c) of this section to include those flexible procedures.

(ii) If the SDO finds the contractor's or individual's submission in opposition to the proposed debarment raises a genuine dispute over facts material to the proposed debarment and the debarment action is not based on a conviction or civil judgment, the SDC shall submit to the SDO the information establishing the dispute of material facts. If the SDO agrees there is a genuine dispute of material facts, the SDO shall conduct a fact-finding proceeding or shall refer the dispute to a designee for resolution pursuant to 1209.470. The SDC shall provide the contractor or individual the disputed material fact(s).

(iii) If the proposed debarment action is based on a conviction or civil judgment, or if there are no disputes over material facts, or if any disputes over material facts have been resolved pursuant to 1209.470, the SDO shall make a decision on the basis of all information available including any written findings of fact submitted by the designated fact finder, and oral or written arguments presented or submitted to the SDC by the contractor.

(e) *Notice of debarring official's decision.* In actions processed under FAR 9.406 where no suspension is in place and where a fact-finding proceeding is not required, DOT shall make the final decision on the proposed debarment within 30 business days after receipt of any information and argument submitted by the contractor by the means of delivery set forth in paragraph (c) of this section, unless the SDO extends this period for good cause.

1209.406–4 Period of debarment.

(b) The SDC, in conjunction with the contracting officer, may submit a recommendation to the SDO to extend or reduce the period of debarment, or amend the scope of the debarment, imposed under FAR 9.406.

1209.407 Suspension.

1209.407–1 General.

(b) For the purposes of FAR 9.407–1, the SDO is the suspending official under the Federal Management Regulation at 41 CFR 102–117.295.

(d) The SDO is authorized to make a written determination of compelling reasons justifying continuing business dealings between the agency and a contractor that is suspended. However, in accordance with FAR 23.506(e), only the Secretary of Transportation may

waive the suspension of contract payments, termination of a contract for default, or suspension of a contractor for actions under FAR subpart 23.5 and FAR 23.506.

1209.407–3 Procedures.

Contracting officers and contracting activities shall comply with DOT Order 4200.5G, Suspension and Debarment, and Ineligibility Policies, and this subpart to include the following procedures—

(a) *Investigation and referral.* Any individual may submit a referral to suspend an individual or contractor to the SDC or SDO (the debarring official) (*see* 1209.403). The SDC shall promptly report, in writing, a proposed suspension action directly to the SDO. Upon review by the SDO, if the matter involves possible criminal or fraudulent activities, the SDO shall also refer the matter to the DOT OIG to ensure coordination of appropriate activity.

(b) *Decisionmaking process.* When the SDC finds adequate evidence of a cause for suspension, as listed in FAR 9.407–2, the SDC shall prepare a recommendation and draft notice of suspension for the SDO's consideration. After receipt of the report from the SDC, the SDO may request from interested parties, including the contractor if deemed appropriate, a meeting or additional supporting information to assist in the suspension decision. The SDC creates a case in the DOT Suspension and Debarment Tracking System as set forth in DOT Order 4200.5G. The contractor (and any specifically named affiliates) are provided an opportunity to submit, in person, in writing, or through a representative, information and argument in opposition to the proposed debarment as set forth in paragraph (d) of this section.

(c) *Notice of suspension.* DOT shall send the notice of suspension to the last known address of the individual or contractor, the individual or contractor's counsel, or agent for service of process, by certified mail, return receipt requested, or any other means that allows for confirmation of delivery to include by mail, to the last known street address, to the last known facsimile numbers, or to the last known email address. In the case of a contractor, DOT may send the notice of suspension to the contractor, any partner, principal, officer, director, owner or co-owner, or joint venture; to the contractor's identified counsel for purposes of administrative proceedings; or to the contractor's agent for the service of process. If sent by email, it shall be sent to the last known email addresses for all three, if known. Additionally, for each specifically named affiliate, the notice shall be sent to the affiliate itself, the affiliate's identified counsel for purposes of the administrative proceedings, or the affiliate's agency for service of process. If sent by email, it shall be sent to the last known email addresses for all three, if known. The SDO shall also ensure that the appropriate parties are listed as excluded in SAM in accordance with FAR 9.404. After reviewing the SDC's report, and any additional information received in accordance with paragraph (b) of this section, the SDO shall prepare and coordinate with legal counsel a written notice of suspension.

(5) The SDO, upon the request of the contractor suspended, shall, as soon as practicable, allow the contractor an opportunity to appear before the SDO to present information or argument, in person or through a representative. The contractor may supplement the oral presentation with written information and argument. DOT shall conduct the proceeding in an informal manner and without requirement for a transcript.

(6)(i) If the SDC finds the contractor's or individual's submission in opposition to the suspension raises a genuine dispute over facts material to the suspension, or for the purposes of FAR 9.407–3(b)(2), in actions not based on an indictment, the SDC shall submit to the SDO the information establishing the dispute of material facts. If the SDO agrees there is a genuine dispute of material facts, the SDO shall conduct a fact-finding proceeding or refer the dispute to a designee for resolution pursuant to 1209.470. The SDC shall provide the contractor or individual the information that established the dispute of material fact(s) in advance of the fact-finding proceeding, in the event the contractor would like to add to the facts prior to the decision of the SDO.

(ii) If the suspension is based on a conviction or civil judgment, or if there are no disputes over material facts, or if any disputes over material facts have been resolved pursuant to 1209.470, the SDO shall make a decision on the basis of all information available including any written findings of fact submitted by the designated fact finder, and oral or written arguments presented or submitted by the contractor. The contractor may supplement the oral presentation with written information and argument. The proceeding will be conducted in an informal manner and without requirement for a transcript.

(d) *Suspending official's decision.* The SDO shall notify the contractor of the decision whether to impose a suspension. The SDO shall then forward the original signed decision to the contracting officer for inclusion in the contract file. The SDO reviews submittals and case documents, and acts in accordance with DOT Order 4200.5G and the General DOT Guidelines for Suspension and Debarment, paragraph 12c. The SDO may use flexible procedures to allow a contractor to present matters in opposition via telephone of internet. If so, the debarring official should change the notice in paragraph (c) of this section to include those flexible procedures.

1209.470 Fact-finding procedures.

The provisions of this section constitute the procedures to be used to resolve genuine disputes of material fact pursuant to 1209.406–3 and 1209.407–3. The SDC shall establish the date for the fact-finding hearing, normally to be held within 30 business days after notifying the contractor or individual that the SDO has determined a genuine dispute of material fact(s) exists.

(a) The Government's representative and the contractor shall each have an opportunity to present evidence relevant to the genuine dispute(s) of material fact identified by the SDO. The contractor or individual may appear in person or through counsel at the fact-finding hearing and should address all defenses, contested facts, admissions, remedial actions taken, and, if a proposal to debar is involved, mitigating and aggravating factors. The contractor or individual may submit documentary evidence, present witnesses, and confront any person the agency presents.

(b) Witnesses may testify in person. Witnesses will be reminded of the official nature of the proceedings and that any false testimony given is subject to criminal prosecution. Witnesses are subject to cross-examination. The fact-finding proceeding is an informal evidentiary hearing, during which the Rules of Evidence and Civil Procedure do not apply. Hearsay evidence may be presented and will be given appropriate weight by the fact-finder.

(c) The proceedings shall be transcribed and a copy of the transcript shall be made available at cost to the contractor upon request, unless the contractor and the factfinder, by mutual agreement, waive the requirement for a transcript.

(d) The fact-finder shall prepare a written finding(s) of fact for the record by a preponderance of the evidence for proposed debarments, and by adequate evidence for suspensions. A copy of the findings of fact shall be provided to the SDO, the Government's representative, and the contractor or individual. The

SDO will consider the written findings of fact in the decision regarding the suspension or proposed debarment.

1209.471 Appeals.

Based on the decision by the SDO, the respondent may elect to request reconsideration as provided for in paragraph (a) of this section. If the request for reconsideration is denied, the respondent may seek judicial review as provided for in paragraph (b) of this section.

(a) *Request for reconsideration.* Upon receiving a final decision to debar from the SDO, a debarred individual or entity may ask the SDO to reconsider the debarment decision or to modify the debarment by reducing the time period or narrowing the scope of the debarment. This request must be in writing and supported with documentation.

(b) *Judicial review.* A suspended or debarred individual or entity may seek judicial review upon denial of a request for reconsideration.

Subpart 1209.5—Organizational and Consultant Conflicts of Interest

1209.507 Solicitation provisions and contract clause.

1209.507–270 Contract clauses.

(a) In accordance with FAR 9.507–2, the contracting officer shall insert a clause substantially the same as the clause at 1252.209–70, Organizational and Consultant Conflicts of Interest, as applicable, in solicitations and contracts.

(b) In accordance with FAR 9.507–2, the contracting officer shall insert a clause substantially the same as the clause at 1252.209–71, Limitation of Future Contracting, as applicable, in solicitations and contracts.

Subpart 1209.6—Contractor Team Arrangements

1209.602 General.

(c) Contracting officers shall require offerors to disclose teaming arrangements as a part of any offer. The teaming arrangement shall be evaluated as a part of overall prime contractor responsibility, as well as under the technical and/or management approach evaluation factor where applicable.

PART 1211—DESCRIBING AGENCY NEEDS

Subpart 1211.2—Using and Maintaining Requirements Documents

Sec.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1211.2—Using and Maintaining Requirements Documents

1211.204 Solicitation provisions and contract clauses.

1211.204–70 Contract clauses.

The contracting officer shall insert the clause at 1252.211–70, Index for Specifications, when an index or table of contents may be furnished with the specification.

PART 1212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

Subpart 1212.3—Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services

Sec.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1212.3—Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services

1212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

(f) The following DOT provisions and clauses are authorized for use in acquisitions of commercial products or commercial services when required by the individual provision or clause prescription:

(1) 1252.201–70, Contracting Officer's Representative.

(2) 1252.204–70, Contractor Personnel Security and Agency Access.

(3) 1252.209–70, Organizational and Consultant Conflicts of Interest.

(4) 1252.209–71, Limitation of Future Contracting.

(5) 1252.211–70, Index for Specifications.

(6) 1252.216–70, Evaluation of Offers Subject to an Economic Price Adjustment Clause.

(7) 1252.216–71, Determination of Award Fee.

(8) 1252.216–72, Award Fee Plan.

(9) 1252.216–73, Distribution of Award Fee.

(10) 1252.216–74, Settlement of Letter Contract.

(11) 1252.222–70, Strikes or Picketing Affecting Timely Completion of the Contract Work.

(12) 1252.222–71, Strikes or Picketing Affecting Access to a DOT Facility.

(13) 1252.223–70, Removal or Disposal of Hazardous Substances—Applicable Licenses and Permits.

(14) 1252.223–71, Accident and Fire Reporting.

(15) 1252.223–73, Seat Belt Use Policies and Programs.

(16) 1252.232–70, Electronic Submission of Payment Requests.

(17) 1252.237–70, Qualifications of Contractor Employees.

(18) 1252.237–71, Certification of Data.

(19) 1252.237–72, Prohibition on Advertising.

(20) 1252.237–73, Key Personnel.

(21) 1252.239–70, Security Requirements for Unclassified Information Technology Resources.

(22) 1252.239–71, Information Technology Security Plan and Accreditation.

(23) 1252.239–72, Compliance with Safeguarding DOT Sensitive Data Controls.

(24) 1252.239–73, Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information.

(25) 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting.

(26) 1252.239–75, DOT Protection of Information About Individuals, PII, and Privacy Risk Management Requirements.

(27) 1252.239–76, Cloud Computing Services.

(28) 1252.239–77, Data Jurisdiction.

(29) 1252.239–78, Validated Cryptography for Secure Communications.

(30) 1252.239–79, Authentication, Data Integrity, and Non-Repudiation.

(31) 1252.239–80, Audit Record Retention for Cloud Service Providers.

(32) 1252.239–81, Cloud Identification and Authentication (Organizational Users) Multi-Factor Authentication.

(33) 1252.239–82, Identification and Authentication (Non-Organizational Users).

(34) 1252.239–83, Incident Reporting Timeframes.

(35) 1252.239–84, Media Transport.

(36) 1252.239–85, Personnel Screening—Background Investigations.

(37) 1252.239–86, Boundary Protection—Trusted Internet Connections.

(38) 1252.239–87, Protection of Information at Rest.

(39) 1252.239–88, Security Alerts, Advisories, and Directives.

(40) 1252.239–89, Technology Modernization.

(41) 1252.239–90, Technology Upgrades/Refreshment.
(42) 1252.239–91, Records Management.
(43) 1252.239–92, Information and Communication Technology Accessibility Notice.
(44) 1252.239–93, Information and Communication Technology Accessibility.
(45) 1252.242–70, Dissemination of Information—Educational Institutions.
(46) 1252.242–71, Contractor Testimony.
(47) 1252.242–72, Dissemination of Contract Information.

Subchapter C—Contracting Methods and Contract Types

PART 1213—SIMPLIFIED ACQUISITION PROCEDURES

Subpart 1213.70—Department of Transportation Procedures for Acquiring Training Services

Sec.
1213.7000 Applicability.
1213.7001 Solicitation provision and contract clause.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1213.70—Department of Transportation Procedures for Acquiring Training Services

1213.7000 Applicability.

(a) DOT policy at 1237.7000 applies to Standard Form (SF) 182, Request, Authorization, Agreement and Certification of Training, which may be used to acquire training services; however, the policy does not apply to training services acquired by Governmentwide commercial purchase card. The Governmentwide commercial purchase card may only be used to acquire training services valued at the micro-purchase threshold level or less.

(b) As reflected in 1237.7002, this policy does not apply to training attended by DOT employees that is scheduled and conducted by Government sources of supply, educational institutions, or private entities where DOT does not control or sponsor the training. Examples of when the policy does and does not apply include:

(1) When SF 182s are issued for three DOT employees to attend a one-week course at a university or other private entity, the policy does not apply. DOT does not control the course because the university or private entity has a contract in place with the training provider and DOT is placing an order under an existing contract; and

(2) When DOT awards a contract to a university or other private entity to provide training for DOT and/or other Government personnel, the policy applies. DOT controls this course; therefore, no soliciting or advertising of private non-Government training while conducting the contracted-for training is permitted.

1213.7001 Solicitation provision and contract clause.

(a) Contracting officers shall insert the provision as prescribed at 1252.237–71, Certification of Data, in all solicitations and requests for quotations, and the clause as prescribed at 1252.237–72, Prohibition on Advertising, in solicitations, requests for quotations, and all contracts (*e.g.,* purchase orders, SF 182s) for training services when the content and/or presentation of the training is controlled by DOT.

(b) Contracting officers shall incorporate the successful offeror's certified data into any resultant contract(s). Certified data may be adopted by reference, if the contracting officer determines it contains information sufficient to reliably describe the certified data submitted. For example, this type of information includes dated material such as resumes and company or personnel qualifications.

PART 1214—[RESERVED]

PART 1215—CONTRACTING BY NEGOTIATION

Subpart 1215.4—Contract Pricing

Sec.
1215.404 Proposal analysis.
1215.404–470 Payment of profit or fee.

Subpart 1215.6—Unsolicited Proposals

1215.603 General.
1215.604 Agency points of contact.
1215.606 Agency procedures.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1215.4—Contract Pricing

1215.404 Proposal analysis.

1215.404–470 Payment of profit or fee.

The contracting officer shall not pay profit or fee on undefinitized contracts or undefinitized contract modifications. Any profit or fee earned shall be paid after the contract or modification is definitized.

Subpart 1215.6—Unsolicited Proposals

1215.603 General.

DOT will not pay any costs associated with the preparation of unsolicited proposals. Proposals that do not meet the definition and applicable content and marking requirements of FAR subpart 15.6 will not be considered under any circumstances and will be returned to the submitter.

1215.604 Agency points of contact.

(a) Unsolicited proposals should be submitted to the responsible OA contracting office for appropriate handling. Specific information concerning the mission of each DOT OA is available online at *https://www.transportation.gov/.* Offerors are urged to contact these contracting/procurement offices prior to submitting a proposal to ensure that the unsolicited proposal reaches the correct contracting office for action. This action will reduce unnecessary paperwork and wasted time for both the Government and offerors.

1215.606 Agency procedures.

The OA contracting office is the designated point of contact for receipt and handling of unsolicited proposals (*see* 1215.604). The assigned DOT contracting office will review and evaluate the proposal within 30 calendar days, if practicable, in accordance with FAR 15.606–1, Receipt and initial review, to inform the offeror of the reasons for rejection and the proposed disposition of the unsolicited proposal.

PART 1216—TYPES OF CONTRACTS

Subpart 1216.2—Fixed-Price Contracts

Sec.
1216.203 Fixed-price contracts with economic price adjustment.
1216.203–4 Contract clauses.
1216.203–470 Solicitation provision.

Subpart 1216.4—Incentive Contracts

1216.406–70 DOT contract clauses.

Subpart 1216.5—Indefinite-Delivery Contracts

1216.505 Ordering.

Subpart 1216.6—Time-and-Materials, Labor-Hour, and Letter Contracts

1216.603 Letter contracts.
1216.603–4 Contract clauses.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1216.2—Fixed-Price Contracts

1216.203 Fixed-price contracts with economic price adjustment.

1216.203–4 Contract clauses.

1216.203–470 Solicitation provision.

The contracting officer shall insert the provision at 1252.216–70, Evaluation of

Offers Subject to an Economic Price Adjustment Clause, in solicitations containing an economic price adjustment clause.

Subpart 1216.4—Incentive Contracts

1216.406–70 DOT contract clauses.

(a) As authorized by FAR 16.406(e), the contracting officer shall insert the clause at 1252.216–71, Determination of Award Fee, in all cost-plus-award-fee solicitations and contracts.

(b) The contracting officer shall insert the clause at 1252.216–72, Award Fee Plan, in all cost-plus-award-fee solicitations and contracts.

(c) The contracting officer shall insert the clause at 1252.216–73, Distribution of Award Fee, in all cost-plus-award-fee solicitations and contracts.

Subpart 1216.5—Indefinite-Delivery Contracts

1216.505 Ordering.

(b)(8) *Task-order and delivery-order ombudsman.* Unless otherwise designated by the Head of the Operating Administration, the Advocate for Competition for the Operating Administration (OA) is designated as the OA Task and Delivery Order Ombudsman. If any corrective action is needed after reviewing complaints from contractors on task and delivery order contracts, the OA Ombudsman shall provide a written determination of such action to the contracting officer. Issues that cannot be resolved within the OA shall be forwarded to the DOT Task and Delivery Order Ombudsman for review and resolution. The DOT Task and Delivery Order Ombudsman is located in the Office of the Senior Procurement Executive.

Subpart 1216.6—Time-and-Materials, Labor-Hour, and Letter Contracts

1216.603 Letter contracts.

1216.603–4 Contract clauses.

The contracting officer shall insert the clause at 1252.216–74, Settlement of Letter Contract, in all definitized letter contracts.

PART 1217—SPECIAL CONTRACTING METHODS

Subpart 1217.70—Fixed-Price Contracts for Vessel Repair, Alteration, or Conversion

Sec.
1217.7000 Definition.
1217.7001 Clauses.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1217.70—Fixed-Price Contracts for Vessel Repair, Alteration, or Conversion

1217.7000 Definition.

Lay Days means time allowed to the master of a vessel for loading and unloading the same.

1217.7001 Clauses.

(a) The clause at 1252.217–70, Guarantee, shall be used where general guarantee provisions are deemed desirable by the contracting officer.

(1) When inspection and acceptance tests will afford full protection to the Government in ascertaining conformance to specifications and the absence of defects and deficiencies, no guarantee clause for that purpose shall be included in the contract.

(2) The customary guarantee period, to be inserted in the first sentence of the clause at 1252.217–70, Guarantee, is 60 days. In certain instances, it may be advisable for the contracting officer to include a contract clause for a guarantee period longer than 60 days. These instances are as follows—

(i) If, as a result of a full inquiry, the contracting officer determines that there will be no increased costs as a result of a longer guarantee period, the contracting officer may substitute guarantee longer than the usual 60 days; or

(ii) When the contracting officer's inquiry discloses that increased costs will result or are expected to result from a longer guarantee period, the contracting officer shall submit a letter to the Chief of the Contracting Office, requesting approval for use of guarantee period in excess of 60 days. The letter must contain sufficient facts to justify the use of a longer guarantee period. Upon approval, the contracting officer may insert a longer period in the first sentence of the clause at 1252.217–70, Guarantee.

(b) The contracting officer shall insert the following clauses in solicitations and contracts for vessel repair, alteration or conversion:

(1) 1252.217–71, Delivery and Shifting of Vessel.

(2) 1252.217–72, Performance.

(3) 1252.217–73, Inspection and Manner of Doing Work.

(4) 1252.217–74, Subcontracts.

(5) 1252.217–76, Liability and Insurance.

(6) 1252.217–77, Title.

(7) 1252.217–78, Discharge of Liens.

(8) 1252.217–79, Delays.

(9) 1252.217–80, Department of Labor Safety and Health Regulations for Ship Repair.

(c) The contracting officer may insert the clause at 1252.217–75, Lay Days, in sealed bid fixed-price solicitations and contracts for vessel repair, alteration, or conversion which are to be performed within the United States, the District of Columbia, and all territories and possessions of the United States. The contracting officer may also insert the clause at 1252.217–75, Lay Days, in negotiated solicitations and contracts to be performed outside the United States.

Subchapter D—Socioeconomic Programs

PART 1219—SMALL BUSINESS PROGRAMS

Subpart 1219.2—Policies

Sec.
1219.201 General policy.
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1219.502–8 Rejecting Small Business Administration recommendations.
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1219.815 Release for non-8(a) procurement.

Subpart 1219.70—DOT Mentor-Protégé Program

1219.7000 General.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1219.2—Policies

1219.201 General policy.

(c) The Director, Office of Small and Disadvantaged Business Utilization (OSDBU) shall be a member of the Senior Executive Service and appointed by the Secretary of Transportation. (15 U.S.C. 637, 644, and 657)

(d) The responsible HCA for each OA shall appoint a Small Business Specialist (SBS). The SBS will assist the OSDBU Director in carrying out the functions and duties prescribed in FAR 19.201(d). A list of DOT SBS is provided at OSDBU's website at *https://www.transportation.gov/osdbu/procurement-assistance/talk-dot-small-business-specialist.*

1219.201–70 Procurement goals for small business.

As required by the Small Business Act, the Secretary shall establish annual goals for small business participation in DOT contracts and subcontracts. Each contracting activity in consultation with the OSDBU on behalf of the Secretary shall establish annual goals that present, for that activity, the maximum practicable opportunity for small business concerns to participate in the performance of the activity's contracts and subcontracts.

1219.202 Specific policies.

OSDBU is responsible for reviewing procurement strategies and subcontracting efforts, establishing review thresholds and making recommendations to further the implementation of this part. The OSDBU Director may waive review of certain classes of acquisitions that the Director identifies as providing limited or no opportunity for small business participation or may delegate review of such acquisitions to the OA Small Business Specialists.

1219.202–70 Procurement Forecast.

The OSDBU shall prepare and maintain DOT's Procurement Forecast in coordination with DOT Operating Administrations. The forecast will be published every year on or before October 1st and can be found at *https://www.transportation.gov/osdbu/procurement-forecast/summary.* Contracting officers and small business specialists will work with the OSDBU to maintain accurate procurement forecast information.

Subpart 1219.4—Cooperation With the Small Business Administration

1219.401 General.

(a) The OSDBU Director will be the primary point of contact with the U.S. Small Business Administration and facilitate the formulation of policies to ensure maximum practicable opportunities are available to small business concerns in prime and subcontracting opportunities.

Subpart 1219.5—Set-Asides for Small Business

1219.501 General.

(a) Contracting officers shall set aside to small business concerns acquisitions of supplies or services that have an anticipated dollar value above the micro-purchase threshold but not exceeding the simplified acquisition threshold, as prescribed at FAR 13.003(b)(1). Contracting officers shall set aside proposed acquisitions exceeding the simplified acquisition threshold for small business concerns unless it is determined there is not a reasonable expectation of obtaining offers from two or more responsible small business concerns that are competitive in terms of market prices, quality, and delivery (*see* FAR 19.502–2). Contracting officers will document their determination utilizing the DOT Form 4250.1, which will include the results of the market research performed, including justifications.

1219.502–8 Rejecting Small Business Administration recommendations.

(a) If the contracting officer rejects a recommendation of the SBA procurement center representative, the contracting officer will coordinate with the OSDBU to submit a written notice to the SBA within 5 working days of the contracting officer's receipt of the recommendation.

1219.502–9 Withdrawing or modifying small business set-asides.

(a) If the contracting officer makes a determination before contract award that a set-aside is disadvantageous to the public interest, withdrawal of an individual small business set-aside shall be initiated by giving written notice to the small business specialist, the SBA procurement center representative and the OSDBU stating the reasons for withdrawal.

(b) If the agency small business specialist does not agree to a withdrawal or modification, the case shall be referred to the COCO for review prior to consulting with the assigned SBA representative. The contracting officer shall follow the documentation requirements of FAR 19.506(c).

Subpart 1219.7—The Small Business Subcontracting Program

1219.705 Responsibilities of the contracting officer under the subcontracting assistance program.

1219.705–6 Postaward responsibilities of the contracting officer.

(f) The Office of Small and Disadvantaged Business Utilization (S–40) is responsible for acknowledging receipt of, or rejecting, the Summary Subcontract Report (SSR) in the Electronic Subcontracting Reporting System (eSRS).

Subpart 1219.8—Contracting With the Small Business Administration (the 8(a) Program)

1219.800 General.

(e) The Small Business Administration (SBA) and Department of Transportation (DOT) have entered into a Partnership Agreement (PA) delegating SBA's contract execution and administrative functions to DOT. Contracting officers shall follow the alternate procedures in this subpart, as applicable, to award 8(a) contracts under the PA. (*See https://www.transportation.gov/sites/dot.dev/files/docs/Department%20of%20Transportation_Partnership%20Agreement.pdf.*)

(1) The SBA delegates only the authority to sign contracts on its behalf. Consistent with the provisions of the PA, the SBA remains the prime contractor on all 8(a) contracts, continues to determine eligibility of concerns for contract award, and retains appeal rights under FAR 19.810.

(2) The PA sets forth the delegation of authority and establishes the basic procedures for expediting the award of 8(a) contract requirements as reflected in this subpart.

(3) Contracts awarded under the PA may be awarded directly to the 8(a) participant on either a sole source or competitive basis. An SBA signature on the contract is not required. *See* FAR 19.811–3 for contract clauses to use.

1219.815 Release for non-8(a) procurement.

(b) Contracting officers requesting the release of a requirement for a non-8(a) procurement will follow procedures prescribed at FAR 19.815 and submit requests through the DOT OSDBU Director. The OSDBU Director will submit the request to SBA's Associate Administrator for Business Development for consideration.

Subpart 1219.70—DOT Mentor-Protégé Program

1219.7000 General.

(a) The Small Business Administration provides general oversight to Federal mentor-protégé programs. However, DOT has its own program tailored to assist small business concerns in the transportation industry to enhance their capability to compete for Federal procurement opportunities. The program is administered by the

DOT Office of Small and Disadvantaged Business Utilization (OSDBU) at *https://www.transportation.gov/osdbu/procurement-assistance/mentor-protege-pilot-program.*

(b) Small business concerns and large DOT prime contractors are encouraged to participate in the Department's Mentor-Protégé Program. Mentor firms provide eligible small business Protégé firms with developmental assistance to enhance their business capabilities and ability to obtain Federal contracts.

(c) Mentor firms are eligible small businesses and large DOT prime contractors or other socioeconomic firms capable of providing developmental assistance. Protégé firms are small businesses as defined in 13 CFR part 121.

(d) Developmental assistance is technical, managerial, financial, and other mutually beneficial assistance that assists Protégé firms. The costs for developmental assistance will not be reimbursed to the Mentor firm.

(e) Mentor and Protégé firms shall submit an evaluation of the overall experience in the program to OSDBU at the conclusion of the agreement or the voluntary withdrawal by either party from the program, whichever occurs first. At the end of each year, the Mentor and Protégé firms will submit a report regarding program accomplishments under their agreement.

(f) Mentor or Protégé firms shall notify OSDBU in writing, at least 30 calendar days in advance of the effective date of the firm's withdrawal from the program.

PART 1222—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

Subpart 1222.1—Basic Labor Policies

Sec.

Subpart 1222.8—Equal Employment Opportunity

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1222.1—Basic Labor Policies

1222.101 Labor relations.

1222.101–70 Admittance of union representatives to DOT installations.

(a) It is DOT policy to admit labor union representatives of contractor employees to DOT installations to visit work sites and transact labor union business with contractors, their employees, or union stewards pursuant to existing union collective bargaining agreements. Their presence shall not interfere with the contractor's work progress under a DOT contract, nor violate the safety or security regulations that may be applicable to persons visiting the installation. The union representatives will not be permitted to conduct meetings, collect union dues, or make speeches concerning union matters while visiting a work site.

(b) Whenever a union representative is denied entry to a work site, the person denying entry shall make a written report to the labor advisor for the applicable Operating Administration or to the DOT labor coordinator, the Office of the General Counsel, Office of General Law, within the Office of the Secretary of Transportation, within two working days after the request for entry is denied. The report shall include the reason(s) for the denial, the name of the representative denied entry, the union affiliation and number, and the name and title of the person that denied the entry.

1222.101–71 Contract clauses.

(a) When applicable, the contracting officer may insert the clause at 1252.222–70, Strikes or Picketing Affecting Timely Completion of the Contract Work, in solicitations and contracts.

(b) When applicable, the contracting officer may insert the clause at 1252.222–71, Strikes or Picketing Affecting Access to a DOT Facility, in solicitations and contracts.

Subpart 1222.8—Equal Employment Opportunity

1222.808 Complaints.

Contractors shall, in good faith, cooperate with the Department of Transportation in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614 and in accordance with clause 1252.222–72 as prescribed in this subpart.

1222.810–70 Contract clause.

The contracting officer shall insert the clause at 1252.222–72, Contractor Cooperation in Equal Employment Opportunity and Anti-Harassment Investigations, in solicitations, contracts, and orders that include the clause at FAR 52.222–26, Equal Opportunity.

PART 1223—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG–FREE WORKPLACE

Subpart 1223.3—Hazardous Material Identification and Material Safety Data

Sec.

Subpart 1223.70—Safety Requirements for Selected DOT Contracts

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1223.3—Hazardous Material Identification and Material Safety Data

1223.303 Contract clause.

The contracting officer shall insert the clause at 1252.223–70, Removal or Disposal of Hazardous Substances—Applicable Licenses and Permits, in solicitations and contracts involving the removal or disposal of hazardous waste material.

Subpart 1223.70—Safety Requirements for Selected DOT Contracts

1223.7000 Contract clauses.

(a) Where all or part of a contract will be performed on Government-owned or leased property, the contracting officer shall insert the clause at 1252.223–71, Accident and Fire Reporting.

(b) For all solicitations and contracts under which human test subjects will be utilized, the contracting officer shall insert the clause at 1252.223–72, Protection of Human Subjects. Contractors can request copies of applicable Operating Administration (OA)-specific policies regarding the protection of human subjects directly from contracting officers.

(c) In all solicitations and contracts exceeding the simplified acquisition threshold, the contracting officer shall insert the clause at 1252.223–73, Seat Belt Use Policies and Programs.

PART 1224—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

Subpart 1224.1—Protection of Individual Privacy

Sec.

Subpart 1224.2—Freedom of Information Act

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1224.1—Protection of Individual Privacy

1224.102–70 General.

(a) Records maintained in a Privacy Act system of records shall not be released except by the Government or at the Government's direction regardless of whether the Government or a contractor acting on behalf of the Government is maintaining the records. Examples of systems of records are:

(1) Personnel, payroll and background records about any officer or employee of DOT, or other person, including his or her residential address;

(2) Medical histories and medical records concerning individuals, including applications for licenses; and

(3) Any other record containing information about an individual which includes that individual's name or other personal identifier.

(b) Examples of records to which the Privacy Act does not apply are:

(1) Records that are maintained by a contractor on individuals employed by the contractor in the process of providing goods and services to the Federal government; and

(2) Student records generated in connection with the student's attendance (*e.g.,* admission forms, grade reports) at an educational institution contracted by the agency to provide training to students. These records must be similar to those maintained on other students and must not be commingled with records of other students.

1224.103 Procedures.

DOT rules and regulations implementing the Privacy Act of 1974 are located at 49 CFR part 10.

Subpart 1224.2—Freedom of Information Act

1224.203 Policy.

DOT rules and regulations implementing the Freedom of Information Act (FOIA) and the names and addresses of the OA FOIA offices are located in 49 CFR part 7. The DOT FOIA website can be found at *https://www.transportation.gov/foia.* Specific contract award information shall be requested from the FOIA office of the OA making the contract award.

Subchapter E—General Contracting Requirements

PART 1227—PATENTS, DATA, AND COPYRIGHTS

Subpart 1227.3—Patent Rights Under Government Contracts

Sec.
1227.304 Procedures.
1227.304–4 Appeals.
1227.305 Administration of patent rights clauses.
1227.305–4 Protection of invention disclosures.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1227.3—Patent Rights Under Government Contracts

1227.304 Procedures.

1227.304–4 Appeals.

(b) Contractors may appeal agency actions listed at FAR 27.304–4(a)(1), (3), and (4) to the cognizant Head of the Contracting Activity (HCA). Contracting officers shall coordinate actions under this section with the legal counsel of the responsible office. The following procedures apply:

(1) Actions must be appealed within 30 days of receipt of the written statement issued by DOT required by FAR 27.304–4(a). The contractor must present all pertinent arguments in the appeal along with documentary evidence, if any.

(2) The HCA shall issue a determination within 45 days from the date the contractor's appeal is received.

(c) Contractor appeal of decisions rendered under FAR 27.304–4(a)(2) are subject to the following requirements:

(1) Actions must be appealed within 30 days of receipt of the written statement required by FAR 27.304–4(a). The contractor must present all pertinent arguments in the appeal along with documentary evidence, if any.

(2) The HCA may hold an informal hearing if deemed appropriate or at the request of the contractor. The informal hearing shall be held after all fact-finding is completed.

(i) If a hearing is held, DOT shall provide for a transcribed record of the hearing unless transcription is waived as provided for in paragraph (c)(2)(ii) of this section. A copy of the transcript shall be available to the contractor at cost.

(ii) Transcription of the hearing may be waived by agreement of the parties.

(3) The HCA shall designate an impartial fact-finding official. The official conducting the fact-finding shall prepare findings of fact and transmit them to the HCA promptly after the conclusion of the fact-finding proceeding along with a recommended determination.

(i) A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by mail, to the last known street address, the last known facsimile number, or the last known email address and to the contractor's identified counsel. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the HCA; and, upon request by the contractor, oral arguments will be held before the HCA as part of an informal hearing. The HCA will make the final determination as to whether the initial agency action was appropriate under the relevant laws and procedures (*see* 1227.304–4(c)).

(ii) Any portion of the informal hearing that involves testimony or evidence shall be closed to the public. Agencies shall not disclose any such information obtained during the appeal to persons outside the Government except when such release is authorized by the contractor (assignee or licensee).

(4) The HCA's final determination shall be based on the findings of facts, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The HCA may reject only those facts that have been found clearly erroneous and must explicitly state the rejection and the basis for the contrary finding. The HCA shall provide the contractor (assignee or exclusive licensee) a written determination by certified or registered mail no later than 90 days after fact-finding is completed or no later than 90 days after oral arguments, whichever is later.

1227.305 Administration of patent rights clauses.

1227.305–4 Protection of invention disclosures.

Solicitations and contracts that include a patent rights clause must provide the contractor the means to report inventions made during contract performance and at contract completion. This requirement may be fulfilled by requiring the contractor to submit a Department of Defense DD Form 882, Report of Inventions and Subcontracts.

PART 1228—BONDS AND INSURANCE

Subpart 1228.1—Bonds and Other Financial Protections

Sec.
1228.106 Administration.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1228.1—Bonds and Other Financial Protections

1228.106 Administration.

1228.106–470 Contract clause-notification of payment bond protection.

The contracting officer must insert the clause at 1252.228–74, Notification of Payment Bond Protection, in solicitations and contracts when payment bonds are required.

1228.106–6 Furnishing information.

(c) When furnishing a copy of a payment bond and contract in accordance with FAR 28.106–6(b), the requirement for a copy of the contract may be satisfied by furnishing a pdf of the contract's first pages which show the contract number and date, the contractor's name and signature, the contracting officer's signature, and the description of the contract work. The contracting officer furnishing the copies shall place the statement ''Certified to be a true and correct copy'' followed by his/her signature, title and name of the Operating Administration using an authenticated electronic signature. The fee for furnishing the requested certified copies shall be determined in accordance with the DOT Freedom of Information Act regulation, 49 CFR part 7, and 1224.203.

1228.106–70 Execution and administration of bonds.

(a) The contracting officer shall notify the surety within 30 days of the contractor's failure to perform in accordance with the terms of the contract.

(b) When a partnership is a principal on a bond, the names of all the members of the firm shall be listed in the bond following the name of the firm, and the phrase ''a partnership composed of.'' If a principal is a corporation, the state of incorporation must also appear on the bond.

(c) Performance or payment bond(s), other than an annual bond, shall not predate the contract to which it pertains.

(d) Bonds may be filed with the original contract to which they apply, or all bonds can be separately maintained and reviewed quarterly for validity. If separately maintained, each contract file shall cross-reference the applicable bonds.

1228.106–71 Performance and payment bonds for certain contracts.

1228.106–7100 Waiver.

Pursuant to the authority vested in the Secretary of Transportation by the Bond statute at 40 U.S.C. chapter 31, subchapter III, Bonds (historically known as the Miller Act), the requirements of 40 U.S.C. 3131 *et seq.* are waived, to the extent authorized in accordance with 40 U.S.C. 3134(b).

1228.106–7101 Exception.

A performance and payment bond for the contracts described under 1228.106–7100 may be advantageous in view of unusual circumstances arising in connection with such contracts. Requests for the authority to include the requirement for either a performance or payment bond, or both in the contracts described under 1228.106–7100 shall be submitted by the contracting officer to the HCA, before a solicitation is issued.

Subpart 1228.3—Insurance

1228.306 Insurance under fixed-price contracts.

1228.306–70 Contracts for lease of aircraft.

(a) The contracting officer shall insert the clauses at 1252.228–70, Loss of or Damage to Leased Aircraft; 1252.228–71, Fair Market Value of Aircraft; and 1252.228–72, Risk and Indemnities, unless otherwise indicated by the specific instructions for their use, in any contract for the lease of aircraft (including aircraft used in out-service flight training), except in the following circumstances—

(1) When the hourly rental rate does not exceed $250 and the total rental cost for any single transaction is not in excess of $2,500;

(2) When the cost of hull insurance does not exceed 10 percent of the contract rate; or

(3) When the lessor's insurer does not grant a credit for uninsured hours, thereby preventing the lessor from granting the same to the Government.

(b) As codified, 49 U.S.C. 44112, as amended, provides that an aircraft lessor under a lease of 30 days or more is not liable for injury or death of persons, or damage or loss of property, unless the aircraft is in the actual possession or control of the lessor and the damage occurs because of—

(1) The aircraft, engine, or propeller; or

(2) The flight of, or an object falling from, the aircraft, engine, or propeller.

(c) On short-term or intermittent-use leases, however, the owner may be liable for damage caused by operation of the aircraft. It is usual for the aircraft owner to retain insurance covering this liability during the term of such lease. Such insurance can, often for little or no increase in premium, be made to cover the Government's exposure to liability as well. To take advantage of this coverage, the Risks and Indemnities clause at 1252.228–72, prescribed in paragraph (d) of this section, shall be used.

(d) The contracting officer shall insert the clause at 1252.228–72, Risk and Indemnities, in any contract for out-service flight training or for the lease of aircraft when the Government will have exclusive use of the aircraft for a period of less than thirty days.

(e) During the performance of a contract for out-service flight training for DOT, whether the instruction to DOT personnel is in leased, contractor-provided, or Government-provided aircraft, contractor personnel shall always, during the entirety of the course of training and operation of the aircraft, remain in command of the aircraft. At no time shall Government personnel or other personnel be permitted to take command of the aircraft. The contracting officer shall insert the clause at 1252.228–73, Command of Aircraft, in any solicitation and contract for out-service flight training, whether performed utilizing DOT-leased aircraft, contractor-provided aircraft, or Government-provided aircraft.

1228.307–1 Group insurance plans.

(a) *Prior approval requirements.* Contractors shall provide plans required by FAR 28.307–1(a) to the contracting officer for approval.

1228.311–1 Contract clause.

The contracting officer shall insert the clause at FAR 52.228–7, Insurance Liability to Third Persons, as prescribed in FAR 28.311–1 unless it is waived by an official one level above the contracting officer.

PART 1231—CONTRACT COST PRINCIPLES AND PROCEDURES

Subpart 1231.2—Contracts With Commercial Organizations

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1231.2—Contracts With Commercial Organizations

1231.205 Selected costs.

1231.205–3270 Precontract costs—incurrence of costs.

(a) The decision to incur precontract costs is the responsibility of the contractor. DOT officials shall not authorize, demand, or require a contractor to incur precontract costs. The contracting officer may advise the prospective contractor that any costs incurred before contract award are at the contractor's sole risk and that if negotiations fail to result in a binding contract, payment of these costs may not be made by the Government.

(b) When the contracting officer determines that incurring precontract costs was necessary to meet the proposed contract delivery schedule of a cost-reimbursement contract, the clause at 1252.231–70, Date of Incurrence of Costs, may be inserted in the resultant contract.

PART 1232—CONTRACT FINANCING

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1232.7—Contract Funding

1232.770 Incremental funding during a Continuing Resolution.

1232.770–1 Scope of section.

This section provides policy and procedures for using incremental funding for fixed-price, time-and-material and labor-hour contracts during a period in which funds are provided to the DOT and its operating administrations under a continuing resolution. Heads of the contracting activities may develop necessary supplemental internal procedures and guidance to advise offerors and contractors of these policies and procedures.

1232.770–2 Definition.

Continuing Resolution (CR) means an appropriation, in the form of a joint resolution, that provides budget authority for Federal agencies, specific activities, or both to continue operation until the regular appropriations are enacted. Typically, a continuing resolution is used when legislative action on appropriations is not completed by the beginning of a fiscal year.

1232.770–3 General.

The Anti-Deficiency Act, 31 U.S.C. 1341, and FAR 32.702, state that no officer or employee of the Government may create or authorize an obligation in excess of the funds available, or in advance of appropriations unless otherwise authorized by law. A CR provides funding for continuing projects or activities that were conducted in the prior fiscal year for which appropriations, funds, or other authority was previously made available. Each CR is governed by the specific terms in that specific CR (*e.g.,* duration of the CR) and under certain CRs, the funding amounts available for award of some contract actions are inadequate to fund the entire amounts needed.

1232.770–4 Policy.

(a) A fixed-price, time-and-materials, or labor-hour contract or order for commercial or non-commercial severable services may be incrementally funded when—

(1) Funds are provided to DOT or operating administration under a CR. This includes funds appropriated to DOT or an operating administration, funds appropriated to another entity that will be directly obligated on a DOT contract, and funds in a revolving fund or similar account that will be reimbursed by a customer agency funded by a CR;

(2) The responsible fiscal authority has not allocated sufficient funds to fully fund the contract action that is otherwise authorized to be issued;

(3) There is no statutory restriction that would preclude the proposed use of funds;

(4) Funds are available and unexpired, as of the date the funds are obligated;

(5) Assurance is provided by the responsible financial authority that full funding is anticipated once an appropriations act is enacted; and

(6) The clause prescribed by 1232.770–7 is incorporated into the contract or order.

(b) Incremental funding may be limited to an individual line item(s) or a particular order(s).

1232.770–5 Limitations.

This policy does not apply to contract actions using funds that are not covered by the CR.

1232.770–6 Procedures.

(a) An incrementally funded fixed-price, time-and-materials, or labor-hour contract shall be fully funded once funds are available.

(b) The contracting officer shall ensure that sufficient funds are allotted to the contract to cover the total amount payable to the contractor in the event of termination for convenience by the Government.

(c) Upon receipt of the contractor's notice under paragraph (c) of the clause at 1252.232–71, Limitation of Government's Obligation, the contracting officer shall promptly provide written notice to the contractor that the Government is—

(1) Obligating additional funds for continued performance and increasing the Government's limitation of obligation in a specified amount;

(2) Obligating the full amount of funds needed;

(3) Terminating for convenience, as applicable, the affected line items or contract; or

(4) Considering whether to allot additional funds; and

(i) The contractor is entitled by the contract terms to stop work when the Government's limitation of obligation is reached; and

(ii) Any costs expended beyond the Government's limitation of obligation are at the contractor's risk.

(d) Upon learning that the contract will receive no further funds by the date provided in the notice under paragraph (c) of the clause at 1252.232–71, Limitation of Government's Obligation, the contracting officer shall promptly give the contractor written notice of the Government's decision and terminate the affected line items or contract, as applicable, for the convenience of the Government.

1232.770–7 Clause.

(a) The contracting officer shall insert the clause at 1252.232–71, Limitation of Government's Obligation, in—

(1) Solicitations and contracts for severable services when incremental funding of a fixed-price, time-and-material, or labor-hour contract due to a CR is anticipated; or

(2) Contracts or orders for severable services when incremental funding of a fixed-price, time-and-material, or labor-hour contract is authorized and DOT or its operating administrations are operating under a CR (*see* 1232.770–4).

(b) The contracting officer shall insert the information required in paragraphs (a) and (c) of clause 1252.232–71. Contracting officers are authorized, in appropriate cases, to revise paragraph (a) of clause 1252.232–71 to specify the work required under the contract, in lieu of using contract line item numbers, as well as revise paragraph (c) of the clause to specify a different notification period and percentage. The 30-day period may be varied up to 90 days, and the 75 percent can be varied from 75 up to 85 percent.

Subpart 1232.9—Prompt Payment

1232.905–70 Payment documentation and process—form of invoice.

(a) Under fixed-price contracts, the contracting officer shall require the contractor to submit an invoice or voucher on any form or format meeting FAR 32.905(b) requirements.

(b) Under other than fixed-price contracts, the contracting officer shall require the contractor to submit the Standard Form (SF) 1034, Public Voucher for Purchases and Services Other Than Personal, and the SF 1035, Public Voucher for Purchases and Services Other Than Personal (Continuation Sheet), to request payments. The forms must be completed as required by figure 1 to this section, Instructions for Completing the SF 1034, and figure 2 to this section, Instructions for Completing the SF 1035.

Figure 1 to 1232.905–70

Instructions for Completing the SF 1034

The SF 1034, Public Voucher for Purchases and Services Other Than Personal, shall be completed in accordance with the below instructions. The numbered items correspond to the entries on the form.

Caption on the SF 1034	Data to be inserted in the block
1. U.S. DEPARTMENT, BUREAU, OR ESTABLISHMENT AND LOCATION.	Name and address of the contracting office which issued the contract.
2. DATE VOUCHER PREPARED	Date voucher submitted to the designated billing office cited under the contract or order.
3. CONTRACT NO. AND DATE	Contract No. and, when applicable, the Order No. and date as shown on the award document.
4. REQUISITION NO. AND DATE	Leave blank or fill-in in accordance with the instructions in the contract.
5. VOUCHER NO	Start with "1" and number consecutively. A separate series of consecutive numbers must be used beginning with "1" for each contract number or order number (when applicable). Note: Insert the word "FINAL" if this is the last voucher.
6. SCHEDULE NO.; PAID BY; DATE INVOICE RECEIVED; DISCOUNT TERMS; PAYEE'S ACCOUNT NO.; SHIPPED FROM/TO; WEIGHT; GOVERNMENT B/L.	Leave all these blocks blank.
7. PAYEE'S NAME AND ADDRESS	Name and address of contractor as it appears on the contract. If the contract is assigned to a bank, also show "CONTRACT ASSIGNED" below the name and address of the contractor.
8. NUMBER AND DATE OF ORDER	Leave blank. (*See* #3 above.).
9. DATE OF DELIVERY OR SERVICE	The period for which the incurred costs are being claimed (*e.g.,* month and year; beginning and ending date of services, etc.).
10. ARTICLES OR SERVICES	Insert the following: "For detail, *see* the total amount of the claim transferred from the attached SF 1035, page X of X." One space below this line, insert the following: "COST REIMBURSABLE–PROVISIONAL PAYMENT."
11. QUANTITY; UNIT PRICE; (COST; PER)	Leave blank.
12. AMOUNT	Insert the total amount claimed from the last page of the SF 1035.
Payee must NOT use the space below	Do NOT write or type below this line.

Figure 2 to 1232.905–70

Instructions for Completing the SF 1035

The SF 1035, Public Voucher for Purchases and Services Other Than Personal (Continuation Sheet), shall be completed in accordance with the below instructions.

1. Use the same basic instructions for the SF 1035 as used for the SF 1034. Ensure that the contract and, if applicable, order number, are shown on each continuation sheet. Use as many sheets as necessary to show the information required by the contract, contracting officer, or responsible audit agency; however, if more than one sheet of SF 1035 is used, each sheet shall be in numerical sequence.

2. The following items are generally entered below the line with Number and Date of Order; Date of Delivery or Service; Articles or Services; Quantity; Unit Price; and Amount (but do not necessarily tie to these captions).

3. Description of data to be inserted as it applies to the contract or order number including the CLIN or SLIN.

a. Show, as applicable, the target or estimated costs, target or fixed-fee, and total contract value, as adjusted by any modifications to the contract or order. The FAR permits the contracting officer to withhold a percentage of fixed fee until a reserve is set aside in an amount that is considered necessary to protect the Government's interest.

b. Show the following costs and supporting data (as applicable) to the contract or order:

(1) *Direct Labor.* List each labor category, rate per labor hour, hours worked, and extended total labor dollars per labor category.

(2) *Premium Pay/Overtime.* List each labor category, rate per labor hour, hours worked, and the extended total labor dollars per labor category. *Note:* Advance written authorization must be received from the contracting officer to work overtime or to pay premium rates; therefore, identify the contracting

officer's written authorization to the contractor.

(3) *Fringe Benefits.* If fringe benefits are included in the overhead pool, no entry is required. If the contract allows for a separate fringe benefit pool, cite the formula (rate and base) in effect during the time the costs were incurred. If the contract allows for billing fringe benefits as a direct expense, show the actual fringe benefit costs.

(4) *Materials, Supplies, Equipment.* Show those items normally treated as direct costs. Expendable items need not be itemized and may be grouped into major classifications such as office supplies. However, items valued at $5,000 or more must be itemized. *See* FAR part 45, Government Property, for reporting of property.

(5) *Travel.* List the name and title of traveler, place of travel, and travel dates. If the travel claim is based on the actual costs expended, show the amount for the mode of travel (*i.e.,* airline, private auto, taxi, etc.), lodging, meals, and other incidental expenses separately, on a daily basis. These actual costs must be supported with receipts to substantiate the costs paid. Travel costs for consultants must be shown separately and also supported.

(6) *Other Direct Costs.* Itemize those costs that cannot be placed in categories (1) through (5) above. Categorize these costs to the extent possible.

(7) *Total Direct Costs.* Cite the sum of categories (1) through (6) above.

(8) *Overhead.* Cite the rate, base, and extended amount.

(9) *G&A Expense.* Cite the rate, base, and extended amount.

(10) *Total Costs.* Cite the sum of categories (7) through (9) above.

(11) *Fee.* Cite the rate, base, and extended amount.

(12) *Total Cost and Fee Claimed.* Enter this amount on the SF 1034.

Completion Voucher

The completion (final) voucher is the last voucher to be submitted for incurred, allocable, and allowable costs expended to perform the contract or order. This voucher should include all contract reserves, allowable cost withholdings, balance of fixed fee, etc. However, the amount of the completion voucher when added to the total amount previously paid cannot exceed the total amount of the contract.

Subpart 1232.70—Electronic Invoicing Requirements

1232.7000 Scope of subpart.

This subpart prescribes policy and procedures for submitting and processing payment requests in electronic form.

1232.7001 Definition.

Payment request, as used in this subpart, means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation.

1232.7002 Electronic payment requests—invoices.

(a) *Requirements.* Contracts shall require the electronic submission of payment requests, except for—

(1) Purchases paid for with a Governmentwide commercial purchase card;

(2) Classified contracts or purchases when electronic submission and processing of payment requests could compromise classified information or national security; or

(3) As directed by the contracting officer to submit payment requests by mail.

(b) *Alternate procedures.* Where a contract requires the electronic submission of invoices, the contracting officer may authorize alternate procedures only if the contracting officer makes a written determination that the Department of the Transportation (DOT) is unable to receive electronic payment requests or provide acceptance electronically and it is approved one level above the contracting officer.

(c) *DOT electronic invoicing system.* The Department of Transportation utilizes the DELPHI eInvoicing System. The DELPHI module for submitting invoices is called *iSupplier.* Except as provided in paragraphs (a) and (b) of this section, contracting officers and DOT finance officials shall process electronic payment submissions through the DELPHI System and the DELPHI module for submitting invoices, *iSupplier. iSupplier* is also the official system of record for DOT payment requests. If the requirement for electronic submission of payment requests is waived under paragraph (a) or (b) of this section, the contract or alternate payment authorization, as applicable, shall specify the form and method of payment request submission.

1232.7003 Payment system registration.

1232.7003–1 Electronic authentication.

Access to DELPHI is granted with electronic authentication of credentials (name & valid email address) utilizing the General Services Administration (GSA) credentialing platform *login.gov*. Vendors submitting invoices will be required to submit invoices via *iSupplier* (DELPHI) and authenticated via *www.login.gov*.

1232.7004 Waivers.

If a vendor is unable to utilize DOT's DELPHI electronic invoicing system, DOT may consider waivers on a case-by-case basis. Vendors should contact their COR for procedures, or access the DELPHI website at *http://www.dot.gov/cfo/delphi-einvoicing-system.html.*

1232.7005 Contract clause.

The contracting officer shall insert the clause at 1252.232–70, Electronic Submission of Payment Requests, in solicitations and contracts exceeding the micro-purchase threshold, except those for which the contracting officer has directed or approved otherwise under 1232.7002, and those paid with a Governmentwide commercial purchase card.

PART 1233—PROTESTS, DISPUTES, AND APPEALS

Subpart 1233.1—Protests

Subpart 1233.2—Disputes and Appeals

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1233.1—Protests

1233.103 Protests to the agency.

(c) DOT Operating Administrations (OAs) shall consider the use of alternative dispute resolution (ADR) in all agency protest actions.

1233.104 Protests to GAO.

The protest process at the Government Accountability Office (GAO) may include ADR assistance by GAO. The contracting officer shall, with advice of counsel, explore the possibility of using ADR for all GAO protests.

Subpart 1233.2—Disputes and Appeals

1233.211 Contracting officer's decision.

(a)(4)(v) In accordance with FAR 33.211(a)(4)(i) through (vi), contracting officers shall include in a statement of the contracting officer's decision referenced at FAR 33.211(a)(4)(iv), paragraphs substantially as follows:

''This is the final decision of the Contracting Officer. You may appeal this decision to the Civilian Board of Contract Appeals. If you decide to appeal, you must, within 90 days from the date you receive this decision, mail or otherwise furnish written notice to the Civilian Board of Contract Appeals as set forth below and provide a

copy to the Contracting Officer from whose decision this appeal is taken. The notice shall indicate that an appeal is intended, reference this decision, and identify the contract by number.

Where to File: All filings must be submitted to the Clerk of the Board. Filings shall be to Civilian Board of Contract Appeals, 1800 F Street NW, Washington, DC 20405 in any of the ways as set forth at their website at *https://cbca.gov/howto/index.html.*

With regard to appeals to the Civilian Board of Contract Appeals, you may, solely at your election, proceed under the board's—

(1) Small claim procedure for claims of $50,000 or less or, in the case of a small business concern (as defined in the Small Business Act and regulations under that Act), $150,000 or less; or

(2) Accelerated procedure for claims of $100,000 or less.

Instead of appealing to the Civilian Board of Contract Appeals, you may bring an action directly in the United States Court of Federal Claims (except as provided in 41 U.S.C. 7102(d), regarding Maritime Contracts) within 12 months of the date you receive this decision.''

1233.214 Alternative dispute resolution (ADR).

(c) The Administrative Dispute Resolution Act (ADRA) of 1990, Public Law 101–552, as reauthorized by the Administrative Dispute Resolution Act (ADRA) of 1996, Public Law 104–320, authorizes and encourages agencies to use mediation, conciliation, arbitration, and other techniques for the prompt and informal resolution of disputes, either before or after appeal, and for other purposes. ADR procedures may be used when—

(1) There is mutual consent by the parties to participate in the ADR process (with consent being obtained either before or after an issue in controversy has arisen); and either

(2) Prior to the submission of a claim; or

(3) In resolution of a formal claim.

(d)(1) Use of ADR shall be coordinated with counsel. For all matters filed with the Civilian Board of Contract Appeals (CBCA), the CBCA Alternate Dispute Resolution (ADR) procedures contained in 48 CFR 6101.54 shall be followed.

(2) For other matters, pursuant to the Administrative Dispute Resolution Act (ADRA), DOT has appointed a Dispute Resolution Specialist, who is responsible for the operations of the Center for Alternative Dispute Resolution. The Center may provide an internal DOT neutral agreeable to the parties to conduct any of the alternative means of dispute resolution set forth in the ADRA, 5 U.S.C. 571(3), on a non-reimbursable basis for DOT operating administrations and their contracting partners. Alternative means of dispute resolution include settlement negotiations, conciliation, facilitation, mediation, fact-finding, mini-trials, and arbitration, or any combination of these methods. The Center may also arrange for an external public or private neutral at the parties' expense.

Subchapter F—Special Categories of Contracting

PART 1234 [RESERVED]

PART 1235—RESEARCH AND DEVELOPMENT CONTRACTING

Sec.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

1235.003 Policy.

(b) *Cost sharing.* DOT cost sharing policies that are not otherwise required by law shall be in accordance with FAR 16.303 and 42.707(a) and Operating Administration (OA) procedures.

(c) *Recoupment.* DOT recoupment not otherwise required by law shall be in accordance with OA procedures.

1235.011–70 Contract clause.

The contracting officer shall insert the clause at 1252.235–71, Technology Transfer, in all solicitations and contracts for experimental, developmental, or research work.

1235.012 Patent rights.

Patent rights shall be in accordance with FAR part 27 and any OA implementing procedures in this part.

1235.070 Research misconduct.

(a) *Applicability.* DOT policy on scientific integrity is implemented in the Deputy Secretary's memorandum dated April 10, 2012, Implementation of Departmental Scientific Integrity Policy at *https://www.transportation.gov/administrations/assistant-secretary-research-and-technology/memorandum-implementation-departmental.* The Department is dedicated to preserving the integrity of the research it conducts and funds and will not tolerate misconduct in the performance of these activities. This policy applies to all DOT-funded or DOT-conducted research, including intramural research, research conducted by contractors, and research performed at research institutions, including universities and industry.

(b) *Definition. Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. A finding of research misconduct means a determination based on a preponderance of the evidence that research misconduct has occurred, including a conclusion that there has been a significant departure from accepted practices of the relevant research community and that it was knowingly, intentionally, or recklessly committed.

1235.070–1 Contract clause.

The contracting officer shall insert the clause at 1252.235–70, Research Misconduct, in all solicitations and contracts for research and development.

PART 1236—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

Subpart 1236.5—Contract Clauses

Sec.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1236.5—Contract Clauses

1236.570 Special precautions for work at operating airports.

Where any acquisition will require work at an operating airport, insert the clause at 1252.236–70, Special Precautions for Work at Operating Airports, in solicitations and contracts.

PART 1237—SERVICE CONTRACTING

Subpart 1237.1—Service Contracts—General

Sec.

Subpart 1237.70—Procedures for Acquiring Training Services

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1237.1—Service Contracts—General

1237.110–70 Contract clauses.

(a) The contracting officer shall insert the clause at 1252.237–70, Qualifications of Contractor Employees, in all solicitations and contracts for services where contractor employees

will have access to Government facilities and sensitive information, including proprietary data and/or resources.

(b) The contracting officer shall insert the clause at 1252.237–73, Key Personnel, in solicitations and contracts for services when the selection for award is substantially based on the offeror's possession of special capabilities regarding personnel.

Subpart 1237.70—Procedures for Acquiring Training Services

1237.7000 Policy.

When training services are provided under contract, DOT policy requires that all prospective contractors:

(a) Certify that the data provided concerning company qualifications, background statements, and resumes, for example, is current, accurate, and complete; and

(b) Agree to not solicit or advertise private, non-Government training while conducting a training course.

1237.7001 Certification of data.

Towards fulfilling DOT's policy at 1237.7000(a), contracting officers shall request information from prospective contractors for certification purposes. The type of information requested is dependent upon the criticality of the service and/or any unique or essential qualification requirements.

1237.7002 Applicability.

The policy at 1237.7000 applies to all contracts (as defined in FAR 2.101) awarded by DOT for training services when DOT controls the content and/or presentation of the course. This policy does not apply to courses attended by DOT employees that are offered and sponsored by Government sources of supply, educational institutions, or private entities where DOT does not control the course content or presentation (*see* 1213.7100 for examples).

1237.7003 Solicitation provision and contract clause.

(a) The contracting officer shall insert the provision at 1252.237–71, Certification of Data, in solicitations and the clause at 1252.237–72, Prohibition on Advertising, in solicitations and contracts for training services when the content and/or presentation of the course is controlled by DOT.

(b) The contracting officer shall incorporate the successful offeror's certified data into any resultant contract(s). Certified data may be adopted by reference, if the contracting officer determines it contains sufficient descriptive information (*i.e.,* dated material such as resumes, company and/or personnel qualifications) to reliably describe the certified data submitted.

PART 1239—ACQUISITION OF INFORMATION TECHNOLOGY

Sec.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

1239.000 Scope of part.

In addition to FAR 39.000, this part prescribes acquisition policies and procedures for use in acquiring information technology and information technology-related supplies, services and systems, including information security, to include—

(a) Software management and development;

(b) Section 508 standards and compliance for contracts;

(c) Information security and incident response reporting;

(d) Protection of data about individuals;

(e) Cloud computing;

(f) Technology modernization and upgrade/refreshment; and

(g) Record management.

1239.002 Definitions.

As used in this part—

Information means any communication or representation of knowledge such as facts, data, or opinions in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Media means physical devices or writing surfaces including, but not limited to, magnetic tapes, optical disks, magnetic disks, large-scale integration memory chips, and printouts onto which information is recorded, stored, or printed within an information system.

Subpart 1239.1—General

1239.101 Policy.

1239.101–70 Policy—software management and development.

1239.101–71 Scope.

This subpart applies to all acquisitions of products or services supporting the development or maintenance of software.

1239.101–72 Definitions.

As used in this subpart—

Application means software that resides above system software and includes applications such as database programs, word processors and spreadsheets. Application software may be bundled with system software or published alone.

Programming software means tools to aid developers in writing programs including compilers, linkers, debuggers, interpreters and text editors.

Software means a set of instructions or programs instructing a computer to do specific tasks including scripts, applications, programs and a set of instructions. Includes System, Programming, and Application software.

System software means a platform comprised of Operating System (OS) programs and services, including settings and preferences, file libraries and functions used for system applications. System software also includes device drivers that run basic computer hardware and peripherals.

1239.101–73 Policy.

The contracting officer will ensure all documents involving the acquisition of products or services supporting the development or maintenance of DOT software applications, systems, infrastructure, and services contain the appropriate clauses as may be required by Federal Acquisition Regulation (FAR) and other Federal authorities, in order to ensure that information system modernization is prioritized accordance with Federal law, OMB Guidance, and DOT policy.

1239.106–70 Contract clauses.

The contracting officer shall insert the clause at 1252.239–70, Security Requirements for Unclassified Information Technology Resources, and the clause at 1252.239–71, Information Technology Security Plan and Accreditation, in all solicitations and contracts exceeding the micro-purchase threshold that include information technology services.

Subpart 1239.2—Information and Communication Technology

1239.201 Scope of subpart.

This subpart applies to the acquisition of Information and Communication Technology (ICT) supplies and services. It concerns the access to and use of information and data, by both Federal employees with disabilities, and members of the public with disabilities in accordance with FAR 39.201. This subpart implements DOT policy on section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as it applies to contracts and acquisitions.

1239.203 Applicability.

(a) Solicitations for information and communication technology supplies and services may require submission of a section 508 Checklist available at *https://www.section508.gov/sell/vpat.*

1239.203–70 Information and communication technology accessibility standards—contract clause and provision.

(a) The contracting officer shall insert the provision at 1252.239–92, Information and Communication Technology Accessibility Notice, in all solicitations.

(b) The contracting officer shall insert the clause at 1252.239–93, Information and Communication Technology Accessibility, in all contracts and orders.

Subpart 1239.70—Information Security and Incident Response Reporting

1239.7000 Scope of subpart.

(a) This subpart applies to contracts and subcontracts requiring contractors and subcontractors to safeguard DOT sensitive data that resides in or transits through covered contractor information systems by applying specified network security requirements. It also requires reporting of cyber incidents.

(b) This subpart does not abrogate any other requirements regarding contractor physical, personnel, information, technical, or general administrative security operations governing the protection of unclassified information, nor does it affect requirements of the National Industrial Security Program.

1239.7001 Definitions.

As used in this subpart—

Adequate security means protective measures that are commensurate with the consequences and probability of loss, misuse, or unauthorized access to, or modification of information.

Contractor attributional/proprietary information means information that identifies the contractor(s), whether directly or indirectly, by the grouping of information that can be traced back to the contractor(s) (*e.g.,* program description, facility locations), personally identifiable information, as well as trade secrets, commercial or financial information, or other commercially sensitive information that is not customarily shared outside of the company.

Contractor information system means an unclassified information system that is owned, or operated by or for, a contractor and that processes, stores, or transmits DOT sensitive information.

Cyber incident means actions taken through the use of computer networks that result in a compromise or an actual or potentially adverse effect on an information system and/or the information residing therein.

DOT sensitive data means unclassified information that requires safeguarding or dissemination controls pursuant to and consistent with law, regulations, and Governmentwide policies, and is—

(1) Marked or otherwise identified in the contract, task order, or delivery order and provided to the contractor by or on behalf of DOT in support of the performance of the contract; or

(2) Collected, developed, received, transmitted, used, or stored by or on behalf of the contractor in support of the performance of the contract.

Rapidly report means reporting within two (2) hours of discovery of any cyber incident.

Technical information means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information. Examples of technical information include research and engineering data, engineering drawings, and associated lists, specifications, standards, process sheets, manuals, technical reports, technical orders, catalog-item identifications, data sets, studies and analyses and related information, and computer software executable code and source code.

1239.7002 Policy.

(a) Contractors and subcontractors are required to provide adequate security on all contractor information systems that will collect, use, process, store, or disseminate DOT sensitive data.

(b) Contractors and subcontractors shall report cyber incidents directly to DOT via the DOT Security Operations Center (SOC) 24 hours-a-day, 7 days-a-week, 365 days a year (24x7x365) at phone number: 571–209–3080 (Toll Free: 866–580–1852) within two (2) hours of discovery. Subcontractors will provide to the prime contractor the incident report number automatically assigned by DOT. Lower-tier subcontractors likewise report the incident report number automatically assigned by DOT to their higher-tier subcontractor, until the prime contractor is reached.

(c) If a cyber incident occurs, contractors and subcontractors shall submit to DOT, in accordance with the instructions contained in the clause at 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting—

(1) A cyber incident report;

(2) The malicious software, if detected and isolated; and

(3) The medium or media (or access to covered contractor information systems and equipment) upon request.

(d) Notwithstanding the requirement in this subpart for the reporting of cyber incidents, if existing safeguards have ceased to function or the Government or Contractor discovers new or unanticipated threats or hazards, the discoverer shall immediately bring the situation to the attention of the other party.

(1) Information shared by the contractor may include contractor attributional/proprietary information. The Government will protect against the unauthorized use or release of information that includes contractor attributional/proprietary information.

(2) A cyber incident that is reported by a contractor or subcontractor shall not, by itself, be interpreted as evidence that the contractor or subcontractor has failed to provide adequate security on their covered contractor information systems, or has otherwise failed to meet the requirements of the clause at 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting. When a cyber incident is reported, the contracting officer shall consult with the DOT component Chief Information Officer/cyber security office prior to assessing contractor compliance (*see* 1239.7003). The contracting officer shall consider such cyber incidents in the context of an overall assessment of a contractor's compliance with the requirements of the clause at 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting.

(3) Support services contractors directly supporting Government activities related to safeguarding DOT sensitive data and cyber incident reporting (*e.g.,* forensic analysis, damage assessment, or other services that require access to data from another contractor) are subject to restrictions on use and disclosure of reported information.

1239.7003 Contract clauses.

(a) The contracting officer shall insert the clause at 1252.239–72, Compliance with Safeguarding DOT Sensitive Data Controls, in all solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial products and commercial services, except for solicitations solely for the acquisition of commercially available off-the-shelf (COTS) items.

(b) The contracting officer shall insert clause at 1252.239–73, Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information, in all solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, for commercial services that include support for the Government's activities related to safeguarding DOT sensitive data and cyber incident reporting.

(c) The contracting officer shall insert clause at 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting, in all solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, except for solicitations and contracts solely for the acquisition of COTS items.

Subpart 1239.71—Protection of Data About Individuals

1239.7100 Scope of subpart.

This subpart includes Privacy Act and data protection considerations for DOT contracts. Data protection requirements are in addition to provisions concerning the general protection of individual privacy (*see* FAR subpart 24.1) and privacy in the acquisition of information technology (*see* FAR 39.105). DOT rules and regulations implementing the Privacy Act of 1974 are located at 49 CFR part 10.

1239.7101 Definitions.

As used in this subpart—

Breach means the disclosure of information to unauthorized persons, or a violation of the security policy of a system, in which unauthorized access, compromise, use, disclosure, modification, destruction, access or loss use of data, or the copying of information to unauthorized media may have occurred.

Data protection means the practice of protecting data and managing risks associated with the collection, display, use, processing, storage, transmission, and disposal of information or data as well as the systems and processes used for those purposes. Data protection uses physical, technical, and administrative controls to protect the integrity, availability, authenticity, non-repudiation, and confidentiality of data by incorporating protection, detection, and reaction capabilities. Data protection encompasses not only digital data, but also data in analog or physical form, and applies to data in transit as well as data at rest.

Information security means the protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

(1) *Integrity,* which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

(2) *Confidentiality,* which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) *Availability,* which means ensuring timely and reliable access to and use of information.

Personally Identifiable Information (PII) means the definition as set forth in FAR 24.101.

Privacy incident means the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or unauthorized access to PII regardless of format.

1239.7102 Policy.

DOT must ensure that data protection is provided for information and information systems in accordance with current policies, procedures, and statutes, including:

(a) The Clinger-Cohen Act.

(b) The E-Government Act.

(c) Federal Information Systems Modernization Act.

(d) Federal Information Processing Standards.

(e) OMB Circular A–130, Managing Information as a Strategic Resource.

(f) 49 CFR part 10, Maintenance of and Access to Records Pertaining to Individuals.

(g) DOT Order 1351.18, Privacy Risk Management Policy.

(h) DOT Order 1351.19, PII Breach Notification Controls.

(i) DOT Order 1351.28, Records Management.

(j) DOT Order 1351.37, Departmental Cyber Security Policy.

1239.7103 Responsibilities.

(a) The contracting officer will include appropriate data protection requirements in all contracts and other acquisition-related documents for DOT information created, collected, displayed, used, processed, stored, transmitted, and disposed of by contractors.

(b) The contracting officer will ensure all contracts with contractors maintaining information systems containing PII contain the appropriate clauses as may be required by the Federal Acquisition Regulation (FAR) and other OMB and agency memorandums and directives, to ensure that PII under the control of the contractor is maintained in accordance with Federal law and DOT policy.

(c) The contracting officer and assigned contracting officer's representatives and program and project managers will obtain contractual assurances from third parties working on official DOT business that third parties will protect PII in a manner consistent with the privacy practices of the Department during all phases of the system development lifecycle.

(d) Program and project managers and requiring activities will address the need to protect information about individuals and/or PII in the statement

of work (SOW), performance work statement (PWS) or statement of objectives (SOO). Contracting officers will notify the appropriate organization or office when it intends to issue a solicitation for items or services requiring access to personal information or PII. Contracting officers will identify the Component Privacy Officer as the point of contact for oversight of privacy protection and identify the Component Information Systems Security Manager for the component for oversight of information security to the contractor after award.

(e) See 1252.239–75, DOT Protection of Information about Individuals, PII and Privacy Risk Management Requirements, for additional information regarding the requirements of DOT Order 1351.18, Privacy Risk Management Policy and DOT Order 1351.37, Departmental Cyber Security Policy.

1239.7104 Contract clause.

The contracting officer shall insert the clause at 1252.239–75, DOT Protection of Information About Individuals, PII and Privacy Risk Management Requirements, in solicitations and contracts involving contractor performance of data protection functions and for contracts involving the design, development, or operation of an information system with access to personally identifiable information as described in DOT Order 1351.18, Privacy Risk Management, and DOT Order 1351.37, Departmental Cyber Security Policy.

Subpart 1239.72—Cloud Computing

1239.7200 Scope of subpart.

This subpart prescribes policies and procedures for the acquisition of cloud computing services.

1239.7201 Definitions.

As used in this subpart—

Authorizing official means the senior Federal official or executive with the authority to formally assume responsibility for operating an information system at an acceptable level of risk to organizational operations (including mission, functions, image, or reputation), organizational assets, individuals, other organizations, and the Nation.

Cloud computing means a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (*e.g.,* networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. This includes other commercial terms, such as on-demand self-service, broad network access, resource pooling, rapid elasticity, and measured service. It also includes commercial offerings for software-as-a-service, infrastructure-as-a-service, and platform-as-a-service.

Government data means any information, document, media, or machine-readable material regardless of physical form or characteristics, that is created or obtained by the Government in the course of official Government business.

Government-related data means any information, document, media, or machine-readable material regardless of physical form or characteristics that is created or obtained by a contractor through the storage, processing, or communication of Government data. This does not include a contractor's business records (*e.g.,* financial records, legal records, and other similar records) or data such as operating procedures, software coding, or algorithms that are not uniquely applied to the Government data.

1239.7202 Policy.

(a) *General.* Generally, DOT entities shall acquire cloud computing services using commercial terms and conditions that are consistent with Federal law and the agency's needs, including those requirements specified in this subpart. Some examples of commercial terms and conditions are license agreements, End User License Agreements (EULAs), Terms of Service (TOS), or other similar legal instruments or agreements. Contracting officers shall carefully review commercial terms and conditions and consult counsel to ensure these are consistent with Federal law, regulations, and the agency's needs. Contracting officers shall incorporate any applicable service provider terms and conditions into the contract by attachment or other appropriate mechanism.

(b) *FedRAMP provisional authorization.* Except as provided in paragraph (b)(1) of this section, the contracting officer shall only award a contract to acquire cloud computing services from a cloud service provider (*e.g.,* contractor or subcontractor, regardless of tier) that has been granted provisional authorization by the General Services Administration (GSA) Federal Risk and Authorization Management Program (FedRAMP), and meets the security requirements set out by the DOT Chief Information Officer (CIO), at the level appropriate to the requirement to provide the relevant cloud computing services.

(1) The contracting officer may award a contract to acquire cloud computing services from a cloud service provider that has not been granted provisional authorization when—

(i) The requirement for a provisional authorization is waived by the DOT CIO; or

(ii) The cloud computing service requirement is for a private, on-premises version that will be provided from Government facilities. Under this circumstance, the cloud service provider must obtain a provisional authorization prior to operational use.

(2) When contracting for cloud computing services, the contracting officer shall ensure the following information is provided by the requiring activity:

(i) Government data and Government-related data descriptions.

(ii) Data ownership, licensing, delivery, and disposition instructions specific to the relevant types of Government data and Government-related data (*e.g.,* Contract Data Requirements List; work statement task; line items). Disposition instructions shall provide for the transition of data in commercially available, or open and non-proprietary format (and for permanent records, in accordance with disposition guidance issued by National Archives and Record Administration).

(iii) Appropriate requirements to support applicable inspection, audit, investigation, or other similar authorized activities specific to the relevant types of Government data and Government-related data, or specific to the type of cloud computing services being acquired.

(iv) Appropriate requirements to support and cooperate with applicable system-wide search and access capabilities for inspections, audits, investigations.

(c) *Required storage of data within the United States or outlying areas.* (1) Cloud computing service providers are required to maintain within the 50 States, the District of Columbia, or outlying areas of the United States, all Government data that is not physically located on DOT premises, unless otherwise authorized by the DOT CIO.

(2) The contracting officer shall provide written approval to the contractor when the contractor is permitted to maintain Government data at a location outside the 50 States, the District of Columbia, and outlying areas of the United States.

1239.7203 DOT FedRAMP specific requirements.

DOT entities shall set forth DOT FedRAMP specific cloud service

requirements. DOT cloud service providers shall adhere to specific requirements when providing services to DOT and its operating administrations whenever DOT or other Federal agency information, sensitive information as defined by DOT policy, personally identifiable information, or third-party provided information and data will transit through or reside on the cloud services system and infrastructure and that requires protection according to required National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS). In addition to the requirements found elsewhere in the FAR, the following are required—

(a) *Validated cryptography for secure communications.* The FedRAMP security control baseline requires cryptographic mechanisms to prevent unauthorized disclosure of information during transmission unless otherwise protected by alternative physical measures (see NIST FIPS 140–2). DOT entities must require FIPS 140–2 validated cryptography be used between DOT and the cloud service provider. The program/project manager or requiring activity shall specify which level (1–4) of FIPS 140–2 validation is required. See the clause prescribed at 1239.7204(c).

(b) *Digital signature cryptography—(authentication, data integrity, and non-repudiation).* Cloud service providers are required to implement FIPS 140–2 validated cryptography for digital signatures. If DOT entities require integration with specific digital signature technologies, contracting officers shall specify what level (1–4) of FIPS 140–2 encryption is required. See the clause prescribed at 1239.7204(d).

(c) *Audit record retention for cloud service providers.* DOT entities should consider the length of time Cloud Service Providers (CSP) must retain audit records. DOT implements the FedRAMP requirement for a service provider to retain system audit records on-line for at least ninety calendar days and to further preserve audit records off-line for a period that is in accordance with DOT and NARA requirements. See the clause prescribed at 1239.7204(e).

(d) *Cloud identification and authentication (organizational users) multi-factor authentication.* Cloud Service Providers pursuing a FedRAMP authorization must provide a mechanism for DOT activities and operating administrations (*i.e.,* Government consuming end-users) to use multi-factor authentication. DOT follows National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS) Publication (PUB) Number 201–2, Personal Identity Verification (PIV) of Federal Employees and Contractors. See the clause prescribed at 1239.7204(f).

(e) *Identification and authentication (non-organizational users).* Contracting officers shall require that Cloud Service Providers pursuing a FedRAMP authorization provide multi-factor authentication for the provider's administrators. See the clause prescribed at 1239.7204(g).

(f) *Incident reporting timeframes.* Contracting officers shall specify in solicitations and contracts the required FedRAMP parameters for Incident Reporting at the levels stipulated in NIST SP 800–61, as well as the requirement for an Incident Reporting Plan that complies with those requirements. The program office shall include specific incident reporting requirements including who and how to notify the agency. See 1239.7002(b) and the clause prescribed at 1239.7204(h).

(g) *Media transport.* DOT or other Federal agency information and data require protection. Contracting officers shall set forth specific DOT media transport requirements. See the clause prescribed at 1239.7204(i).

(h) *Personnel screening—background investigations.* When DOT leverages FedRAMP Provisional Authorizations, DOT conducts the required background investigations, but may accept reciprocity from other agencies that have implemented the Cloud Service Provider's systems. DOT's screening procedures, process, and additional screening requirements are set forth at 1252.204–70 and the clause prescribed at 1239.7204(j).

(i) *Minimum personnel security requirements—U.S. citizenship and clearance.* Contractors shall provide support personnel who are U.S. persons maintaining a NACI clearance or greater in accordance with OMB memoranda and contract clauses, and who shall undergo required DOT background investigations prior to providing services and performing on the contract. See clause 1252.204–70(b) and the clause prescribed at 1239.7204(j). Reinvestigations are required for cloud services provider personnel as follows—

(1) Moderate risk law enforcement and high impact public trust level—a reinvestigation is required during the 5th year; and

(2) There is no reinvestigation for other moderate risk positions or any low risk positions.

1239.7204 Contract clauses.

(a) The contracting officer shall insert the clause at 1252.239–76, Cloud Computing Services, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(b) The contracting officer shall insert a clause substantially as follows at 1252.239–77, Data Jurisdiction, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(c) The contracting officer shall insert a clause substantially as follows at 1252.239–78, Validated Cryptography for Secure Communications, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(d) The contracting officer shall insert a clause substantially as follows at 1252.239–79, Authentication, Data Integrity, and Non-Repudiation, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(e) The contracting officer shall insert a clause substantially as follows at 1252.239–80, Audit Record Retention for Cloud Service Providers, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(f) The contracting officer shall insert a clause substantially as follows at 1252.239–81, Cloud Identification and Authentication (Organizational Users) Multi-Factor Authentication, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(g) The contracting officer shall insert a clause substantially as follows at 1252.239–82, Identification and Authentication (Non-Organizational Users), in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(h) The contracting officer shall insert a clause substantially as follows at

1252.239–83, Incident Reporting Timeframes, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(i) The contracting officer shall insert a clause substantially as follows at 1252.239–84, Media Transport, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(j) The contracting officer shall insert a clause substantially as follows at 1252.239–85, Personnel Screening—Background Investigations, in all services solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(k) The contracting officer shall insert a clause substantially as follows at 1252.239–86, Boundary Protection—Trusted Internet Connections, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(l) The contracting officer shall insert a clause substantially as follows at 1252.239–87, Protection of Information at Rest, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

(m) The contracting officer shall insert a clause substantially as follows at 1252.239–88, Security Alerts, Advisories, and Directives, in solicitations and contracts, including those using FAR part 12 procedures for the acquisition of commercial products and commercial services, for information technology services involving cloud computing services.

Subpart 1239.73—Technology Modernization and Upgrades/Refreshment

1239.7300 Scope of subpart.

This subpart prescribes policies and procedures for incorporating technology modernization, upgrades, and refreshment into acquisitions involving information technology products or services supporting the development of applications, information systems, or system software.

1239.7301 Definitions.

As used in this subpart—

Application means the software that resides above system software and includes applications such as database programs, word processors and spreadsheets. Application software may be bundled with system software or published alone.

Modernization means the conversion, rewriting or porting of a legacy system to a modern computer programming language, software libraries, protocols, or hardware platform.

Refresh means the periodic replacement of equipment to ensure continuing reliability of equipment and/or improved speed and capacity.

System software means a platform composed of operating system programs and services, including settings and preferences, file libraries and functions used for system applications. System software also includes device drivers that run basic computer hardware and peripherals.

Upgrade means an updated version of existing hardware, software or firmware. The purpose of an upgrade is improved and updated product features, including performance, product life, usefulness and convenience.

1239.7302 Policy.

Contracting officers will ensure all documents involving the acquisition of development or maintenance of DOT applications, systems, infrastructure, and services contain the appropriate clauses as may be required by the Federal Acquisition Regulation (FAR) and other Federal authorities, in order to ensure that information system modernization is prioritized accordance with Federal law, OMB Guidance, and DOT policy.

1239.7303 Contract clauses.

(a) The contracting officer shall insert the clause at 1252.239–89, Technology Modernization, in solicitations and contracts when the contractor or a subcontractor, at any tier, proposes a modernization approach to develop or maintain information systems, applications, infrastructure, or services.

(b) The contracting officer shall insert the clause at 1252.239–90, Technology Upgrades/Refreshment, in solicitations and contracts when the contractor or a subcontractor at any tier, proposes technology improvements (upgrades/refreshments) to develop or maintain information systems, applications, infrastructure, or services.

Subpart 1239.74—Records Management

1239.7400 Scope of subpart.

This subpart prescribes policies for records management requirements for contractors who create, work with, or otherwise handle Federal records, regardless of the medium in which the records exist.

1239.7401 Definition.

As used in this subpart—

Federal record, as defined in 44 U.S.C. 3301, means all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them. The term Federal record:

(1) Includes all DOT records.

(2) Does not include personal materials.

(3) Applies to records created, received, or maintained by contractors pursuant to a DOT contract.

(4) May include deliverables and documentation associated with deliverables.

1239.7402 Policy.

(a) *Requirements*—(1) *Compliance.* Contractors shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to 44 U.S.C. chapters 21, 29, 31, and 33, NARA regulations at 36 CFR chapter XII, subchapter B, and those policies associated with the safeguarding of records covered by Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.

(2) *Applicability.* In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended, and the Privacy Act of 1974 (5 U.S.C. 552a), as amended, and must be managed and scheduled for disposition only as permitted by relevant records management laws and regulations and DOT Order 1351.28,

Departmental Records Management Policy.

(3) *Records maintenance.* While DOT records are in a contractor's custody, the contractor is responsible for preventing the alienation or unauthorized destruction of the DOT records, including all forms of mutilation. Records may not be removed from the legal custody of DOT or destroyed except in accordance with the provisions of the agency records schedules and with the written concurrence of the DOT or Component Records Officer, as appropriate. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, the contractor must report the event to the contracting officer, in accordance with 36 CFR part 1230, for reporting to NARA.

(4) *Unauthorized disclosure.* Contractors shall notify the contracting officer within two hours of discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Contractors shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of the information, data, documentary material, records and/or equipment accessed, maintained, or created. Contractors shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the contracting officer or contracting officer's representative. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to DOT control or the contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the contracting officer or address prescribed in the contract. Destruction of records is expressly prohibited unless authorized.

(b) *Non-public information.* Contractors shall not create or maintain any records containing any non-public DOT information that are not specifically tied to or authorized by the contract.

1239.7403 Contract clause.

The contracting officer shall insert the clause at 1239.239–91, Records Management, in all solicitations and contracts involving services where contractors or subcontractors and their employees or associates collect, access, maintain, use, disseminate, or otherwise handle Federal records.

PART 1241 [RESERVED]

Subchapter G—Contract Management

PART 1242—CONTRACT ADMINISTRATION AND AUDIT SERVICES

Subpart 1242.1—Contract Audit Services

Sec.

Subpart 1242.2—Contract Administration Services

Subpart 1242.3—Contract Administration Office Functions

Subpart 1242.15—Contractor Performance Information

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1242.1—Contract Audit Services

1242.101 Contract audit responsibilities.

(b) It is DOT policy that private certified public accounting (CPA) firms may be used to provide audit services as described in FAR 42.101 to DOT contracting officers when procurement schedule demands cannot be met by the Defense Contract Audit Agency (DCAA) or the agency with audit cognizance.

1242.102 Assignment of contract audit services.

(b) In accordance with 1242.101, when the responsible audit agency declines a request for services, DOT contracting officers may utilize audit services from commercial CPA firms as authorized in 1242.101.

1242.170 Contract clause.

The contracting officer shall insert the clause at 1252.242–74, Contract Audit Support, in solicitation and contracts when other than firm-fixed-price contracts are contemplated.

Subpart 1242.2—Contract Administration Services

1242.270 Contract clauses.

(a) The contracting officer may use the clause at 1252.242–70, Dissemination of Information–Educational Institutions, in lieu of the clause at 1252.242–72, Dissemination of Contract Information, in DOT research contracts with educational institutions, except contracts that require the release or coordination of information.

(b) The contracting officer shall insert the clause at 1252.242–71, Contractor Testimony, in all solicitations and contracts issued by NHTSA. Other OAs may use the clause as deemed appropriate.

(c) The contracting officer may insert the clause at 1252.242–72, Dissemination of Contract Information, in all DOT contracts except contracts that require the release or coordination of information.

Subpart 1242.3—Contract Administration Office Functions

1242.302 Contract administration functions.

(a) If a cognizant Federal agency has not performed the functions identified in FAR 42.302(a)(5), (9), (11), and (12), then DOT contracting officers are authorized to perform these functions with the assistance of the cognizant government auditing agency, if assigned and available to provide support in a timely manner. If the cognizant government auditing agency is not assigned and/or available in the necessary timeframe, DOT contracting officers may use the audit services of a CPA firm.

(13) The assignment of contract administration to a Defense Contract Management Agency (DCMA) office by the contracting officer does not affect the designation of the paying office unless a transfer of DOT funds to the agency of the Contract Administration Office (CAO) is effected, and the funds are converted to the CAO agency's account for payment purposes. When the contracting officer proposes to delegate the contract payment function to another agency (*e.g.,* DCMA), the contracting officer shall discuss the transfer of funds procedures with the cognizant OA payment office. The CAO, the contracting officer, or the designated contract specialist in the contracting office shall review and approve the invoices and vouchers under the assigned contracts. The review and approval of invoices under cost-reimbursement and time-and-materials type contracts cannot be delegated to the Contracting Officer's Representative.

Subpart 1242.15—Contractor Performance Information

1242.1503 Procedures.

(a)(1) Each OA is responsible for assigning responsibility and management accountability for the

completeness of past performance submissions as required in FAR 42.1503(a).

PART 1245 [RESERVED]

PART 1246—QUALITY ASSURANCE

Subpart 1246.1—General

Subpart 1246.7—Warranties

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1246.1—General

1246.101 Definitions.

1246.101–70 Additional definitions.

As used in this subpart—

At no additional cost to the Government means at no increase in price for firm-fixed-price contracts, at no increase in target or ceiling price for fixed price incentive contracts (*see* FAR 46.707), or at no increase in estimated cost or fee for cost-reimbursement contracts.

Defect means any condition or characteristic in any supplies or services furnished by the contractor under the contract that is not in compliance with the requirements of the contract.

Major acquisition means an acquisition or for supplies or services that requires submission of an OMB Exhibit 300 (Capital Asset Plan/Business Case) in accordance with OMB Circular A–11, Preparation, Submission and Execution of the Budget, and for information technology or information technology related acquisitions, compliance with the Department Chief Information Officer (CIO) Policy (CIOP). A major acquisition typically has one or more of the following characteristics—

(1) Life-cycle costs of $150 million or more;

(2) Is a financial system, e-gov system, or e-business system with a life-cycle cost of $500,000 or more; or

(3) An acquisition that does not meet the dollar thresholds of paragraph (1) or (2) of this definition but—

(i) Is mission-critical;

(ii) Requires special management attention because of its importance to an OA mission;

(iii) Plays a significant role in the administration of OA programs, processes or other resources; or

(iv) Directly supports the President's Management Agenda.

Performance requirements means the operating capabilities, maintenance, and reliability characteristics of a system that are determined to be necessary for it to fulfill the requirement for which the system is designed.

Subpart 1246.7—Warranties

1246.705–70 Limitations—restrictions.

The following restrictions are applicable to DOT contracts:

(a) The contractor shall not be required to honor the warranty on any property furnished by the Government except for—

(1) Defects in installation; and

(2) Installation or modification in such a manner that invalidates a warranty provided by the manufacturer of the property.

(b) Any warranty obtained shall specifically exclude coverage of damage in time of war (combat damage) or national emergency.

(c) Contracting officers shall not include in a warranty clause any terms that require the contractor to incur liability for loss, damage, or injury to third parties.

1246.706–70 Warranty terms and conditions—requirements.

(a) When appropriate and cost effective, the contracting officer shall comply with the following requirements when developing the warranty terms and conditions—

(1) Identify the affected line item(s) and the applicable specification(s);

(2) Require that the line item's design and manufacture will conform to—

(i) An identified revision of a top-level drawing; and/or

(ii) An identified specification or revision thereof;

(3) Require that the line item conform to the specified Government performance requirements;

(4) Require that all line items and components delivered under the contract will be free from defects in materials and workmanship;

(5) State that if the contractor fails to comply with specification or there are defects in material and workmanship, the contractor will bear the cost of all work necessary to achieve the specified performance requirements, including repair and/or replacement of all parts;

(6) Require the timely replacement/repair of warranted items and specify lead times for replacement/repair where possible;

(7) Identify the specific paragraphs containing Government performance requirements that the contractor must meet;

(8) Ensure that any performance requirements identified as goals or objectives beyond specification requirements are excluded from the warranty provision;

(9) Specify what constitutes the start of the warranty period (*e.g.,* delivery, acceptance, in-service date) and the end of the warranty period (*e.g.,* passing a test or demonstration, or operation without failure for a specified period), and specify circumstances requiring an extension of warranty duration (*e.g.,* extending the warranty period as a result of mass defect correction during warranty period);

(10) Identify what transportation costs will be paid by the contractor in relation to the warranty coverage;

(11) In addition to combat damage, identify any conditions which will not be covered by the warranty; and

(12) Identify any limitation on the total dollar amount of the contractor's warranty exposure, or agreement to share costs after a certain dollar threshold to avoid unnecessary warranty returns.

(b) In addition to the terms and conditions listed in paragraph (a) of this section, the contracting officer shall consider the following when a warranty clause is being used for a major system, as defined in FAR 2.101:

(1) For line items or components that are commercially available, obtaining a warranty as is normally provided by the manufacturer or supplier, in accordance with FAR 46.703(d) and 46.710(b)(2).

(2) Obtaining a warranty of compliance with the stated requirements for line items or components provided in accordance with either design and manufacturing or performance requirements as specified in the contract or any modification to that contract.

(3) A warranty provided under paragraph (b)(2) of this section shall provide that in the event the line items or any components thereof fails to meet the terms of the warranty provided, the contracting officer may—

(i) Require the contractor to promptly take such corrective action as the contracting officer determines to be necessary at no additional cost to the Government, including repairing or replacing all parts necessary to achieve the requirements set forth in the contract;

(ii) Require the contractor to pay costs reasonably incurred by the United States in taking necessary corrective action; or

(iii) Equitably reduce the contract price.

(4) Inserting remedies, exclusions, limitations and durations, provided these are consistent with the specific

requirements of this subpart and FAR 46.706.

(5) Excluding from the terms of the warranty certain defects for specified supplies (exclusions) and limiting the contractor's liability under the terms of the warranty (limitations), as appropriate, if necessary to derive a cost-effective warranty considering the technical risk, contractor financial risk, or other program uncertainties.

(6) Structuring of a broader and more comprehensive warranty where such is advantageous. Likewise, the contracting officer may narrow the scope of a warranty when appropriate (*e.g.,* where it would be inequitable to require a warranty of all performance requirements because a contractor had not designed the system).

(c) Any contract that contains a warranty clause must contain warranty implementation procedures, including warranty notification content and procedures, and identify the individuals responsible for implementation of warranty provisions. The contract may also permit the contractor's participation in investigation of system failures, if the contractor is reimbursed at established rates for fault isolation work, and that the Government receive credit for any payments where equipment failure is covered by warranty provisions.

PART 1247—TRANSPORTATION

Subpart 1247.5—Ocean Transportation by U.S.-Flag Vessels

Sec.

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1247.5—Ocean Transportation by U.S.-Flag Vessels

1247.506 Procedures.

(a) The Maritime Administration (MARAD) is the enforcing agency of the cargo preference statutes. MARAD can assist contractors in locating U.S.-flag carriers and determine when such services are not available. MARAD can also assist contracting officers in evaluating costs, services, and other matters regarding ocean transportation.

(d) If no transportation officer is available, the contracting officer shall submit a copy of the rated ''on board'' bill of lading, for each shipment, no later than 20 days after the vessel's loading date for exports and 30 days for imports as stated in 46 CFR 381.3. All non-vessel ocean common carrier bills of lading should be accompanied by the underlying carrier's ocean bill of lading. The documents shall be sent to the Maritime Administration, Office of Cargo and Commercial Sealift, MAR–620, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. The bill of lading shall contain the following information—

(1) Name of sponsoring Government agency or department;

(2) Name of vessel;

(3) Vessel flag of registry;

(4) Date of loading;

(5) Port of loading;

(6) Port of final discharge;

(7) Commodity description;

(8) Gross weight in kilos; and

(9) Total ocean freight revenue in U.S. dollars.

Subchapter H—Clauses and Forms

PART 1252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart 1252.1—Instructions for Using Provisions and Clauses

Sec.

Subpart 1252.2—Text of Provisions and Clauses

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1252.1—Instructions for Using Provisions and Clauses

1252.101–70 Using this part.

TAR provisions or clauses that supplement the FAR shall follow the following numbering conventions in accordance with FAR 52.101(b)(2)(i):

(a) Agency-prescribed provisions and clauses permitted by TAR and used on a standard basis (*i.e.,* normally used in two or more solicitations or contracts regardless of contract type) shall be prescribed and contained in the TAR. Operating Administrations (OAs) desiring to use a provision or a clause on a standard basis shall submit a request containing a copy of the clause(s), justification for its use, and evidence of legal counsel review to the Office of the Senior Procurement Executive in accordance with 1201.304 for possible inclusion in the TAR (*see* FAR 52.101(b)(2)(i)(A)).

(b) Provisions and clauses used on a one-time basis (*i.e.,* non-standard provisions and clauses) may be approved by the contracting officer, unless a higher level is designated by the OA (*see* FAR 52.101(b)(2)(i)(C)). This authority is permitted subject to—

(1) Evidence of legal counsel review in the contract file;

(2) Inserting these clauses in the appropriate sections of the uniform contract format; and

(3) Ensuring the provisions and clauses do not deviate from the requirements of the FAR and TAR.

Subpart 1252.2—Text of Provisions and Clauses

1252.201–70 Contracting Officer's Representative.

As prescribed in 1201.604–70, insert the following clause:

Contracting Officer's Representative (NOV 2022)

(a) The Contracting Officer may designate Government personnel to act as the Contracting Officer's Representative (COR) to perform functions under the contract such as review and/or inspection and acceptance of supplies, services, including construction, and other functions of a technical nature. The Contracting Officer will provide a written notice of such designation to the Contractor within five working days after contract award or for construction, not less than five working days prior to giving the contractor the notice to proceed. The designation letter will set forth the authorities and limitations of the COR under the contract.

(b) The Contracting Officer cannot authorize the COR or any other representative to sign documents (*i.e.,* contracts, contract modifications, etc.) that require the signature of the Contracting Officer.

(End of clause)

1252.204–70 Contractor Personnel Security and Agency Access.

As prescribed in 1204.1303, insert the following clause:

Contractor Personnel Security and Agency Access (NOV 2022)

(a) *Definitions.* As used in this clause—

Agency access means access to DOT facilities, sensitive information, information systems or other DOT resources.

Applicant means a contractor employee for whom the Contractor applies for a DOT identification card.

Contractor employee means a prime contractor and subcontractor employee who requires agency access to perform work under a DOT contract.

Identification card (or ''ID card'') means a government issued or accepted identification card such as a Personal Identity Verification (PIV) card, a PIV-Interoperable (PIV–I) card from an authorized PIV–1 issuer, or a non-PIV card issued by DOT, or a nonPIV card issued by another Federal agency and approved by DOT. PIV and PIV–1 cards have physical and electronic attributes that other (non-PIV) ID cards do not have.

Issuing office means the DOT entity that issues identification cards to contractor employees.

Local security servicing organization means the DOT entity that provides security services to the DOT organization sponsoring the contract.

(b) *Risk and sensitivity level designations.* For contracts requiring access to DOT facilities, sensitive information, information systems or other DOT resources, contractor employees will be required to complete background investigations, identity proofing, and government identification card application procedures to determine suitability for access. DOT will assign a risk and sensitivity level designation to the overall contract and/or to contractor employee positions by category, group or individual. The risk and sensitivity level designations will be the basis for determining the level of personnel security processing required for contractor employees. The following risk and sensitivity level designations and associated level of processing are required, and each level includes the prior levels—

(1) Low risk level: National Agency Check with Written Inquiries (NACI);

(2) Moderate risk level: Minimum Background Investigation (MBI); and

(3) High risk level: Background Investigation.

(c) *Security clearances.* Contractor employees may also be required to obtain security clearances (*i.e.,* Confidential, Secret, or Top Secret). National Security work designated ''special sensitive,'' ''critical sensitive,'' or ''non-critical sensitive,'' will determine the level of clearance required for contractor employees. Personnel security clearances for national security contracts in DOT will be processed according to the Department of Defense National Industrial Security Program Operating Manual (NISPOM).

(d) *Pre-screening of contractor employees.* The Contractor must pre-screen individuals designated for employment under any DOT contract by verifying minimal suitability requirements to ensure that only candidates that appear to meet such requirements are considered for contract employment, and to mitigate the burden on the Government of conducting background investigations on objectionable applicants. The Contractor must exercise due diligence in pre-screening all employees prior to submission to DOT for agency access. DOT may decline to grant agency access to a contractor employee for reasons including, but not limited to—

(1) Conviction of a felony, a crime of violence, or a misdemeanor involving moral turpitude;

(2) Falsification of information entered on forms or of other documents submitted;

(3) Improper conduct including criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct or other conduct adverse to the Government regardless of whether the conduct is directly related to the contract; and

(4) Any behavior judged to pose a potential threat to DOT facilities, sensitive information, information systems or other resources.

(e) *Citizenship status.* The Contractor must monitor a non-citizen's continued authorization for employment in the United States. The Contractor must provide documentation to the Contracting Officer or the Contracting Officer's Representative (COR) during the background investigation process that validates that the E-Verify requirement has been met for each contractor employee.

(f) *Background investigation and adjudication.* A contractor employee must have a favorable adjudication of background investigation before DOT will issue an ID card to the contractor employee granting access to DOT facilities, sensitive information, information systems or other DOT resources. DOT may accept favorable adjudications of background investigations from other Federal agencies when applicants have held PIV cards issued by those agencies with no break in service. DOT may also accept PIV–I (Interoperable) cards issued by an authorized PIV–1 issuer as evidence of identity. A favorable adjudication does not preclude DOT from initiating a new investigation when deemed necessary. At a minimum, the FBI National Criminal History Check (fingerprint check) must be favorably completed before a DOT identification card can be issued. Each Contractor must use the Office of Personnel Management's (OPM) e-QIP system to complete any required investigative forms. Instructions for obtaining fingerprints will be provided by the COR or Contracting Officer. The DOT Office of

Security, M–40, or a DOT organization delegated authority by M–40, is responsible for adjudicating the suitability of contractor employees.

(g) *Agency access denied.* Upon contract award, DOT will initiate the agency access procedure for all contractor employees requiring access to DOT facilities, sensitive information, information systems and other DOT resources for contract performance. DOT may deny agency access to any individual about whom an adverse suitability determination is made. Failure to submit the required security information or to truthfully answer all questions shall constitute grounds for denial of access. The Contractor must not provide agency access to contractor employees until the COR or Contracting Officer provides notice of approval, which is authorized only by the DOT Office of Security (M–40) or a DOT organization delegated authority by M–40. Where a proposed contractor employee is denied agency access by the Government or, if for any reason a proposed application is withdrawn by the Contractor during the agency access process, the additional costs and administrative burden for conducting additional background investigations caused by a lack of effective prescreening or planning on the part of the Contractor may be considered as part of the Contractor's overall performance evaluation.

(h) *Identification card application process.* The COR will be the DOT ID card Sponsor and point of contact for the Contractor's application for a DOT ID card. The COR shall review and approve the DOT ID card application before an ID card is issued to the applicant. An applicant may be issued either a Personal Identity Verification (PIV) card that meets the standards of Homeland Presidential Security Directive (HSPD–12), or an applicant may be issued a non-PIV card. Generally, a non-PIV card will be issued for contracts that expire in six months or less, including option periods. The COR may request the issuing office to waive the six-month eligibility requirement when it is in DOT's interest for contract performance. The following applies—

(1) PIV card. The applicant must complete a DOT on-line application for a PIV card;

(2) Non-PIV card. The applicant must complete and submit a hard copy of Form 1681 to the COR/Sponsor; and

(3) Regardless of the type of card to be issued (PIV or non-PIV), the applicant must appear in person to provide two forms of identity source documents in original form to DOT. The identity source documents must come from the list of acceptable documents included in Form F–9, OMB No. 1115–0136, Employment Eligibility Verification. At least one document must be a valid State or Federal government-issued picture identification. For a PIV card, the applicant may be required to appear in-person a second time for enrollment and activation.

(i) *Identification card custody and control.* The Contractor is responsible for the custody and control of all forms of government identification issued by DOT to contractor employees for access to DOT facilities, sensitive information, information systems and other DOT resources. The Contractor shall:

(1) Provide a listing of personnel for whom an identification (ID) card is requested to the COR or PM who will provide a copy of the listing to the card issuing office. This may include Contractor and subcontractor personnel. Follow issuing office directions for submittal of an application package(s).

(2) While visiting or performing work on a DOT facility, as specified by the issuing office, PM or COR, ensure that contractor employees prominently display their ID card.

(3) Immediately notify the COR or, if the COR is unavailable, the Contracting Officer when a contractor employee's status changes and no longer requires agency access (*e.g.,* employee's transfer, completion of a project, retirement, removal from work on the contract, or termination of employment) that may affect the employee's eligibility for access to the facility, sensitive information, or resources.

(4) Promptly deliver to the issuing office: (a) all ID cards assigned to an employee who no longer requires access to the facility; and (b) all expired ID cards within five (5) days of their expiration or all cards at time of contract termination, whichever occurs first.

(5) Immediately report any lost or stolen ID cards to the issuing office and follow its instructions.

(i) The Contractor is responsible for maintaining and safeguarding the DOT ID card upon issuance to the contractor employee. The Contractor must ensure that contractor employees comply with DOT requirements concerning the renewal, loss, theft, or damage of an ID card. The Contractor must immediately notify the COR or, if the COR is unavailable, the Contracting Officer when an ID card is lost, stolen or damaged.

(ii) Failure to comply with the requirements for custody and control of DOT ID cards may result in withholding final payment or contract termination based on the potential for serious harm caused by inappropriate access to DOT facilities, sensitive information, information systems or other DOT resources.

(iii) Specific actions and activities are required in certain events—

(A) *Renewal.* A contractor employee's DOT issued ID card is valid for a maximum of three years or until the contract expiration date (including option periods), whichever occurs first. The renewal process should begin six weeks before the PIV card expiration date. If a PIV card is not renewed before it expires, the contractor employee will be required to sign-in daily for facility access and may have limited access to information systems and other resources.

(B) *Lost/stolen.* Immediately upon detection, the Contractor or contractor employee must report a lost or stolen DOT ID card to the COR, or if the COR is unavailable, the Contracting Officer, the issuing office, or the local servicing security organization. The Contractor must submit an incident report within 48 hours, through the COR or, if the COR is unavailable, the Contracting Officer, the issuing office, or the local security servicing organization describing the circumstances of the loss or theft. The Contractor must also report a lost or stolen PIV card through the DOT on-line registration system. If the loss or theft is reported by the Contractor to the local police, a copy of the police report must be provided to the COR or Contracting Officer. From the date of notification to DOT, the Contractor must wait three days before getting a replacement ID card. During the 3-day wait period, the contractor employee must sign in daily for facility access.

(C) *Replacement.* An ID card will be replaced if it is damaged, contains incorrect data, or is lost or stolen for more than 3 days, provided there is a continuing need for agency access to perform work under the contract.

(D) *Surrender of ID cards.* Upon notification that routine access to DOT facilities, sensitive information, information systems or other DOT resources is no longer required, the Contractor must surrender the DOT issued ID card to the COR, or if the COR is unavailable, the Contracting Officer, the issuing office, or the local security servicing organization in accordance with agency procedures.

(j) *Flow down of clause.* The Contractor is required to include this clause in any subcontracts at any tier that require the subcontractor or subcontractor's employees to have access to DOT facilities, sensitive information, information systems or other resources.

(End of clause)

1252.209–70 Organizational and Consultant Conflicts of Interest.

As prescribed in 1209.507–270(a), the contracting officer shall insert a clause substantially as follows in solicitations and contracts:

Organizational and Consultant Conflicts of Interest (NOV 2022)

(a) An offeror shall identify in its proposal, quote, bid or any resulting contract, any potential or actual Organizational and Consultant Conflicts of Interest (OCCI) as described in FAR subpart 9.5. This includes actual or potential conflicts of interests of proposed subcontractors. If an offeror identifies in its proposal, quote, bid or any resulting contract, a potential or actual conflict of interests the offeror shall submit an Organizational and Consultant Conflicts of Interest Plan (OCCIP) to the contracting officer. The OCCIP shall describe how the offeror addresses potential or actual conflicts of interest and identify how they will avoid, neutralize, or mitigate present or future conflicts of interest.

(b) Offerors must consider whether their involvement and participation raises any OCCI issues, especially in the following areas when:

(1) Providing systems engineering and technical direction.

(2) Preparing specifications or work statements and/or objectives.

(3) Providing evaluation services.

(4) Obtaining access to proprietary information.

(c) If a prime contractor or subcontractor breaches any of the OCCI restrictions, or does not disclose or misrepresents any relevant facts concerning its conflict of interest, the government may take appropriate action,

including terminating the contract, in additional to any remedies that may be otherwise permitted by the contract or operation of law.

(End of clause)

1252.209–71 Limitation of Future Contracting.

As prescribed in 1209.507–270(b), the contracting officer shall insert a clause substantially as follows in solicitations and contracts:

Limitation of Future Contracting (NOV 2022)

(a) The Contracting Officer has determined that this acquisition may give rise to a potential organizational conflict of interest. Accordingly, prospective offerors are encouraged to review FAR subpart 9.5—Organizational Conflicts of Interest.

(b) The nature of this conflict is [*describe the conflict*].

(c) The restrictions upon future contracting are as follows:

(1) If the Contractor, under the terms of this contract, or through the performance of tasks pursuant to this contract, is required to develop specifications or statements of work that are to be incorporated into a solicitation, the Contractor shall be ineligible to perform the work described in that solicitation as a prime or first-tier subcontractor under an ensuing government contract. This restriction shall remain in effect for a reasonable time, as agreed to by the Contracting Officer and the Contractor, sufficient to avoid unfair competitive advantage or potential bias (this time shall in no case be less than the duration of the initial ensuing contract).

(2) To the extent that the work under this contract requires access to proprietary, business confidential, or financial data of other companies, and if these data remain proprietary or confidential, the Contractor shall protect such data from unauthorized use and disclosure and agrees not to use the data to compete with those other companies.

(End of clause)

1252.211–70 Index for Specifications.

As prescribed in 1211.204–70, insert the following clause:

Index for Specifications (NOV 2022)

If an index or table of contents is furnished in connection with specifications, such index or table of contents is for convenience only. Its accuracy and completeness is not guaranteed, and it is not a part of the specification. In case of discrepancy between the index or table of contents and the specifications, the specifications shall govern.

(End of clause)

1252.216–70 Evaluation of Offers Subject to an Economic Price Adjustment Clause.

As prescribed in 1216.203–470, insert the following provision:

Evaluation of Offers Subject to an Economic Price Adjustment Clause (NOV 2022)

Offers shall be evaluated without an amount for an economic price adjustment being added. Offers will be rejected that—(1) increase the ceiling stipulated; (2) limit the downward adjustment; or (3) delete the economic price adjustment clause. If the offer stipulates a ceiling lower than that included in the solicitation, the lower ceiling will be incorporated into any resulting contract.

(End of provision)

1252.216–71 Determination of Award Fee.

As prescribed in 1216.406–70(a), insert the following clause:

Determination of Award Fee (NOV 2022)

(a) The Government shall evaluate Contractor performance at the end of each specified evaluation period to determine the amount of award. The contractor agrees that the amount of award and the award fee determination methodology are unilateral decisions to be made at the sole discretion of the Government.

(b) Contractor performance shall be evaluated according to the Award Fee Plan. The Contractor shall be periodically informed of the quality of its performance and areas in which improvements are expected.

(c) The contractor shall be promptly advised, in writing, of the determination and reasons why the award fee was or was not earned. The Contractor may submit a performance self-evaluation for each evaluation period. The amount of award is at the sole discretion of the Government but any self-evaluation received within_____(*insert number*) days after the end of the current evaluation period will be given such consideration, as may be deemed appropriate by the Government.

(d) The amount of award fee that can be awarded in each evaluation period is limited to the amounts set forth at_____(*identify location of award fee amounts*). Award fee that is not earned in an evaluation period cannot be reallocated to future evaluation periods.

(End of clause)

1252.216–72 Award Fee Plan.

As prescribed in 1216.406–70(b), insert the following clause:

Award Fee Plan (NOV 2022)

(a) An Award Fee Plan shall be unilaterally established by the Government based on the criteria stated in the contract and used for the determination of award fee. This plan shall include the criteria used to evaluate each area and the percentage of award fee, if any, available for each area. A copy of the plan shall be provided to the Contractor_____(*insert number*) calendar days prior to the start of the first evaluation period.

(b) The criteria contained within the Award Fee Plan may relate to: (1) Technical (including schedule) requirements, if appropriate; (2) Management; and (3) Cost.

(c) The Award Fee Plan may, consistent with the contract, be revised unilaterally by the Government at any time during the period of performance. Notification of such changes shall be provided to the Contractor_____(*insert number*) calendar days prior to the start of the evaluation period to which the change will apply.

(End of clause)

1252.216–73 Distribution of Award Fee.

As prescribed in 1216.406–70(c), insert the following clause:

Distribution of Award Fee (NOV 2022)

(a) The total amount of award fee available under this contract is assigned according to the following evaluation periods and amounts—

Evaluation Period:

Available Award Fee:

[*Contracting Officer insert appropriate information*]

(b) After the Contractor has been paid 85 percent of the base fee and potential award fee, the Government may withhold further payment of the base fee and award fee until a reserve is set aside in an amount that the Government considers necessary to protect its interest. This reserve shall not exceed 15 percent of the total base fee and potential award fee or $150,000, whichever is less. Thereafter, base fee and award fee payments may continue.

(c) In the event of contract termination, either in whole or in part, the amount of award fee available shall represent a pro-rata distribution associated with evaluation period activities or events as determined by the Government.

(d) The Government will promptly make payment of any award fee upon the submission by the Contractor to the Contracting Officer's Representative, of a public voucher or invoice in the amount of the total fee earned for the period evaluated. Payment may be made without using a contract modification.

(End of clause)

1252.216–74 Settlement of Letter Contract.

As prescribed in 1216.603–4, insert the following clause:

Settlement of Letter Contract (NOV 2022)

(a) This contract constitutes the definitive contract contemplated by issuance of letter contract_____[*insert number*] dated_____[*insert effective date*]. It supersedes the letter contract and its modification number(s)_____[*insert number(s)*] and, to the extent of any inconsistencies, governs.

(b) The cost(s) and fee(s), or price(s), established in this definitive contract represents full and complete settlement of letter contract_____[*insert number*] and modification number(s)_____[*insert number(s)*]. Payment of the agreed upon fee or profit withheld pending definitization of the letter contract, may commence immediately at the rate and times stated within this contract.

(End of clause)

1252.217–70 Guarantee.

As prescribed at 1217.7001(a), insert the following clause:

Guarantee (NOV 2022)

(a) In the event any work performed or materials furnished by the Contractor prove defective or deficient within 60 days from the date of redelivery of the vessel(s), the Contractor, as directed by the Contracting Officer and at its own expense, shall correct and repair the deficiency in accordance with the contract terms and conditions.

(b) If the Contractor or any subcontractor has a guarantee for work performed or materials furnished that exceeds the 60-day period, the Government shall be entitled to rely upon the longer guarantee until its expiration.

(c) With respect to any individual work item identified as incomplete at the time of redelivery of the vessel(s), the guarantee period shall run from the date the item is completed.

(d) If practicable, the Government shall give the Contractor an opportunity to correct the deficiency.

(1) If the Contracting Officer determines it is not practicable or is otherwise not advisable to return the vessel(s) to the Contractor, or the Contractor fails to proceed with the repairs promptly, the Contracting Officer may direct that the repairs be performed elsewhere, at the Contractor's expense.

(2) If correction and repairs are performed by other than the Contractor, the Contracting Officer may discharge the Contractor's liability by making an equitable deduction in the price of the contract.

(e) The Contractor's liability shall extend for an additional 90-day guarantee period on those defects or deficiencies that the Contractor corrected.

(f) At the option of the Contracting Officer, defects and deficiencies may be left uncorrected. In that event, the Contractor and Contracting Officer shall negotiate an equitable reduction in the contract price. Failure to agree upon an equitable reduction shall constitute a dispute under the Disputes clause of this contract.

(End of clause)

1252.217–71 Delivery and Shifting of Vessel.

As prescribed at 1217.7001(b), insert the following clause:

Delivery and Shifting of Vessel (NOV 2022)

The Government shall deliver the vessel to the Contractor at his place of business. Upon completion of the work, the Government shall accept delivery of the vessel at the Contractor's place of business. The Contractor shall provide, at no additional charge, upon 24 hours' advance notice, a tug or tugs and docking pilot, acceptable to the Contracting Officer, to assist in handling the vessel between (to and from) the Contractor's plant and the nearest point in a waterway regularly navigated by vessels of equal or greater draft and length. While the vessel is in the hands of the Contractor, any necessary towage, cartage, or other transportation between ship and shop or elsewhere, which may be incident to the work herein specified, shall be furnished by the Contractor without additional charge to the Government.

(End of clause)

1252.217–72 Performance.

As prescribed at 1217.7001(b), insert the following clause:

Performance (NOV 2022)

(a) Upon the award of the contract, the Contractor shall promptly start the work specified and shall diligently prosecute the work to completion. The Contractor shall not start work until the contract has been awarded except in the case of emergency work ordered by the Contracting Officer in writing.

(b) The Government shall deliver the vessel described in the contract at the time and location specified in the contract. Upon completion of the work, the Government shall accept delivery of the vessel at the time and location specified in the contract.

(c) The Contractor shall without charge—

(1) Make available to personnel of the vessel while in dry dock or on a marine railway, sanitary lavatory and similar facilities at the plant acceptable to the Contracting Officer;

(2) Supply and maintain suitable brows and gangways from the pier, dry dock, or marine railway to the vessel;

(3) Treat salvage, scrap or other ship's material of the Government resulting from performance of the work as items of Government-furnished property, in accordance with clause 52.245–1, Government Property;

(4) Perform, or pay the cost of, any repair, reconditioning or replacement made necessary as the result of the use by the Contractor of any of the vessel's machinery, equipment or fittings, including, but not limited to, winches, pumps, rigging, or pipe lines; and

(5) Furnish suitable offices, office equipment and telephones at or near the site of the work for the Government's use.

(d) The contract will state whether dock and sea trials are required to determine whether the Contractor has satisfactorily performed the work.

(1) If dock and sea trials are required, the vessel shall be under the control of the vessel's commander and crew.

(2) The Contractor shall not conduct dock and sea trials not specified in the contract without advance approval of the Contracting Officer. Dock and sea trials not specified in the contract shall be at the Contractor's expense and risk.

(3) The Contractor shall provide and install all fittings and appliances necessary for dock and sea trials. The Contractor shall be responsible for care, installation, and removal of instruments and apparatus furnished by the Government for use in the trials.

(End of clause)

1252.217–73 Inspection and Manner of Doing Work.

As prescribed at 1217.7001(b), insert the following clause:

Inspection and Manner of Doing Work (NOV 2022)

(a) The Contractor shall perform work in accordance with the contract, any drawings and specifications made a part of the job order, and any change or modification issued under the Changes clause.

(b)(1) Except as provided in paragraph (b)(2) of this clause, and unless otherwise specifically provided in the contract, all operational practices of the Contractor and all workmanship, material, equipment, and articles used in the performance of work under this contract shall be in accordance with the best commercial marine practices and the rules and requirements of all appropriate regulatory bodies including, but not limited to the American Bureau of Shipping, the U.S. Coast Guard, and the Institute of Electrical and Electronic Engineers, in effect at the time of Contractor's submission of offer, and shall be intended and approved for marine use.

(2) When Navy specifications are specified in the contract, the Contractor shall follow Navy standards of material and workmanship. The solicitation shall prescribe the Navy standard whenever applicable.

(c) The Government may inspect and test all material and workmanship at any time during the Contractor's performance of the work.

(1) If, prior to delivery, the Government finds any material or workmanship is defective or not in accordance with the contract, in addition to its rights under the Guarantee clause, the Government may reject the defective or nonconforming material or workmanship and require the Contractor to correct or replace it at the Contractor's expense.

(2) If the Contractor fails to proceed promptly with the replacement or correction of the material or workmanship, the Government may replace or correct the defective or nonconforming material or workmanship and charge the Contractor the excess costs incurred.

(3) As specified in the contract, the Contractor shall provide and maintain an inspection system acceptable to the Government.

(4) The Contractor shall maintain complete records of all inspection work and shall make them available to the Government during performance of the contract and for 90 days after the completion of all work required.

(d) The Contractor shall not permit any welder to work on a vessel unless the welder is, at the time of the work, qualified to the standards established by the U.S. Coast Guard, American Bureau of Shipping, or Department of the Navy for the type of welding being performed. Qualifications of a welder shall be as specified in the contract.

(e) The Contractor shall—

(1) Exercise reasonable care to protect the vessel from fire;

(2) Maintain a reasonable system of inspection over activities taking place in the vicinity of the vessel's magazines, fuel oil tanks, or storerooms containing flammable materials.

(3) Maintain a reasonable number of hose lines ready for immediate use on the vessel

at all times while the vessel is berthed alongside the Contractor's pier or in dry dock or on a marine railway;

(4) Unless otherwise provided in the contract, provide sufficient security patrols to reasonably maintain a fire watch for protection of the vessel when it is in the Contractor's custody;

(5) To the extent necessary, clean, wash, and steam out or otherwise make safe, all tanks under alteration or repair.

(6) Furnish the Contracting Officer a ''gas-free'' or ''safe-for-hotwork'' certificate before any hot work is done on a tank;

(7) Treat the contents of any tank as Government property in accordance with clause 52.245–1, Government Property; and

(8) Dispose of the contents of any tank only at the direction, or with the concurrence, of the Contracting Officer.

(9) Be responsible for the proper closing of all openings to the vessel's underwater structure upon which work has been performed. The Contractor additionally must advise the COR of the status of all valve closures and openings for which the Contractor's workers were responsible.

(f) Except as otherwise provided in the contract, when the vessel is in the custody of the Contractor or in dry dock or on a marine railway and the temperature is expected to go as low as 35 Fahrenheit, the Contractor shall take all necessary steps to—

(1) Keep all hose pipe lines, fixtures, traps, tanks, and other receptacles on the vessel from freezing; and

(2) Protect the stern tube and propeller hubs from frost damage.

(g) The Contractor shall, whenever practicable—

(1) Perform the required work in a manner that will not interfere with the berthing and messing of Government personnel attached to the vessel; and

(2) Provide Government personnel attached to the vessel access to the vessel at all times.

(h) Government personnel attached to the vessel shall not interfere with the Contractor's work or workers.

(i)(1) The Government does not guarantee the correctness of the dimensions, sizes, and shapes set forth in any contract, sketches, drawings, plans, or specifications prepared or furnished by the Government, unless the contract requires that the Contractor perform the work prior to any opportunity to inspect.

(2) Except as stated in paragraph (i)(1) of this clause, and other than those parts furnished by the Government, and the Contractor shall be responsible for the correctness of the dimensions, sizes, and shapes of parts furnished under this contract.

(j) The Contractor shall at all times keep the site of the work on the vessel free from accumulation of waste material or rubbish caused by its employees or the work. At the completion of the work, unless the contract specifies otherwise, the Contractor shall remove all rubbish from the site of the work and leave the immediate vicinity of the work area ''broom clean.''

(End of clause)

1252.217–74 Subcontracts.

As prescribed at 1217.7001(b), insert the following clause:

Subcontracts (NOV 2022)

(a) Nothing contained in the contract shall be construed as creating any contractual relationship between any subcontractor and the Government. The divisions or sections of the specifications are not intended to control the Contractor in dividing the work among subcontractors or to limit the work performed by any trade.

(b) The Contractor shall be responsible to the Government for acts and omissions of its own employees, and of subcontractors and their employees. The Contractor shall also be responsible for the coordination of the work of the trades, subcontractors, and material men.

(c) The Contractor shall, without additional expense to the Government, employ specialty subcontractors where required by the specifications.

(d) The Government or its representatives will not undertake to settle any differences between the Contractor and its subcontractors, or any differences between subcontractors.

(End of clause)

1252.217–75 Lay Days.

As prescribed at 1217.7001(c), insert the following clause:

Lay Days (NOV 2022)

(a) Lay day time will be paid by the Government at the Contractor's stipulated bid price for this item of the contract when the vessel remains on the dry dock or marine railway as a result of any change that involves work in addition to that required under the basic contract.

(b) No lay day time shall be paid until all items of the basic contract for which a price was established by the Contractor and for which docking of the vessel was required have been satisfactorily completed and accepted.

(c) Days of hauling out and floating, whatever the hour, shall not be paid as lay day time, and days when no work is performed by the Contractor shall not be paid as lay day time.

(d) Payment of lay day time shall constitute complete compensation for all costs, direct and indirect, to reimburse the Contractor for use of dry dock or marine railway.

(End of clause)

1252.217–76 Liability and Insurance.

As prescribed at 1217.7001(b), insert the following clause:

Liability and Insurance (NOV 2022)

(a) The Contractor shall exercise its best efforts to prevent accidents, injury, or damage to all employees, persons, and property, in and about the work, and to the vessel or part of the vessel upon which work is done.

(b) *Loss or damage to the vessel, materials, or equipment.* (1) Unless otherwise directed or approved in writing by the Contracting Officer, the Contractor shall not carry insurance against any form of loss or damage to the vessel(s) or to the materials or equipment to which the Government has title or which have been furnished by the Government for installation by the Contractor. The Government assumes the risks of loss of and damage to that property.

(2) The Government does not assume any risk with respect to loss or damage compensated for by insurance or otherwise or resulting from risks with respect to which the Contractor has failed to maintain insurance, if available, as required or approved by the Contracting Officer.

(3) The Government does not assume risk of and will not pay for any costs of the following:

(i) Inspection, repair, replacement, or renewal of any defects in the vessel(s) or material and equipment due to—

(A) Defective workmanship performed by the Contractor or its subcontractors;

(B) Defective materials or equipment furnished by the Contractor or its subcontractors; or

(C) Workmanship, materials, or equipment which do not conform to the requirements of the contract, regardless of whether the defect is latent or whether the nonconformance is the result of negligence.

(ii) Loss, damage, liability, or expense caused by, resulting from, or incurred as a consequence of any delay or disruption, willful misconduct or lack of good faith by the Contractor or any of its representatives that have supervision or direction of—

(A) All or substantially all of the Contractor's business; or

(B) All or substantially all of the Contractor's operation at any one plant.

(4) As to any risk that is assumed by the Government, the Government shall be subrogated to any claim, demand or cause of action against third parties that exists in favor of the Contractor. If required by the Contracting Officer, the Contractor shall execute a formal assignment or transfer of the claim, demand, or cause of action.

(5) No party other than the Contractor shall have any right to proceed directly against the Government or join the Government as a codefendant in any action.

(6) Notwithstanding the foregoing, the Contractor shall bear the first $5,000 of loss or damage from each occurrence or incident, the risk of which the Government would have assumed under the provision of this paragraph (b).

(c) *Indemnification.* The Contractor indemnifies the Government and the vessel and its owners against all claims, demands, or causes of action to which the Government, the vessel or its owner(s) might be subject as a result of damage or injury (including death) to the property or person of anyone other than the Government or its employees, or the vessel or its owner, arising in whole or in part from the negligence or other wrongful act of the Contractor, or its agents or employees, or any subcontractor, or its agents or employees.

(1) The Contractor's obligation to indemnify under this paragraph shall not exceed the sum of $300,000 as a consequence of any single occurrence with respect to any one vessel.

(2) The indemnity includes, without limitation, suits, actions, claims, costs, or demands of any kind, resulting from death,

personal injury, or property damage occurring during the period of performance of work on the vessel or within 90 days after redelivery of the vessel. For any claim, etc., made after 90 days, the rights of the parties shall be as determined by other provisions of this contract and by law. The indemnity applies to death occurring after 90 days where the injury was received during the period covered by the indemnity.

(d) *Insurance.* (1) The Contractor shall, at its own expense, obtain and maintain the following insurance—

(i) Casualty, accident, and liability insurance, as approved by the Contracting Officer, insuring the performance of its obligations under paragraph (c) of this clause.

(ii) Workers Compensation Insurance (or its equivalent) covering the employees engaged on the work.

(2) The Contractor shall ensure that all subcontractors engaged on the work obtain and maintain the insurance required in paragraph (d)(1) of this clause.

(3) Upon request of the Contracting Officer, the Contractor shall provide evidence of the insurance required by paragraph (d) of this clause.

(e) The Contractor shall not make any allowance in the contract price for the inclusion of any premium expense or charge for any reserve made on account of self-insurance for coverage against any risk assumed by the Government under this clause.

(f) The Contractor shall give the Contracting Officer written notice as soon as practicable after the occurrence of a loss or damage for which the Government has assumed the risk.

(1) The notice shall contain full details of the loss or damage.

(2) If a claim or suit is later filed against the Contractor as a result of the event, the Contractor shall immediately deliver to the Government every demand, notice, summons, or other process received by the Contractor or its employees or representatives.

(3) The Contractor shall cooperate with the Government and, upon request, shall assist in effecting settlements, securing and giving evidence, obtaining the attendance of witnesses, and the conduct of suits. The Government shall reimburse the Contractor for expenses incurred in this effort, other than the cost of maintaining the Contractor's usual organization.

(4) The Contractor shall not, except at its own expense, voluntarily make any payments, assume any obligation, or incur any expense other than what would be imperative for the protection of the vessel(s) at the time of the event.

(g) In the event of loss of or damage to any vessel(s), material, or equipment which may result in a claim against the Government under the insurance provisions of this contract, the Contractor shall promptly notify the Contracting Officer of the loss or damage. The Contracting Officer may, without prejudice to any right of the Government, either—

(1) Order the Contractor to proceed with replacement or repair, in which event the Contractor shall effect the replacement or repair;

(i) The Contractor shall submit to the Contracting Officer a request for reimbursement of the cost of the replacement or repair together with whatever supporting documentation the Contracting Officer may reasonably require, and shall identify the request as being submitted under the Insurance clause of this contract.

(ii) If the Government determines that the risk of the loss or damage is within the scope of the risks assumed by the Government under this clause, the Government will reimburse the Contractor for the reasonable allowable cost of the replacement or repair, plus a reasonable profit (if the work or replacement or repair was performed by the Contractor) less the deductible amount specified in paragraph (b) of this clause.

(iii) Payments by the Government to the Contractor under this clause are outside the scope of and shall not affect the pricing structure of the contract, and are additional to the compensation otherwise payable to the Contractor under this contract; or

(2) Decide that the loss or damage shall not be replaced or repaired and in that event, the Contracting Officer shall—

(i) Modify the contract appropriately, consistent with the reduced requirements reflected by the unreplaced or unrepaired loss or damage; or

(ii) Terminate the repair of any part or all of the vessel(s) under the Termination for Convenience of the Government clause of this contract.

(End of clause)

1252.217–77 Title.

As prescribed at 1217.7001(b), insert the following clause:

Title (NOV 2022)

(a) Unless otherwise provided, title to all materials and equipment to be incorporated in a vessel in the performance of this contract shall vest in the Government upon delivery at the location specified for the performance of the work.

(b) Upon completion of the contract, or with the approval of the Contracting Officer during performance of the contract, all Contractor-furnished materials and equipment not incorporated in, or placed on, any vessel, shall become the property of the Contractor, unless the Government has reimbursed the Contractor for the cost of the materials and equipment.

(c) The vessel, its equipment, movable stores, cargo, or other ship's materials shall not be considered Government-furnished property.

(End of clause)

1252.217–78 Discharge of Liens.

As prescribed at 1217.7001(b), insert the following clause:

Discharge of Liens (NOV 2022)

(a) The Contractor shall immediately discharge or cause to be discharged, any lien or right *in rem* of any kind, other than in favor of the Government, that exists or arises in connection with work done or materials furnished under this contract.

(b) If any such lien or right *in rem* is not immediately discharged, the Government, at the expense of the Contractor, may discharge, or cause to be discharged, the lien or right.

(End of clause)

1252.217–79 Delays.

As prescribed at 1217.7001(b), insert the following clause:

Delays (NOV 2022)

When during the performance of this contract the Contractor is required to delay work on a vessel temporarily, due to orders or actions of the Government respecting stoppage of work to permit shifting the vessel, stoppage of hot work to permit bunkering, stoppage of work due to embarking or debarking passengers and loading or discharging cargo, and the Contractor is not given sufficient advance notice or is otherwise unable to avoid incurring additional costs on account thereof, an equitable adjustment shall be made in the price of the contract pursuant to the ''Changes'' clause.

(End of clause)

1252.217–80 Department of Labor Safety and Health Regulations for Ship Repair.

As prescribed at 1217.7001(b), insert the following clause:

Department of Labor Safety and Health Regulations for Ship Repair (NOV 2022)

Nothing contained in this contract shall relieve the Contractor of any obligations it may have to comply with—

(a) The Occupational Safety and Health Act of 1970 (29 U.S.C. 651, *et seq.*);

(b) The Occupational Safety and Health Standards for Shipyard Employment (29 CFR part 1915); or

(c) Any other applicable Federal, State, and local laws, codes, ordinances, and regulations.

(End of clause)

1252.222–70 Strikes or Picketing Affecting Timely Completion of the Contract Work.

As prescribed in 1222.101–71(a), insert the following clause:

Strikes or Picketing Affecting Timely Completion of the Contract Work (NOV 2022)

Notwithstanding any other provision hereof, the Contractor is responsible for delays arising out of labor disputes, including but not limited to strikes, if such strikes are reasonably avoidable. A delay caused by a strike or by picketing which constitutes an unfair labor practice is not excusable unless the Contractor takes all reasonable and appropriate action to end such a strike or picketing, such as the filing of a charge with the National Labor Relations Board, the use of other available Government procedures, and the use of private boards or organizations for the settlement of disputes.

(End of clause)

1252.222–71 Strikes or Picketing Affecting Access to a DOT Facility.

As prescribed in 1222.101–71(b), insert the following clause:

Strikes or Picketing Affecting Access to a DOT Facility (NOV 2022)

If the Contracting Officer notifies the Contractor in writing that a strike or picketing—(a) Is directed at the Contractor or subcontractor or any employee of either; and (b) Impedes or threatens to impede access by any person to a DOT facility where the site of the work is located, the Contractor shall take all appropriate action to end such strike or picketing, including, if necessary, the filing of a charge of unfair labor practice with the National Labor Relations Board or the use of other available judicial or administrative remedies.

(End of clause)

1252.222–72 Contractor Cooperation in Equal Employment Opportunity and Anti-Harassment Investigations.

As prescribed in 1222.810–70, insert the following clause:

Contractor Cooperation in Equal Employment Opportunity and Anti–harassment Investigations (NOV 2022)

(a) *Definitions.* As used in this clause—

Complaint means a formal or informal complaint that has been filed with DOT management, DOT agency Equal Employment Opportunity (EEO) officials, the Equal Employment Opportunity Commission (EEOC), the Office of Federal Contract Compliance Programs (OFCCP) or a court of competent jurisdiction.

Contractor employee means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide DOT with that employee's last known mailing address, email address, and telephone number, if that employee has been identified as a witness in an EEO or Anti-Harassment complaint or investigation.

Good faith cooperation means, but is not limited to, making Contractor employees available, with the presence or assistance of counsel as deemed appropriate by the Contractor, for:

(1) Formal and informal interviews by EEO counselors, the OFCCP, or other Agency officials processing EEO or Anti-Harassment complaints;

(2) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;

(3) Reviewing and signing appropriate affidavits or declarations summarizing statements provided by such Contractor employees during EEO or Anti-Harassment investigations;

(4) Producing documents requested by EEO counselors, EEO investigators, OFCCP investigators, Agency employees, or the EEOC in connection with a pending EEO or Anti-Harassment complaint; and

(5) Preparing for and providing testimony in depositions or in hearings before the Merit Systems Protection Board, EEOC, OFCCP, and U.S. District Court.

(b) *Cooperation with investigations.* In addition to complying with the clause at FAR 52.222–26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Transportation in investigations of EEO complaints processed pursuant to 29 CFR part 1614 and internal Anti-Harassment investigations.

(c) *Compliance.* Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default or for cause in accordance with the termination clauses in the contract.

(d) *Subcontract flowdown.* The Contractor shall include the provisions of this clause in all subcontract solicitations and subcontracts awarded, at any tier, under this contract.

(End of clause)

1252.223–70 Removal or Disposal of Hazardous Substances—Applicable Licenses and Permits.

As prescribed in 1223.303, insert the following clause:

Removal or Disposal of Hazardous Substances—Applicable Licenses and Permits (NOV 2022)

The Contractor has____or does not have____[*Contractor check applicable response*] all licenses and permits required by Federal, State, and local laws to perform hazardous substance(s) removal or disposal services. If the Contractor does not currently possess these documents, it must obtain all requisite licenses and permits within_____[*Contracting Officer insert number*] calendar days after date of award. The Contractor shall provide evidence of said documents to the Contracting Officer or designated Government representative prior to commencement of work under the contract.

(End of clause)

1252.223–71 Accident and Fire Reporting.

As prescribed in 1223.7000(a), insert the following clause:

Accident and Fire Reporting (NOV 2022)

(a) The Contractor shall report to the Contracting Officer any accident or fire occurring at the site of the work which causes—

(1) A fatality or as much as one lost workday on the part of any employee of the Contractor or subcontractor at any tier;

(2) Damage of $1,000 or more to Government-owned or leased property, either real or personal;

(3) Damage of $1,000 or more to Contractor or subcontractor owned or leased motor vehicles or mobile equipment; or

(4) Damage for which a contract time extension may be requested.

(b) Accident and fire reports required by paragraph (a) of this section shall be accomplished by the following means:

(1) Accidents or fires resulting in a death, hospitalization of five or more persons, or destruction of Government-owned or leased property (either real or personal), the total value of which is estimated at $100,000 or more, shall be reported immediately by telephone to the Contracting Officer or his/her authorized representative and shall be confirmed in writing within 24 hours to the Contracting Officer. Such report shall state all known facts as to extent of injury and damage and as to cause of the accident or fire.

(2) Other accident and fire reports required by paragraph (a) of this section may be reported by the Contractor using a state, private insurance carrier, or Contractor accident report form which provides for the statement of—

(i) The extent of injury; and

(ii) The damage and cause of the accident or fire.

Such report shall be mailed or otherwise delivered to the Contracting Officer within 48 hours of the occurrence of the accident or fire.

(c) The Contractor shall assure compliance by subcontractors at all tiers with the requirements of this clause.

(End of clause)

1252.223–72 Protection of Human Subjects.

As prescribed in 1223.7000(b), insert the following clause:

Protection of Human Subjects (NOV 2022)

(a) The Contractor shall comply with 49 CFR part 11, DOT's regulations for the protection of human subjects participating in activities supported directly or indirectly by contracts from DOT. In addition, the Contractor shall comply with any DOT Operating Administration (OA)-specific policies and procedures on the protection of human subjects.

(b) To demonstrate compliance with the subject DOT regulations and to protect human subjects, the Contractor shall ensure the following:

(1) The Contractor shall establish and maintain a committee competent to review projects and activities that involve human subjects.

(2) The committee shall be assigned responsibility to determine, for each activity planned and conducted, that—

(i) The rights and welfare of subjects are adequately protected;

(ii) The risks to subjects are outweighed by potential benefits; and

(iii) The informed consent of subjects shall be obtained by methods that are adequate and appropriate.

(3) Committee reviews shall be conducted with objectivity and in a manner to ensure the exercise of independent judgment of the

members. Members shall be excluded from review of projects or activities in which they have an active role or a conflict of interests.

(4) Continuing constructive communication between the committee and the project directors must be maintained as a means of safeguarding the rights and welfare of subjects.

(5) Facilities and professional attention required for subjects who may suffer physical, psychological, or other injury as a result of participating in an activity shall be provided.

(6) The committee shall maintain records of committee review of applications and active projects, of documentation of informed consent, and of other documentation that may pertain to the selection, participation, and protection of subjects. Detailed records shall be maintained of circumstances of any review that adversely affects the rights or welfare of the individual subjects. Such materials shall be made available to DOT upon request.

(7) The retention period of such records and materials shall be as specified at FAR 4.703.

(c) Periodic reviews shall be conducted by the Contractor to assure, through appropriate administrative overview, that the practices and procedures designed for the protection of the rights and welfare of subjects are being effectively applied.

(d) If the Contractor has or maintains a relationship with a Department of Health and Human Services approved Institutional Review Board (IRB) which can appropriately review this contract in accordance with the technical requirements and any applicable OA policies and procedures that apply, that IRB will be considered acceptable for the purposes of this contract.

(End of clause)

1252.223–73 Seat Belt Use Policies and Programs.

As prescribed in 1223.7000(c), insert the following clause:

Seat Belt Use Policies and Programs (NOV 2022)

In accordance with Executive Order 13043, Increasing Seat Belt Use in the United States, dated April 16, 1997, the Contractor is encouraged to adopt and enforce on-the-job seat belt use policies and programs for its employees when operating company-owned, rented, or personally-owned vehicles. The National Highway Traffic Safety Administration (NHTSA) is responsible for providing leadership and guidance in support of this Presidential initiative. For information on how to implement such a program or for statistics on the potential benefits and cost-savings to your company or organization, please visit the Click it or Ticket seat belt safety section of NHTSA's website at *https://www.nhtsa.gov/campaign/click-it-or-ticket* and *https://www.nhtsa.gov/risky-driving/seat-belts.*

(End of clause)

1252.228–70 Loss of or Damage to Leased Aircraft.

As prescribed in 1228.306–70(a), insert the following clause:

Loss of or Damage to Leased Aircraft (NOV 2022)

(a) Except normal wear and tear, the Government assumes all risk of loss of, or damage to, the leased aircraft during the term of this lease while the aircraft is in the possession of the Government.

(b) In the event of damage to the aircraft, the Government, at its option, shall make the necessary repairs with its own facilities or by contract, or pay the Contractor the reasonable cost of repair of the aircraft.

(c) In the event the aircraft is lost or damaged beyond repair, the Government shall pay the Contractor a sum equal to the fair market value of the aircraft at the time of such loss or damage, which value may be specifically agreed to in clause 1252.228–71, Fair Market Value of Aircraft, less the salvage value of the aircraft. However, the Government may retain the damaged aircraft or dispose of it in its discretion. In that event, the Contractor will be paid the fair market value of the aircraft as stated in the clause.

(d) The Contractor agrees that the contract price does not include any cost attributable to hull insurance or to any reserve fund it has established to protect its interest in the aircraft. If, in the event of loss or damage to the leased aircraft, the Contractor receives compensation for such loss or damage in any form from any source, the amount of such compensation shall be credited to the Government in determining the amount of the Government's liability.

(e) In the event of loss of or damage to the aircraft, the Government shall be subrogated to all rights of recovery by the Contractor against third parties for such loss or damage and the Contractor shall promptly assign such rights in writing to the Government.

(End of clause)

1252.228–71 Fair Market Value of Aircraft.

As prescribed in 1228.306–70(a), insert the following clause:

Fair Market Value of Aircraft (NOV 2022)

For purposes of clause 1252.228–70, Loss of or Damage to Leased Aircraft, the fair market value of the aircraft to be used in the performance of this contract shall be the lesser of the two values set out in paragraphs (a) and (b) below—

(a) $_____; [*Contracting Officer insert value*] or

(b) If the Contractor has insured the same aircraft against loss or destruction in connection with other operations, the amount of such insurance coverage on the date of the loss or damage for which the Government may be responsible under this contract.

(End of clause)

1252.228–72 Risk and Indemnities.

As prescribed in 1228.306–70(a) and (d), insert the following clause:

Risk and Indemnities (NOV 2022)

The Contractor hereby agrees to indemnify and hold harmless the Government, its officers and employees from and against all claims, demands, damages, liabilities, losses, suits and judgments (including all costs and expenses incident thereto) which may be suffered by, accrue against, be charged to or recoverable from the Government, its officers and employees by reason of injury to or death of any person other than officers, agents, or employees of the Government or by reason of damage to property of others of whatsoever kind (other than the property of the Government, its officers, agents or employees) arising out of the operation of the aircraft. In the event the Contractor holds or obtains insurance in support of this covenant, evidence of insurance shall be delivered to the Contracting Officer.

(End of clause)

1252.228–73 Command of Aircraft.

As prescribed in 1228.306–70(d), insert the following clause:

Command of Aircraft (NOV 2022)

During the performance of a contract for out-service flight training for DOT, whether the instruction to DOT personnel is in leased, contractor-provided, or Government-provided aircraft, contractor personnel shall always, during the entirety of the course of training and during operation of the aircraft, remain in command of the aircraft. At no time shall other personnel be permitted to take command of the aircraft.

(End of clause)

1252.228–74 Notification of Payment Bond Protection.

As prescribed in guidance at 1228.106–470, insert the following clause:

Notification of Payment Bond Protection (NOV 2022)

(a) The prime contract is subject to the Bonds statute (historically referred to as the Miller Act) (40 U.S.C. chapter 31, subchapter III), under which the prime contractor has obtained a payment bond. This payment bond may provide certain unpaid employees, suppliers, and subcontractors a right to sue the bonding surety under the Bonds statute for amounts owned for work performed and materials delivery under the prime contract.

(b) Persons believing that they have legal remedies under the Bonds statute should consult their legal advisor regarding the proper steps to take to obtain these remedies. This notice clause does not provide any party any rights against the Federal Government, or create any relationship, contractual or otherwise, between the Federal Government and any private party.

(c) The surety which has provided the payment bond under the prime contract is: [*Contracting Officer fill-in prime contractor's surety information*]

_____

(Name)

_____

(Street Address)

(City, State, Zip Code)

(Contact & Tel. No.)

(d) Subcontract flowdown requirements. This clause shall be flowed down to all subcontractors. Prime contractors shall insert this notice clause in all first-tier subcontracts and shall require the clause to be subsequently flowed down by all first-tier subcontractors to all their subcontractors, at any tier. This notice contains information pertaining to the surety that provided the payment bond under the prime contract and is required to be inserted in its entirety to include the information set forth in paragraph (c).

(End of clause)

1252.231–70 Date of Incurrence of Costs.

As prescribed in 1231.205–3270(b), insert the following clause:

Date of Incurrence of Costs (NOV 2022)

The Contractor shall be entitled to reimbursement for costs incurred on or after____ [*Contracting Officer insert date*] in an amount not to exceed $____ [*Contracting Officer insert amount*] that, if incurred after this contract had been entered into, would have been reimbursable under this contract.

(End of clause)

1252.232–70 Electronic Submission of Payment Requests.

As prescribed in 1232.7005, insert the following clause:

Electronic Submission of Payment Requests (NOV 2022)

(a) *Definitions.* As used in this clause—

(1) *Contract financing payment* has the meaning given in FAR 32.001.

(2) *Payment request* means a bill, voucher, invoice, or request for contract financing payment or invoice payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), ''Content of Invoices,'' this clause, and the applicable Payment clause included in this contract.

(3) *Electronic form* means an automated system transmitting information electronically according to the accepted electronic data transmission methods and formats identified in paragraph (c) of this clause. Facsimile, email, and scanned documents are not acceptable electronic forms for submission of payment requests.

(4) *Invoice payment* has the meaning given in FAR 32.001.

(b) *Electronic payment requests.* Except as provided in paragraph (e) of this clause, the contractor shall submit payment requests in electronic form. Purchases paid with a Governmentwide commercial purchase card are considered to be an electronic transaction for purposes of this rule, and therefore no additional electronic invoice submission is required.

(c) *Processing system.* The Department of Transportation utilizes the DELPHI system for processing invoices. The DELPHI module for submitting invoices is called *iSupplier.* Access to DELPHI is granted with electronic authentication of credentials (name & valid email address) utilizing the GSA credentialing platform *login.gov.* Vendors submitting invoices are required to submit invoices via *iSupplier* (DELPHI) and authenticated via *www.login.gov.*

(d) *Invoice requirements.* To receive payment and in accordance with the Prompt Payment Act, all invoices submitted as attachments in *iSupplier* (DELPHI) shall contain the following:

(1) Invoice number and invoice date.

(2) Period of performance covered by invoice.

(3) Contract number and title.

(4) Task/Delivery Order number and title (if applicable).

(5) Amount billed (by CLIN), current and cumulative.

(6) Total ($) of billing.

(7) Cumulative total billed for all contract work to date.

(8) Name, title, phone number, and mailing address of person to be contacted in the event of a defective invoice.

(9) Travel. If the contract includes allowances for travel, all invoices which include charges pertaining to travel expenses will catalog a breakdown of reimbursable expenses with the appropriate receipts to substantiate the travel expenses.

(e) *Payment system registration.* All persons accessing the *iSupplier* (DELPHI) will be required to have their own unique user ID and password and be credentialed through *login.gov.*

(1) *Electronic authentication. See www.login.gov* for instructions.

(2) To create a *www.login.gov* account, the user will need a valid email address and a working phone number. The user will create a password and then *www.login.gov* will reply with an email confirming the email address.

(3) *iSupplier* (DELPHI) registration instructions: New users should navigate to: *http://einvoice.esc.gov* to establish an account. Users are required to log in to *iSupplier* (DELPHI) every 45 days to keep it active.

(4) *Training on DELPHI.* To facilitate use of DELPHI, comprehensive user information is available at *http://einvoice.esc.gov.*

(5) *Account Management.* Vendors are responsible to contact their assigned COR when their firm's points of contacts will no longer be submitting invoices, so they can be removed from the system.

(f) *Waivers.* For contractors/vendors who are unable to utilize DOT's DELPHI system, waivers may be considered by DOT on a case-by-case basis. Vendors should contact their Contracting Officer's Representative (COR) for procedures.

(g) *Exceptions and alternate payment procedures.* If, based on one of the circumstances set forth in 1232.7002(a) or (b), and the contracting officer directs that payment requests be made by mail, the contractor shall submit payment requests by mail through the United States Postal Service to the designated agency office. If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request. If DELPHI is succeeded by later technology, the Contracting Officer will supply the Contractor with the latest applicable electronic invoicing instructions.

(End of clause)

1252.232–71 Limitation of Government's Obligation.

As prescribed in 1232.770–7, insert the following clause:

Limitation of Government's Obligation (NOV 2022)

(a) Funding is not currently available to fully fund this contract due to the Government operating under a continuing resolution (CR). The item(s) listed in the table below are being incrementally funded as described below. The funding allotted to these item(s) is presently available for payment and allotted to this contract. This table will be updated by a modification to the contract when additional funds, if any, are made available to this contract.

Contract line item No. (CLIN)	CLIN total price	Funds allotted to the CLIN	Funds required for complete funding of the CLIN
	$ $ $ $	$ $ $ $	$ $ $ $
Totals	$	$	$

(b) For the incrementally funded CLIN(s) identified in paragraph (a) of this clause, the Contractor agrees to perform up to the point at which the total amount payable by the Government, including any invoice payments to which the Contractor is entitled and

reimbursement of authorized termination costs in the event of termination of those CLIN(s) for the Government's convenience, does not exceed the total amount currently obligated to those CLIN(s). The Contractor is not authorized to continue work on these item(s) beyond that point. The Government will not be obligated—in any event—to reimburse the Contractor in excess of the amount allotted to the CLIN(s) of the contract regardless of anything to the contrary in any other clause, including but not limited to the clause entitled ''Termination for Convenience of the Government'' or paragraph (l) entitled ''Termination for the Government's Convenience'' of the clause at FAR 52.212–4,''Commercial Terms and Conditions—Commercial Products and Commercial Services.''

(c) Notwithstanding paragraph (h) of this clause, the Contractor shall notify the Contracting Officer in writing at least 30 days prior to the date when, in the Contractor's best judgment, the work will reach the point at which the total amount payable by the Government, including any cost for termination for convenience, will approximate 85 percent of the total amount then allotted to the contract for performance of the item(s) identified in paragraph (a) of this clause. The notification shall state the estimated date when that point will be reached and an estimate of additional funding, if any, needed to continue performance. The notification shall also advise the Contracting Officer of the estimated amount of additional funds required for the timely performance of the item(s) funded pursuant to this contract. If after such notification additional funds are not allotted by the date identified in the Contractor's notification, or by an agreed upon substitute date, the Contracting Officer will terminate any item(s) for which additional funds have not been allotted, pursuant to the terms of this contract authorizing termination for the convenience of the Government. Failure to make the notification required by this paragraph, whether for reasons within or beyond the Contractor's control, will not increase the maximum amount payable to the Contractor under paragraphs (a) and (b) of this clause.

(d) The Government may, at any time prior to termination, allot additional funds for the performance of the item(s) identified in paragraph (a) of this clause.

(e) The termination provisions of paragraphs (a) through (h) of this clause do not limit the rights of the Government under the clause entitled ''Default'' or paragraph (m) entitled ''Termination for Cause,'' of the clause at FAR 52.212–4, ''Commercial Terms and Conditions—Commercial Products and Commercial Services.'' The provisions of this clause are limited to the work and allotment of funds for the item(s) set forth in paragraph (a) of this clause. This clause no longer applies once the contract is fully funded.

(f) Nothing in this clause affects the right of the Government to terminate this contract pursuant to the Government's termination for convenience terms set forth in this contract.

(g) Nothing in this clause shall be construed as authorization of voluntary services whose acceptance is otherwise prohibited under 31 U.S.C. 1342.

(h) The parties contemplate that the Government will allot funds to this contract from time to time as the need arises and as funds become available. There is no fixed schedule for providing additional funds.

(End of clause)

1252.235–70 Research Misconduct.

As prescribed in 1235.070–1, insert the following clause:

Research Misconduct (NOV 2022)

(a) *Definitions.* As used in this clause—

Adjudication means the process of reviewing recommendations from the investigation phase and determining appropriate corrective actions.

Complainant means the person who makes an allegation of research misconduct or the person who cooperates with an inquiry or investigation.

DOT Oversight Organization is the Department of Transportation (DOT) operating administration or Secretarial office sponsoring or managing Federally-funded research.

Evidence includes, but is not limited to, research records, transcripts, or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, expert analyses, and electronic data.

Fabrication means making up data or results and recording or reporting them.

Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Inquiry means preliminary information gathering and fact-finding to determine if an allegation, or apparent instance of research misconduct, warrants an investigation.

Investigation means formal collection and evaluation of information and facts to determine if research misconduct can be established, to assess its extent and consequences, and to recommend appropriate action.

Plagiarism means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

Research and Technology Coordinating Council (RTCC) is the lead DOT entity for coordination of all actions related to allegations of research misconduct. The respondent in a research misconduct finding may appeal through the RTCC to the Deputy Secretary of Transportation.

Research institution includes any Contractor conducting research under DOT-funded contractual instruments, contracts, and similar instruments.

Research misconduct means fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or difference of opinion.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

Respondent means the person against whom an allegation of research misconduct has been made, or the person whose actions are the focus of the inquiry or investigation.

(b) *General guidelines.* (1) *Confidentiality.* DOT organizations, including research organizations, are required to safeguard the confidentiality of the inquiry, investigation and decision-making processes, including maintaining complete confidentiality of all records and identities of respondents and complainants.

(2) *Retaliation prohibited.* If a complainant who has reported possible research misconduct alleges retaliation on the part of DOT organization management, the report will be addressed by management officials who will conduct an inquiry into the allegations followed by an appropriate management action.

(3) *Separation of phases.* DOT organizations and research organizations must ensure the separation of the Inquiry, Investigation and Determination Phases of this process.

(4) In general, DOT organizations must strive to protect the interests of the Federal Government and the public in carrying out this process.

(c) *Elements to support a finding of research misconduct.* Research institutions (including Contractors) that receive DOT funds shall respond to allegations of research misconduct. The following elements describe the type of behavior, level of intent, and burden of proof required to support a finding of research misconduct:

(1) There must be a significant departure from the accepted practices of the relevant research community;

(2) The misconduct must have been committed intentionally, knowingly, or recklessly; and

(3) The allegation must be proven by a preponderance of the evidence.

(d) *DOT Oversight Organization Investigation.* The DOT oversight organization may proceed with its own investigation at any time if:

(1) DOT determines the research institution is not prepared to handle the allegation in a manner consistent with this policy.

(2) DOT involvement is needed to protect the public interest, including public health and safety.

(3) The allegation involves an entity of sufficiently small size (or an individual) that it cannot sufficiently conduct the investigation itself.

(4) The DOT oversight organization may take, or cause to be taken, interim administrative actions (including special certifications, assurances, or other administrative actions) when deemed appropriate to protect the welfare of human and animal subjects of research, prevent inappropriate use of Federal funds, or otherwise protect the public interest and safety.

(e) *Investigating research misconduct.* Research institutions, or in limited circumstances discussed in paragraph (d) the

DOT Oversight Organization shall use the following procedures to investigate allegations of research misconduct:

(1) Inquire promptly into the research misconduct allegation and complete an initial inquiry within 60 calendar days after receipt of the allegation.

(2) Notify the Contracting Officer immediately, in writing, when an inquiry results in a determination that an investigation is warranted, and promptly begin an investigation.

(3) Ensure the objectivity and expertise of the individuals selected to review allegations and conduct investigations.

(4) Conduct the investigation according to established internal procedures and complete it within 120 calendar days of completing the initial inquiry.

(5) Document the investigation. Include documentation that—

(i) Describes the allegation(s);

(ii) Lists the investigators;

(iii) Describes the methods and procedures used to gather information and evaluate the allegation(s);

(iv) Summarizes the records and data compiled, states the findings, and explains the supporting reasons and evidence;

(v) States the potential impact of any research misconduct; and

(vi) Describes and explains any institutional sanctions or corrective actions recommended or imposed as appropriate within its jurisdiction and as consistent with other relevant laws.

(6) Provide the respondent (the person against whom an allegation of research misconduct has been made) with a reasonable opportunity (*e.g.,* 30 calendar days) to review and respond to the investigation report. The respondent's written comments or rebuttal will be made part of the investigative record.

(7) Within 30 calendar days after completion of an investigation, forward investigative reports, documentation, and respondent's response to the Contracting Officer who will coordinate with the DOT oversight organization(s) sponsoring and/or monitoring the federally-funded research.

(8) Time extensions. Contractors should request time extensions as needed from the Contracting Officer of the appropriate DOT oversight organization. The Contracting Officer has discretion to waive time requirements for good cause.

(f) *Activity sanctions or corrective actions.* Upon receipt of the investigative reports from the contractor, the DOT oversight organization, in conjunction with the Contracting Officer, will review the report, and determine the appropriate administrative action to be taken. In deciding what actions to take, the oversight organizations should consider: the severity of the misconduct; the degree to which the misconduct was knowing, intentional, or reckless; and whether it was an isolated event or part of a pattern. Sanctions or corrective actions may range as follows—

(1) *Minimal restrictions*—such as a letter of reprimand, additional conditions on awards, requiring third-party certification of accuracy or compliance with particular policies, regulations, guidelines, or special terms and conditions;

(2) *Moderate restrictions*—such as limitations on certain activities or expenditures under an active award or special reviews of requests for funding; or

(3) *More severe restrictions*—such as termination of an active award or government-wide suspension or debarment.

(g) *Appeals and final administrative action.* (1) The Federal Acquisition Regulation governs in all matters pertaining to termination of the contract and suspension/debarment.

(2) In all other cases, the Contractor may appeal the sanction or corrective action through the DOT Research and Technology Coordinating Council (RTCC) to the Deputy Secretary of Transportation, in writing within 30 calendar days after receiving written notification of the research misconduct finding and associated administrative action(s). The Contractor shall mail a copy of the appeal to the Contracting Officer.

(3) If there is no request for appeal within 30 calendar days, the administrative actions of the oversight organization shall be final.

(4) If a request for appeal is received by the RTCC within the 30-calendar day limit, the Deputy Secretary may have the RTCC review the appeal and make recommendations.

(5) The RTCC on behalf of the Deputy Secretary will normally inform the appellant of the final decision on an appeal within 60 calendar days of receipt. This decision will then be the final DOT administrative action.

(h) *Criminal or civil fraud violations.* When the DOT oversight organization concludes an investigation with a determination of research misconduct, the DOT Office of the Senior Procurement Executive may notify any other sources of research that provide support to the respondent. If criminal or civil fraud violations may have occurred, the oversight organization should promptly refer the matter to the DOT Inspector General, the Department of Justice or other appropriate investigative body. The DOT oversight organization, in conjunction with the Contracting Officer will notify the respondent in writing of its action, sanctions to be imposed if applicable, and the DOT appeal procedures.

(i) *Subcontract flowdown.* The Contractor shall include the substance of this clause in all subcontracts that involve research.

(End of clause)

1252.235–71 Technology Transfer.

As prescribed in 1235.011–70, insert the following clause:

Technology Transfer (NOV 2022)

(a) The Contractor, in accordance with the provisions in the attached Statement of Work, will develop a Technology Transfer Plan to be approved by_____[*Fill-in: Contracting Officer to fill-in the cognizant DOT/OA*] prior to the initiation of any work under this contract and shall execute the approved plan throughout the conduct of this Agreement. Such plan shall include, at a minimum—

(1) A description of the problem and technical solutions being researched, including any potential or identified technology developments that are the intended output of or which may be derived from the research;

(2) A list identifying and categorizing by interest potential stakeholders in the outputs of the research to be performed;

(3) A plan for engaging the identified potential stakeholders to determine interest in and obtain suggested refinements to the research, before and during the conduct of this contract, to enhance the likelihood of adoption/implementation of the research outputs. Such engagement activities shall comprise communicating research status to identified stakeholders, soliciting their feedback; disseminating research outputs, and identifying whether the outputs were adopted/implemented;

(4) A proposed delivery or demonstration activity (*e.g.,* conference presentation of a final report, demonstration of software, or demonstration of tangible output);

(5) A draft plan for the commercialization of any research outputs, including the specific identification of stakeholders most likely to be interested in the commercialization of the research outputs;

(6) The identification of the specific methods and channels for dissemination of the research outputs (*e.g.,* publication, licensing to a third party, or manufacture and sale); and

(7) A plan for tracking and reporting the research outputs, outcomes, and impacts to [*Fill-in: Contracting Officer to fill in the cognizant DOT/OA*].

(b) The Contractor shall provide to_____[*Fill-in: Contracting Officer to fill-in the cognizant DOT/OA*] at least once every six months, or as an attachment to any more frequent research progress reports, a Technology Transfer Report addressing and updating each element of their approved Technology Transfer Plan. Such report shall include—

(1) An updated description of the problem and technical solution(s) being researched, particularly where any revisions to the research are based on feedback from a stakeholder engagement;

(2) A summary of overall technology transfer progress;

(3) An updated listing of interested stakeholders and an identification of their potential role (*e.g.,* research sponsor, potential end-user, or regulator);

(4) A listing of the stakeholders engaged since the most recently submitted Technology Transfer Report;

(5) The identification of any additional stakeholder engagement activity (including the mechanism used to engage the stakeholder) and the results of such activity;

(6) The conduct and results of any delivery/demonstration activity occurring since the most recently submitted Report update, including the identification of any stakeholder participants;

(7) An acknowledgement of the submission of any technical or progress report that would satisfy the Public Access requirement and whether such submissions are properly represented in the USDOT Research Hub and the National Transportation Library; and

(8) Any information on instances of any use of an output of research conducted under this contract.

(End of clause)

1252.236–70 Special Precautions for Work at Operating Airports.

As prescribed in 1236.570, insert the following clause:

Special Precautions for Work at Operating Airports (NOV 2022)

(a) When work is to be performed at an operating airport, the Contractor must arrange its work schedule so as not to interfere with flight operations. Such operations will take precedence over construction convenience. Any operations of the Contractor that would otherwise interfere with or endanger the operations of aircraft shall be performed only at times and in the manner directed by the Contracting Officer. The Government will make every effort to reduce the disruption of the Contractor's operation.

(b) Unless otherwise specified by local regulations, all areas in which construction operations are underway shall be marked by yellow flags during daylight hours and by red lights at other times. The red lights along the edge of the construction areas within the existing aprons shall be the electric type of not less than 100 watts intensity placed and supported as required. All other construction markings on roads and adjacent parking lots may be either electric or battery type lights. These lights and flags shall be placed to outline the construction areas and the distance between any two flags or lights shall not be greater than 25 feet. The Contractor shall provide adequate watch to maintain the lights in working condition at all times other than daylight hours. The hour of beginning and the hour of ending of daylight will be determined by the Contracting Officer.

(c) All equipment and material in the construction areas or when moved outside the construction area shall be marked with airport safety flags during the day and when directed by the Contracting Officer, with red obstruction lights at nights. All equipment operating on the apron, taxiway, runway, and intermediate areas after darkness hours shall have clearance lights in conformance with instructions from the Contracting Officer. No construction equipment shall operate within 50 feet of aircraft undergoing fuel operations. Open flames are not allowed on the ramp except at times authorized by the Contracting Officer.

(d) Trucks and other motorized equipment entering the airport or construction area shall do so only over routes determined by the Contracting Officer. Use of runways, aprons, taxiways, or parking areas as truck or equipment routes will not be permitted unless specifically authorized for such use. Flag personnel shall be furnished by the Contractor at points on apron and taxiway for safe guidance of its equipment over these areas to assure right of way to aircraft. Areas and routes used during the contract must be returned to their original condition by the Contractor. The maximum speed allowed at the airport shall be established by airport management. Vehicles shall be operated to be under safe control at all times, weather and traffic conditions considered. Vehicles must be equipped with head and tail lights during the hours of darkness.

(End of clause)

1252.237–70 Qualifications of Contractor Employees.

As prescribed in 1237.110–70(a), insert the following clause:

Qualifications of Contractor Employees (NOV 2022)

(a) *Definition. Sensitive information,* as used in this clause, means any information that is proprietary data or, if subject to unauthorized access, modification, loss, or misuse, could adversely affect the national interest, the conduct of Federal programs, or the privacy of individuals specified in The Privacy Act, 5 U.S.C. 552a, but has not been specifically authorized under criteria established by an Executive Order or an Act of Congress to be kept secret in the interest of national defense or foreign policy.

(b) Work under this contract may involve access to DOT facilities or sensitive information or resources (*e.g.,* information technology including computer systems). To protect sensitive information, which shall not be disclosed by the contractor unless authorized in writing by the Contracting Officer, the Contractor shall provide training to any contractor employees authorized to access sensitive information, and upon request of the Government, provide information to assist the Government in determining an individual's suitability to have authorization.

(c) The Contracting Officer may require dismissal from work under this contract of those employees deemed incompetent, careless, insubordinate, unsuitable, or otherwise objectionable, or whose continued employment is deemed contrary to the public interest or inconsistent with the best interest of national security.

(d) Contractor employees working on this contract must complete such forms as may be necessary for security or other reasons, including the conduct of background investigations to determine suitability. Completed forms shall be submitted as directed by the Contracting Officer. Upon the Contracting Officer's Representative (COR) or Program Manager's (PM) request, the Contractor's employees shall be fingerprinted or subject to other investigations as required.

(e) The Contractor shall ensure that contractor employees working on this contract are citizens of the United States of America or non-citizens who have been lawfully admitted for permanent residence or employment (indicated by immigration status) as evidenced by U.S. Citizenship and Immigration Services (USCIS) documentation.

(f) Subcontract flow-down requirement. The Contractor shall include this clause, including this paragraph (f), in subcontracts whenever this clause is included in the prime contractor's contract.

(End of clause)

1252.237–71 Certification of Data.

As prescribed in 1237.7003, insert the following provision:

Certification of Data (NOV 2022)

(a) The offeror represents and certifies that to the best of its knowledge and belief, the information and/or data (*e.g.,* company profile; qualifications; background statements; brochures) submitted with its offer is current, accurate, and complete as of the date of its offer.

(b) The offeror understands that any inaccurate data provided to the Department of Transportation may subject the offeror, its subcontractors, its employees, or its representatives to: (1) prosecution for false statements pursuant to 18 U.S.C. 1001 and/or; (2) enforcement action for false claims or statements pursuant to the Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801–3812 and 49 CFR part 31 and/or; (3) termination for default or for cause under any contract resulting from its offer and/or; (4) debarment or suspension.

(c) The offeror agrees to obtain a similar certification from its subcontractors and submit such certification(s) with its offer.

Signature: _____

Date: _____

Typed Name and Title: _____

Company Name: _____

This certification concerns a matter within the jurisdiction of an agency of the United States and the making of a false, fictitious, or fraudulent certification may render the maker subject to prosecution under 18 U.S.C. 1001.

(End of provision)

1252.237–72 Prohibition on Advertising.

As prescribed in 1213.7101 and 1237.7003, insert the following clause:

Prohibition on Advertising (NOV 2022)

The contractor or its representatives (including training instructors) shall not advertise or solicit business from attendees for private, non-Government training during contracted-for training sessions. This prohibition extends to unsolicited oral comments, distribution or sales of written materials, and/or sales of promotional videos or audio tapes. The contractor agrees to insert this clause in its subcontracts.

(End of clause)

1252.237–73 Key Personnel.

As prescribed in 1237.110–70(b), insert the following clause:

Key Personnel (NOV 2022)

(a) The personnel as specified below are considered essential to the work being performed under this contract and may, with the consent of the contracting parties, be changed during the course of the contract by adding or deleting personnel, as appropriate.

(b) Before removing, replacing, or diverting any of the specified individuals, the Contractor shall notify the contracting officer, in writing, before the change becomes effective. The Contractor shall submit information to support the proposed action to enable the contracting officer to evaluate the potential impact of the change on the contract. The Contractor shall not remove or replace personnel under this contract until the Contracting Officer approves the change

in writing. The key personnel under this contract are:

[*Contracting Officer insert specified key personnel*]

(End of clause)

1252.239–70 Security Requirements for Unclassified Information Technology Resources.

As prescribed in 1239.106–70, insert the following clause:

Security Requirements for Unclassified Information Technology Resources (NOV 2022)

(a) The Contractor shall be responsible for information technology security for all systems connected to a Department of Transportation (DOT) network or operated by the Contractor for DOT, regardless of location. This clause is applicable to all or any part of the contract that includes information technology resources or services in which the Contractor has physical or electronic access to DOT information that directly supports the mission of DOT. The term ''information technology,'' as used in this clause, means any equipment or interconnected system or subsystem of equipment, including telecommunications equipment, that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information. This includes both major applications and general support systems as defined by OMB Circular A–130. Examples of tasks that require security provisions include—

(1) Hosting of DOT e-Government sites or other IT operations;

(2) Acquisition, transmission, or analysis of data owned by DOT with significant replacement cost should the contractor's copy be corrupted; and

(3) Access to DOT general support systems/major applications at a level beyond that granted the general public, *e.g.,* bypassing a firewall.

(b) The Contractor shall develop, provide, implement, and maintain an IT Security Plan. This plan shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources developed, processed, or used under this contract. The plan shall describe those parts of the contract to which this clause applies. The Contractor's IT Security Plan shall comply with applicable Federal Laws that include, but are not limited to, 40 U.S.C. 11331, the Federal Information Security Management Act (FISMA) of 2002, and the E-Government Act of 2002. The plan shall meet IT security requirements in accordance with Federal and DOT policies and procedures, as amended during the term of this contract, which include, but are not limited to the following:

(1) OMB Circular A–130, Managing Information as a Strategic Resource;

(2) National Institute of Standards and Technology (NIST) Guidelines;

(3) DOT CIO IT Policy (CIOP) compendium and associated guidelines;

(4) DOT Order 1630.2C, Personnel Security Management; and

(5) DOT Order 1351.37, Departmental Cyber Security Policy.

(c) Within 30 days after contract award, the contractor shall submit the IT Security Plan to the DOT Contracting Officer for review. This plan shall detail the approach contained in the offeror's proposal or sealed bid. Upon acceptance by the Contracting Officer, the Plan shall be incorporated into the contract by contract modification.

(d) Within six (6) months after contract award, the Contractor shall submit written proof of IT Security accreditation to the Contracting Officer. Such written proof may be furnished either by the Contractor or by a third party. Accreditation shall be in accordance with DOT policy available from the Contracting Officer upon request. The Contractor shall submit along with this accreditation a final security plan, risk assessment, security test and evaluation, and disaster recovery plan/continuity of operations plan. The accreditation and accompanying documents, to include a final security plan, risk assessment, security test and evaluation, and disaster recovery/continuity of operations plan, upon acceptance by the Contracting Officer, will be incorporated into the contract by contract modification.

(e) On an annual basis, the Contractor shall verify in writing to the Contracting Officer that the IT Security Plan remains valid.

(f) The Contractor shall ensure that the official DOT banners are displayed on all DOT systems (both public and private) operated by the Contractor that contain Privacy Act information before allowing anyone access to the system. The DOT CIO will make official DOT banners available to the Contractor.

(g) The Contractor shall screen all personnel requiring privileged access or limited privileged access to systems operated by the Contractor for DOT or interconnected to a DOT network in accordance with DOT Order 1630.2C Personnel Security Management, as amended.

(h) The Contractor shall ensure that its employees performing services under this contract receive annual IT security training in accordance with OMB Circular A–130, FISMA, and NIST requirements, as amended, with a specific emphasis on rules of behavior.

(i) The Contractor shall provide the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases and personnel used in performance of the contract. The Contractor shall provide access to enable a program of IT inspection (to include vulnerability testing), investigation, and audit (to safeguard against threats and hazards to the integrity, availability and confidentiality of DOT data or to the function of information technology systems operated on behalf of DOT), and to preserve evidence of computer crime.

(j) The Contractor shall incorporate and flow down the substance of this clause to all subcontracts that meet the conditions in paragraph (a) of this clause.

(k) The Contractor shall immediately notify the Contracting Officer when an employee who has access to DOT information systems or data terminates employment.

(End of clause)

1252.239–71 Information Technology Security Plan and Accreditation.

As prescribed in 1239.106–70, insert the following provision:

Information Technology Security Plan and Accreditation (NOV 2022)

All offers submitted in response to this solicitation shall address the approach for completing the security plan and accreditation requirements in clause 1252.239–70, Security Requirements for Unclassified and Sensitive Information Technology Resources.

(End of provision)

1252.239–72 Compliance with Safeguarding DOT Sensitive Data Controls.

As prescribed in TAR 1239.7003(a), insert the following clause:

Compliance With Safeguarding DOT Senitive Data Controls (NOV 2022)

(a) The Contractor shall implement security requirements contained in clause 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting, for all DOT sensitive data on all Contractor information systems that support the performance of this contract.

(b) Contractor information systems not part of an information technology service or system operated on behalf of the Government as part of this contract are not subject to the provisions of this clause.

(c) By submission of this offer, the Offeror represents that it will implement the security requirements specified by National Institute of Standards and Technology (NIST) Special Publication (SP) 800–171, Revision 2, ''Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations'' at *https://csrc.nist.gov/publications/detail/sp/800-171/rev-2/final* that are in effect at the time the solicitation is issued or as authorized by the contracting officer.

(d) If the Offeror proposes to vary from any security requirements specified by NIST SP 800–171, Rev. 2 in effect at the time the solicitation is issued or as authorized by the Contracting Officer, the Offeror shall submit to the Contracting Officer, for consideration by the DOT Chief Information Officer (CIO), a written explanation of—

(1) Why a particular security requirement is not applicable; or

(2) How the Contractor will use an alternative, but equally effective, security measure to satisfy the requirements of NIST SP 800–171, Rev. 2.

(e) The Office of the DOT CIO will evaluate offeror requests to vary from NIST SP 800–171, Rev. 2 requirements and inform the Offeror in writing of its decision before contract award. The Contracting Officer will incorporate accepted variance(s) from NIST SP 800–171, Rev. 2 into any resulting contract.

(End of clause)

1252.239–73 Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information.

As prescribed in 1239.7003(b), insert the following clause:

Limitations on the Use or Disclosure of Third–Party Contractor Reported Cyber Incident Information (NOV 2022)

(a) *Definitions.* As used in this clause—

Compromise means disclosure of information to unauthorized persons, or a violation of the security policy of a system, whereby without authorization information is disclosed, modified, destroyed, lost, or copied to unauthorized media—whether intentionally or unintentionally.

DOT sensitive data means unclassified information that requires safeguarding or dissemination controls pursuant to and consistent with law, regulations, and Governmentwide policies, and is—

(1) Marked or otherwise identified in the contract, task order, or delivery order and provided to the Contractor by or on behalf of DOT in support of the performance of the contract; or

(2) Collected, developed, received, transmitted, used, or stored by or on behalf of the Contractor in support of the performance of the contract.

Cyber incident means actions taken through the use of computer networks that result in a compromise or an actual or potentially adverse effect on an information system and/or the information residing therein.

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

Media means physical devices or writing surfaces including, but not limited to, magnetic tapes, optical disks, magnetic disks, large-scale integration memory chips, and printouts onto which DOT sensitive data is recorded, stored, or printed within a covered contractor information system.

DOT technical information means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information. Examples of technical information include research and engineering data, engineering drawings, and associated lists, specifications, standards, process sheets, manuals, technical reports, technical orders, catalog-item identifications, data sets, studies and analyses and related information, and computer software executable code and source code.

(b) *Restrictions.* (1) The Contractor agrees that the following conditions apply to any information it receives or creates in the performance of this contract derived from a third-party's reporting of a cyber incident, pursuant to TAR clause, 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting (or derived from such information obtained under that clause):

(2) The Contractor shall access and use the information only for the purpose of furnishing advice or technical assistance directly to the Government in support of the Government's activities related to clause 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting, and shall not be used for any other purpose.

(3) The Contractor shall protect the information against unauthorized release or disclosure.

(4) The Contractor shall ensure that its employees are subject to use and non-disclosure obligations consistent with this clause prior to the employees being provided access to or use of the information.

(5) The third-party contractor that reported the cyber incident is a third-party beneficiary of the non-disclosure agreement between the Government and Contractor, as required by paragraph (b)(3) of this clause.

(6) A breach of these obligations or restrictions may subject the Contractor to—

(i) Criminal, civil, administrative, and contractual penalties and other appropriate remedies; and

(ii) Civil actions for damages and other appropriate remedies by the third party that reported the cyber incident, as a third-party beneficiary of this clause.

(c) *Subcontract flowdown requirement.* The Contractor shall include this clause, including this paragraph (c), in subcontracts, or similar contractual instruments, for services that include support for the Government's activities related to safeguarding covered DOT sensitive data and cyber incident reporting, including subcontracts for commercial products or commercial services, without alteration, except to identify the parties.

(End of clause)

1252.239–74 Safeguarding DOT Sensitive Data and Cyber Incident Reporting.

As prescribed in 1239.7003(c), insert the following clause:

Safeguarding DOT Sensitive Data and Cyber Incident Reporting (NOV 2022)

(a) *Definitions.* As used in this clause—

Adequate security means protective measures that are commensurate with the consequences and probability of loss, misuse, or unauthorized access to, or modification of information against the probability of occurrence.

Compromise means disclosure of information to unauthorized persons, or a violation of the security policy of a system, whereby without authorization information is disclosed, modified, destroyed, lost, or copied to unauthorized media—whether intentionally or unintentionally.

Contractor attributional/proprietary information means information that identifies the Contractor(s), whether directly or indirectly, by the grouping of information that can be traced back to the Contractor(s) (*e.g.,* program description, facility locations), personally identifiable information, trade secrets, commercial or financial information, or other commercially sensitive information not customarily shared outside of a company.

Covered contractor information system means an unclassified information system owned or operated by or for a Contractor and that processes, stores, or transmits DOT sensitive data.

DOT sensitive data means unclassified information that requires safeguarding or dissemination controls pursuant to and consistent with law, regulation, and Government-wide policies, and is—

(1) Marked or otherwise identified in the contract, task order, or delivery order and provided to the Contractor by or on behalf of DOT in support of the performance of the contract; or

(2) Collected, developed, received, transmitted, used, or stored by or on behalf of the Contractor in support of the performance of the contract.

Cyber incident means actions taken through the use of computer networks that result in a compromise or an actual or potentially adverse effect on an information system and/or the information residing therein.

Federal record as defined in 44 U.S.C. 3301, includes all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them. The term Federal record—

(1) Includes all DOT records;

(2) Does not include personal materials;

(3) Applies to records created, received, or maintained by Contractors pursuant to a DOT contract; and

(4) May include deliverables and documentation associated with deliverables.

Forensic analysis means the practice of gathering, retaining, and analyzing computer-related data for investigative purposes in a manner that maintains the integrity of the data.

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

Malicious software means computer software or firmware intended to perform an unauthorized process that will have adverse impact on the confidentiality, integrity, or availability of an information system. This definition includes a virus, worm, Trojan horse, or other code-based entity that infects a host, as well as spyware and some forms of adware.

Media means physical devices or writing surfaces including, but not limited to, magnetic tapes, optical disks, magnetic disks, large-scale integration memory chips, and printouts onto which DOT sensitive data is recorded, stored, or printed within a covered contractor information system.

Operationally critical support means supplies or services designated by the Government as critical for airlift, sealift, intermodal transportation services, or logistical support that is essential to the mobilization, deployment, or sustainment of the Armed Forces in a contingency operation.

Spillage security incident means an incident that results in the transfer of classified or unclassified information onto an information system not accredited (*i.e.,* authorized) for the appropriate security level.

Technical information means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information, regardless of whether or not the clause is incorporated in this solicitation or contract. Examples of technical information include research and engineering data, engineering drawings, and associated lists, specifications, standards, process sheets, manuals, technical reports, technical orders, catalog-item identifications, data sets, studies and analyses and related information, and computer software executable code and source code.

(b) *Adequate security.* The Contractor shall provide adequate security on all covered contractor information systems. To provide adequate security, the Contractor shall implement, at a minimum, the following information security protections:

(1) For covered Contractor information systems that are part of an information technology (IT) service or system operated on behalf of the Government, the following security requirements apply:

(i) Cloud computing services shall be subject to the security requirements specified in the clause 1252.239–76, Cloud Computing Services, of this contract.

(ii) Any other such IT service or system (*i.e.,* other than cloud computing) shall be subject to the security requirements specified elsewhere in this contract.

(2) For covered Contractor information systems that are not part of an IT service or system operated on behalf of the Government and therefore are not subject to the security requirement specified at paragraph (b)(1) of this clause, the following security requirements apply:

(i) Except as provided in paragraph (b)(2)(iv) of this clause, the contractor information system shall be subject to the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800–171, Revision 2, ''Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations'' (available via the internet at *https://csrc.nist.gov/publications/detail/sp/800-171/rev-2/final*) in effect at the time the solicitation is issued or as authorized by the Contracting Officer.

(ii) The Contractor shall implement NIST SP 800–171, Rev. 2, no later than 30 days after the award of this contract. The Contractor shall notify Contract Officer of any security requirements specified by NIST SP 800–171, Rev. 2 not implemented within 30 days of time of contract award.

(iii) If the Offeror proposes to vary from any security requirements specified by NIST SP 800–171, Rev. 2 in effect at the time the solicitation is issued or as authorized by the Contracting Officer, the Offeror shall submit to the Contracting Officer, for consideration by the DOT Chief Information Officer (CIO), a written explanation of—

(A) Why a particular security requirement is not applicable; or

(B) How the Contractor will use an alternative, but equally effective, security measure to satisfy the requirements of NIST SP 800–171, Rev. 2.

(iv) The Office of the DOT CIO will evaluate offeror requests to vary from NIST SP 800–171, Rev. 2 requirements and inform the Offeror in writing of its decision before contract award. The Government will incorporate accepted variance(s) from NIST SP 800–171, Rev. 2 into any resulting contract.

(v) The Contractor need not implement any security requirement adjudicated by an authorized representative of the DOT CIO to be nonapplicable, or have an alternative, but equally effective, security measure that may be implemented in its place.

(vi) If the DOT CIO has previously adjudicated the contractor's requests indicating that a requirement is not applicable or that an alternative security measure is equally effective, a copy of that approval shall be provided to the Contracting Officer when the Contractor requests its recognition under this contract

(3) If the Contractor intends to use an external cloud service provider to store, process, or transmit any DOT sensitive data in performance of this contract, the Contractor shall require and ensure that the cloud service provider meets security requirements equivalent to those established by the Government for the Federal Risk and Authorization Management Program (FedRAMP) Moderate baseline (*https://www.fedramp.gov/resources/documents/*) and that the cloud service provider complies with requirements in paragraphs (c) through (h) of this clause for cyber incident reporting, malicious software, media preservation and protection, access to additional information and equipment necessary for forensic analysis, and cyber incident damage assessment.

(4) The Contractor will apply other information systems security measures when the Contractor reasonably determines that information systems security measures, in addition to those identified in paragraphs (b)(1) and (b)(2) of this clause, may be required to provide adequate security in a dynamic environment or to accommodate special circumstances (*e.g.,* medical devices) and any individual, isolated, or temporary deficiencies based on an assessed risk or vulnerability. These measures may be addressed in a system security plan, as required by, clause 1252.239–70, Security Requirements for Unclassified Information Technology Resources.

(c) *Cyber incident reporting requirement.* (1) When the Contractor discovers a cyber incident that affects a covered contractor information system or the DOT sensitive data residing therein, or that affects the contractor's ability to perform the requirements of the contract that are designated as operationally critical support and identified in the contract, the Contractor shall—

(i) Conduct a review for evidence of compromise of DOT sensitive data, including, but not limited to, identifying compromised computers, servers, specific data, and user accounts. This review shall also include analyzing covered contractor information system(s) that were part of the cyber incident, as well as other information systems on the Contractor's network(s), that may have been accessed as a result of the incident in order to identify compromised DOT sensitive data or whether the incident affects the Contractor's ability to provide operationally critical support; and

(ii) Rapidly report cyber incidents to DOT Security Operations Center (SOC) 24x7x365 at phone number: 571–209–3080 (Toll Free: 1–866–580–1852).

(d) *Cyber incident report.* The cyber incident report shall be treated as information created by or for DOT and shall include, at a minimum, the required elements in paragraph (c)(1)(i).

(e) *Spillage.* Upon notification by the Government of a spillage, or upon the Contractor's discovery of a spillage, the Contractor shall cooperate with the Contracting Officer to address the spillage in compliance with DOT policy.

(f) *Malicious software.* When the Contractor or subcontractors discover and isolate malicious software in connection with a reported cyber incident, the Contractor shall submit the malicious software to DOT in accordance with instructions provided by the Contracting Officer. Do not send the malicious software to the Contracting Officer.

(g) *Media preservation and protection.* When a Contractor discovers a cyber incident has occurred, the Contractor shall preserve and protect images of all known affected information systems identified in paragraph (c)(1)(i) of this clause and all relevant monitoring/packet capture data for at least 90 days from the submission of the cyber incident report to allow DOT to request the media or decline interest.

(h) *Access to additional information or equipment necessary for forensic analysis.* Upon request by DOT, the Contractor shall provide DOT with access to additional information or equipment that is necessary to conduct a forensic analysis.

(i) *Cyber incident damage assessment activities.* If DOT elects to conduct a damage assessment, the Contracting Officer will request that the Contractor provide all of the damage assessment information gathered in accordance with paragraph (c) of this clause.

(j) *DOT safeguarding and use of Contractor attributional/proprietary information.* The Government shall protect against the unauthorized use or release of information obtained from the Contractor (or derived from information obtained from the Contractor) under this clause that includes Contractor attributional/proprietary information, including such information submitted in accordance with paragraph (c). To the maximum extent practicable, the Contractor shall identify and mark attributional/proprietary information. In making an authorized release of such information, the Government will implement appropriate procedures to minimize the Contractor attributional/proprietary information that is included in such authorized release consistent with applicable law.

(k) *Use and release of Contractor attributional/proprietary information not created by or for DOT.* Information that is obtained from the Contractor (or derived from information obtained from the Contractor) under this clause that is not created by or for DOT is authorized to be released outside of DOT—

(1) To entities with missions that may be affected by such information;

(2) To entities that may be called upon to assist in the diagnosis, detection, or mitigation of cyber incidents;

(3) To Government entities that conduct counterintelligence or law enforcement investigations;

(4) To a support services contractor (''recipient'') that is directly supporting Government activities under a contract that includes the clause at 1252.239–73, Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information; or

(5) With Contractor's consent; or

(6) As otherwise required by law.

(l) *Use and release of Contractor attributional/proprietary information created by or for DOT.* Information that is obtained from the Contractor (or derived from information obtained from the Contractor) under this clause that is created by or for DOT (including the information submitted pursuant to paragraph (c) of this clause) is authorized to be used and released outside of DOT for purposes and activities authorized by paragraph (j) of this clause, and for any other lawful Government purpose or activity, subject to all applicable statutory, regulatory, and policy based restrictions on the Government's use and release of such information.

(m) The Contractor shall conduct activities under this clause in accordance with applicable laws and regulations on the interception, monitoring, access, use, and disclosure of electronic communications and data.

(n) *Other safeguarding or reporting requirements.* The safeguarding and cyber incident reporting required by this clause in no way abrogates the Contractor's responsibility for other safeguarding or cyber incident reporting pertaining to its unclassified information systems as required by other applicable clauses of this contract, or as a result of other applicable Government statutory or regulatory requirements.

(o) *Subcontract flowdown requirements.* The Contractor shall—

(1) Include this clause, including this paragraph (o), in subcontracts, or similar contractual instruments, for operationally critical support, or for which subcontract performance will involve DOT sensitive data, including subcontracts for commercial products and commercial services, without alteration, except to identify the parties. The Contractor shall determine if the information required for subcontractor performance retains its identity as DOT sensitive data and will require protection under this clause, and, if necessary, consult with the Contracting Officer; and

(2) Require subcontractors to—

(i) Notify the prime Contractor (or next higher-tier subcontractor) when submitting a request to vary from a NIST SP 800–171, Rev. 2 security requirement to the Contracting Officer, in accordance with paragraph (b)(2)(iii) of this clause; and

(ii) Provide the incident report number, automatically assigned by DOT, to the prime Contractor (or next higher-tier subcontractor) as soon as practicable, when reporting a cyber incident to DOT as required in paragraph (c) of this clause.

(End of clause)

1252.239–75 DOT Protection of Information About Individuals, PII, and Privacy Risk Management Requirements.

As prescribed in 1239.7104, insert the following clause:

DOT Protection of Information About Individuals, PII, and Privacy Risk Management Requirements (NOV 2022)

(a) *Compliance with standards.* To the extent Contractor creates, maintains, acquires, discloses, uses, or has access to PII in furtherance of the contract, Contractor shall comply with all applicable Federal law, guidance, and standards and DOT policies pertaining to its protection. Contractor shall notify DOT in writing immediately upon the discovery that Contractor is no longer in compliance with DOT data protection standards with respect to any PII.

(b) *Unanticipated threats.* If new or unanticipated threats or hazards are discovered by either the Government or the Contractor, or if existing safeguards have ceased to function, the discoverer shall immediately bring the situation to the attention of the other party.

(c) *Privacy Act.* The Contractor will—

(1) Comply with the Privacy Act of 1974, 5 U.S.C. 552a, DOT implementing regulations (49 CFR part 10), and DOT policies issued under the Act in the design, development, and/or operation of any system of records on individuals to accomplish a DOT function when the contract specifically identifies the work that the Contractor is to perform.

(2) Include the Privacy Act notification contained in this contract in every solicitation and resulting subcontract and in every subcontract awarded without a solicitation, when the work statement in the proposed subcontract requires the redesign, development, and/or operation of a system of records on individuals that is subject to the Act; and

(3) Include this clause, including this paragraph (c), in all subcontracts awarded under this contract which requires the design, development, and/or operation of such a system of records.

(d) *Privacy Act records.* The Contractor shall not release records subject to the Privacy Act except by the direction of the DOT, regardless of whether DOT or the Contractor maintains the records.

(e) *Confidentiality agreement.* Contractor agrees to execute a confidentiality agreement protecting PII, when necessary, and further agrees not to appropriate such PII for its own use or to disclose such information to third parties unless specifically authorized by DOT in writing.

(f) *Surrender of records.* If at any time during the term of the Contract any part of PII, in any form, that Contractor obtains from or on behalf of DOT ceases to be required by Contractor for the performance of its obligations under the Contract, or upon termination of the Contract, whichever occurs first, Contractor shall, within ten (10) business days, notify DOT and securely return such PII to DOT, or, at DOT's written request destroy, un-install and/or remove all copies of such PII in Contractor's possession or control, or such part of the PII which relates to the part of the Contract which is terminated, or the part no longer required, as appropriate, and certify to DOT that the requested action has been completed.

(g) *NIST FIPS 140–2.* At a minimum, the Contractor shall protect all PII created, collected, used, maintained, or disseminated on behalf of the Department using controls consistent with Federal Information Processing Standard Publication 199 (FIPS 199) moderate confidentiality standards, unless otherwise authorized by the DOT Chief Privacy Officer.

(h) *Protection of sensitive information.* The Contractor shall comply with Government and DOT guidance for protecting PII.

(i) *Breach.* The Contractor shall bear all costs, losses, and damages resulting from the Contractor's breach of these clauses. Contractor agrees to release, defend, indemnify, and hold harmless DOT for claims, losses, penalties, and damages and costs to the extent arising out of Contractor's, or its subcontractor's, negligence, unauthorized use or disclosure of PII and/or Contractor's, or its subcontractor's, breach of its obligations under these clauses.

(j) *Breach reporting.* Contractors shall report breaches involving PII directly to DOT at (202) 385–4357 or 1–(866)–466–5221 within two (2) hours of discovery. Contractor shall provide the incident number automatically assigned by DOT for all breaches reported by the Contractor or any subcontractors to the Contracting Officer.

(k) *Applicability.* Contractor shall inform all principals, officers, employees, agents and subcontractors engaged in the performance of this contract of the obligations contained in these clauses.

(l) *Training.* To the extent necessary and/or required by law, the Contractor shall provide training to employees, agents, and subcontractors to promote compliance with these clauses. The Contractor is liable for any breach of these clauses by any of its principals, officers, employees, agents, and subcontractors.

(m) *Subcontractor engagement.* When the Contractor engages a subcontractor in connection with its performance under the contract, and the Contractor provides such subcontractor access to PII, the Contractor shall provide the Contracting Officer with prompt notice of the identity of the subcontractor and the extent of the role that the subcontractor will play in connection with the performance of the contract. This obligation is in addition to any limitations of subcontracting and consent to subcontract requirements identified elsewhere in the clauses and provisions of this contract.

(n) *Subcontract flowdown requirements.* Contractors shall flow down this clause to all subcontracts and purchase orders or other

agreements and require that subcontractors incorporate this clause in their subcontracts, appropriately modified for identification of the parties. The Contractor shall enforce the terms of the clause, including action against its subcontractors, their employees and associates, or third-parties, for noncompliance. All subcontractors given access to any PII must agree to—

(1) Abide by the clauses set forth herein, including, without limitation, provisions relating to compliance with data privacy standards for the Protection of Data about Individuals, Breach Notification Controls, and Notice of Security and/or Privacy Incident;

(2) Restrict use of PII only for subcontractor's internal business purposes and only as necessary to render services to Contractor in connection with Contractor's performance of its obligations under the contract;

(3) Certify in writing, upon completion of services provided by a subcontractor, that the subcontractor has returned to the Contractor all records containing PII within 30 days of subcontractor's completion of services to Contractor. Failure of subcontractor to return all records containing PII within this period will be reported to DOT as a privacy incident; and

(4) Report breaches involving PII directly to DOT at (202) 385–4357 or 1-(866)-466–5221 within two (2) hours of discovery. Subcontractors shall provide the incident report number automatically assigned by DOT to the prime contractor. Lower-tier subcontractors, likewise, shall report the incident report number automatically assigned by DOT to their higher-tier subcontractor until the prime contractor is reached. Contractor shall provide the DOT incident number to the Contracting Officer.

(End of clause)

1252.239–76 Cloud Computing Services.

As prescribed in 1239.7204(a), insert the following clause:

Cloud Computing Services (NOV 2022)

(a) *Definitions.* As used in this clause—

Authorizing official, as described in Appendix B of DOT Order 1350.37, Departmental Cybersecurity Policy, means the senior Federal official or executive with the responsibility for operating an information system at an acceptable level of risk to organizational operations (including mission, functions, image, or reputation), organizational assets, individuals, other organizations, and the Nation.

Cloud computing means a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (*e.g.,* networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. This includes other commercial terms, such as on-demand self-service, broad network access, resource pooling, rapid elasticity, and measured service. It also includes commercial offerings for software-as-a-service, infrastructure-as-a-service, and platform-as-a-service.

Compromise means disclosure of information to unauthorized persons, or a violation of the security policy of a system, whereby without authorization information is disclosed, modified, destroyed, lost, or copied to unauthorized media—whether intentionally or unintentionally.

Cyber incident means actions taken through the use of computer networks that result in a compromise or an actual or potentially adverse effect on an information system and/or the information residing therein.

Government data means any information, document, media, or material regardless of physical form or characteristics, that is created or obtained by the Government in the course of official Government business.

Government-related data means any information, document, media, or material regardless of physical form or characteristics that is created or obtained by a Contractor through the storage, processing, or communication of Government data. This does not include contractor's business records *e.g.,* financial records, legal records etc. or data such as operating procedures, software coding, or algorithms that are not uniquely applied to the Government data.

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

Media means physical devices or writing surfaces including, but not limited to, magnetic tapes, optical disks, magnetic disks, large-scale integration memory chips, and printouts onto which information is recorded, stored, or printed within an information system.

Spillage security incident means an incident that results in the transfer of classified information onto an information system not accredited (*i.e.,* authorized) for the appropriate security level.

(b) *Cloud computing security requirements.* The requirements of this clause are applicable when using cloud computing to provide information technology services in the performance of the contract.

(1) If the Contractor indicated in its offer that it does not anticipate the use of cloud computing services in the performance of a resultant contract, and after the award of this contract, the Contractor proposes to use cloud computing services in the performance of the contract, the Contractor shall obtain approval from the Contracting Officer prior to utilizing cloud computing services in performance of the contract.

(2) The Contractor shall implement and maintain administrative, technical, and physical safeguards and controls with the security level and services required in accordance with the DOT Order 1351.37, Departmental Cybersecurity Policy, and the requirements of DOT Order 1351.18, Departmental Privacy Risk Management Policy (the versions of each that in effect at the time the solicitation is issued or as authorized by the Contracting Officer), unless notified by the Contracting Officer that this requirement has been waived by the DOT Chief Information Officer.

(3) The Contractor shall maintain all Government data not physically located on DOT premises within the United States, the District of Columbia, and all territories and possessions of the United States, unless the Contractor receives written notification from the Contracting Officer to use another location, in accordance with DOT Policy.

(4) DOT will determine the security classification level for the cloud system in accordance with Federal Information Processing Standard 199; the Contractor will then apply the appropriate set of impact baseline controls as required in the FedRAMP Cloud Computing Security Requirements Baseline document to ensure compliance with security standards. The FedRAMP baseline controls are based on NIST Special Publication 800–53, Revision 5, Security and Privacy Controls for Information Systems and Organizations, Security Control Baselines and also includes a set of additional controls for use within systems providing cloud services to the Federal government.

(5) The Contractor shall maintain a security management continuous monitoring environment that meets or exceeds the requirements in the Reporting and Continuous Monitoring section of this contract/task order _____ [*Fill-in: Contracting Officer enter the requirements document paragraph reference number*] based upon the latest edition of FedRAMP Cloud Computing Security Requirements Baseline and FedRAMP Continuous Monitoring Requirements.

(6) The Contractor shall be responsible for the following privacy and security safeguards:

(i) To the extent required to carry out the FedRAMP assessment and authorization process and FedRAMP continuous monitoring, to safeguard against threats and hazards to the security, integrity, and confidentiality of any non-public Government data collected and stored by the Contractor, the Contractor shall provide the Government access to the Contractor's facilities, installations, technical capabilities, operations, documentation, records, and databases.

(ii) The Contractor shall also comply with any additional FedRAMP and DOT Orders containing cybersecurity and privacy policies.

(7) The Government may perform manual or automated audits, scans, reviews, or other inspections of the vendor's IT environment being used to provide or facilitate services for the Government. In accordance with the Federal Acquisition Regulation (FAR) clause 52.239–1, Privacy or Security Safeguards, the Contractor shall provide the Government access to Contractor's facilities, installations, technical capabilities, operations, documentation, records and databases to carry out a program of inspection. Contractors shall provide access within two hours of notification by the Government. The program of inspection shall include, but is not limited to—

(i) Authenticated and unauthenticated operating system/network vulnerability; scans;

(ii) Authenticated and unauthenticated web application vulnerability scans;

(iii) Authenticated and unauthenticated database application vulnerability scans; and

(8) Automated scans can be performed by Government personnel, or agents acting on behalf of the Government, using Government operated equipment, and Government specified tools.

(9) If new or unanticipated threats or hazards are discovered by either the Government or the Contractor, or if existing safeguards have ceased to function, the discoverer shall immediately bring the situation to the attention of the other party.

(10) If the vendor chooses to run its own automated scans or audits, results from these scans may, at the Government's discretion, be accepted in lieu of Government performed vulnerability scans. In these cases, the Government will approve scanning tools and their configuration. In addition, the Contractor shall provide complete results of vendor-conducted scans to the Government.

(c) *Limitations on access to and use and disclosure of Government data and Government-related data.*

(1) The Contractor shall not access, use, or disclose Government data unless specifically authorized by the terms of this contract or a task order or delivery order issued hereunder.

(i) If authorized by the terms of this contract or a task order or delivery order issued hereunder, any access to, or use or disclosure of, Government data shall only be for purposes specified in this contract or task order or delivery order.

(ii) The Contractor shall ensure that its employees are subject to all such access, use, and disclosure prohibitions and obligations.

(iii) These access, use, and disclosure prohibitions and obligations shall survive the expiration or termination of this contract.

(2) The Contractor shall use Government-related data only to manage the operational environment that supports the Government data and for no other purpose unless otherwise permitted with the prior written approval of the Contracting Officer.

(d) *Cloud computing services cyber incident reporting.* The Contractor shall report all cyber incidents related to the cloud computing service provided under this contract. to DOT via the DOT Security Operations Center (SOC) 24 hours-a-day, 7 days-a-week, 365 days a year (24x7x365) at phone number: 571–209–3080 (Toll Free: 866–580–1852) within 2 hours of discovery.

(e) *Spillage.* Upon notification by the Government of a spillage, or upon the Contractor's discovery of a spillage, the Contractor shall cooperate with the Contracting Officer to address the spillage in compliance with agency procedures.

(f) *Malicious software.* The Contractor or subcontractor(s) that discovers and isolates malicious software in connection with a reported cyber incident shall submit the malicious software in accordance with instructions provided by the Contracting Officer.

(g) *Media preservation and protection.* When a Contractor discovers a cyber incident has occurred, the Contractor shall preserve and protect images of all known affected information systems identified in the cyber incident report (*see* paragraphs (b)(5) and (d) of this clause) and all relevant monitoring/packet capture data for at least 90 days from the submission of the cyber incident report to allow DOT to request the media or decline interest.

(h) *Access to additional information or equipment necessary for forensic analysis.* Upon request by DOT, the Contractor shall provide DOT with access to additional information or equipment that is necessary to conduct a forensic analysis.

(i) *Cyber incident damage assessment activities.* If DOT elects to conduct a damage assessment, the Contracting Officer will request that the Contractor provide all of the damage assessment information gathered in accordance with paragraph (b)(7) of this clause.

(j) *Subcontract flowdown requirement.* The Contractor shall include this clause, including this paragraph (j), in all subcontracts that involve or may involve cloud services, including subcontracts for commercial products or commercial services.

(End of clause)

1252.239–77 Data Jurisdiction.

As prescribed in 1239.7204(b), insert a clause substantially as follows:

Data Jurisdiction (NOV 2022)

The Contractor shall identify all data centers in which the data at rest or data backup will reside, including primary and replicated storage. The Contractor shall ensure that all data centers not physically located on DOT premises reside within the United States, the District of Columbia, and all territories and possessions of the United States, unless otherwise authorized by the DOT CIO. The Contractor shall provide a Wide Area Network (WAN), with a minimum of _____ [*Contracting Officer fill-in: Insert specific number*] data center facilities at _____ [*Contracting Officer fill-in number]* different geographic locations with at least _____ [*Contracting Officer fill-in number*] internet Exchange Point (IXP) for each price offering. The Contractor shall provide internet bandwidth at the minimum of _____ [*Contracting Officer fill-in applicable gigabytes*] GB.

(End of clause)

1252.239–78 Validated Cryptography for Secure Communications.

As prescribed in 1239.7204(c), insert a clause substantially as follows:

Validated Cryptography for Secure Communications (NOV 2022)

(a) The Contractor shall use only cryptographic mechanisms that comply with _____ [*Contracting Officer insert FIPS 140–2 level #*]. All deliverables shall be labeled _____ [*Contracting Officer insert appropriate label such as ''For Official Use Only'' (FOUO) or other DOT-agency selected designation per document sensitivity*].

(b) External transmission/dissemination of _____ [*Contracting Officer fill-in: e.g., labeled deliverables*] to or from a Government computer must be encrypted. Certified encryption modules must be used in accordance with _____ [*Contracting Officer shall insert the standard, such as FIPS PUB 140–2, ''Security requirements for Cryptographic Modules.''*

(End of clause)

1252.239–79 Authentication, Data Integrity, and Non-Repudiation.

As prescribed in 1239.7204(d), insert a clause substantially as follows:

Authentication, Data Integrity, and Non-Repudiation (NOV 2022)

The Contractor shall provide a [*Fill-in: Contracting Officer fill-in the ''cloud service'' name*] system that implements _____ [*Contracting Officer insert the required level (1–4) of FIPS 140–2 encryption standard*] that provides for origin authentication, data integrity, and signer non-repudiation.

(End of clause)

1252.239–80 Audit Record Retention for Cloud Service Providers.

As prescribed in 1239.7204(e), insert the following clause:

Audit Record Retention for Cloud Service Providers (NOV 2022)

(a) The Contractor shall support a system in accordance with the requirement for Federal agencies to manage their electronic records in accordance with 36 CFR 1236.20 and 1236.22, including but not limited to capabilities such as those identified in DoD STD–5015.2 V3, Electronic Records Management Software Applications Design Criteria Standard, NARA Bulletin 2008–05, July 31, 2008, Guidance concerning the use of email archiving applications to store email, and NARA Bulletin 2010–05 September 08, 2010, Guidance on Managing Records in Cloud Computing Environments.

(b) The Contractor shall maintain records to retain functionality and integrity throughout the records' full lifecycle including—

(1) Maintenance of links between records and metadata; and

(2) Categorization of records to manage retention and disposal, either through transfer of permanent records to NARA or deletion of temporary records in accordance with NARA approved retention schedules.

(End of clause)

1252.239–81 Cloud Identification and Authentication (Organizational Users) Multi-Factor Authentication.

As prescribed in 1239.7204(f), insert the following clause:

Cloud Identification and Authentication (Organizational Users) Multi-Factor Authentication (NOV 2022)

The Contractor shall support a secure, multi-factor method of remote authentication and authorization to identified Government Administrators that will allow Government-designated personnel the ability to perform management duties on the system. The Contractor shall support multi-factor authentication in accordance with National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS) Publication (PUB) Number 201–2,

Personal Identity Verification (PIV) of Federal Employees and Contractors, and OMB implementation guidance for personal identity verification.

(End of clause)

1252.239–82 Identification and Authentication (Non-Organizational Users).

As prescribed in 1239.7204(g), insert the following clause:

Identification and Authentication (Non-Organizational Users) (NOV 2022)

The Contractor shall support a secure, multi-factor method of remote authentication and authorization to identified Contractor Administrators that will allow Contractor designated personnel the ability to perform management duties on the system as required by the contract.

(End of clause)

1252.239–83 Incident Reporting Timeframes.

As prescribed in 1239.7204(h), insert the following clause:

Incident Reporting Timeframes (NOV 2022)

(a) The Contractor shall report all computer security incidents to the DOT Security Operations Center (SOC) in accordance with Subpart 1239.70—Information Security and Incident Response Reporting.

(b) Contractors and subcontractors are required to report cyber incidents directly to DOT via the DOT SOC 24 hours-a-day, 7 days-a-week, 365 days a year (24x7x365) at phone number: 571–209–3080 (Toll Free: 866–580–1852) within 2 hours of discovery, regardless of the incident category. See 1252.239–74, Safeguarding DOT Sensitive Data and Cyber Incident Reporting.

(End of clause)

1252.239–84 Media Transport.

As prescribed in 1239.7204(i), insert a clause substantially as follows:

Media Transport (NOV 2022)

(a) The Contractor shall document activities associated with the transport of DOT information stored on digital and non-digital media and employ cryptographic mechanisms to protect the confidentiality and integrity of this information during transport outside of controlled areas. This applies to—

(1) Digital media containing DOT or other Federal agency or other sensitive or third-party provided information that requires protection must be encrypted using FIPS 140–2 [*Contracting Officer insert required encryption mode, based on FIPS 199 risk category*] when transported outside of controlled areas; and

(2) Nondigital media must be secured using the same policies and procedures as paper.

(b) Contractors shall ensure accountability for media containing DOT or other Federal agency or other sensitive or third-party provided information that is transported outside of controlled areas. This can be accomplished through appropriate actions such as logging and a documented chain of custody form.

(c) DOT or other Federal agency sensitive or third-party provided information that resides on mobile/portable devices (*e.g.,* USB flash drives, external hard drives, and SD cards) must be encrypted using FIPS 140–2 [*Contracting Officer insert the required encryption mode based on FIPS 199 risk category*]. All Federal agency data residing on laptop computing devices must be protected with NIST-approved encryption software.

(End of clause)

1252.239–85 Personnel Screening—Background Investigations.

As prescribed in 1239.7204(j), insert the clause as follows:

Personnel Screening—Background Investigations (NOV 2022)

(a) Contractors shall provide support personnel who are U.S. persons maintaining a NACI clearance or greater in accordance with OMB memorandum M–05–24, Section C (*see https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2005/m05-24.pdf*).

(b) The Contractor shall furnish documentation reflecting favorable adjudication of background investigations for all personnel supporting the system. The Contractor shall also comply with Executive Order 12968, Access to Classified Information. DOT separates the risk levels for personnel working on Federal computer systems into three categories: low risk, moderate risk, and high risk. The Contractor is responsible for the cost of meeting all security requirements and maintaining assessment and authorization.

(c) The Contractor's employees with access to DOT systems containing sensitive information may be required to obtain security clearances (*i.e.,* Confidential, Secret, or Top Secret). National Security work designated ''special sensitive,'' ''critical sensitive,'' or ''non-critical sensitive,'' will determine the level of clearance required for contractor employees. Personnel security clearances for national security contracts in DOT will be processed according to the Department of Defense National Industrial Security Program Operating Manual (NISPOM).

(d) The Contracting Officer, through the Contracting Officer's Representative (COR) or Program Manager will ensure that all required information is forwarded to the Federal Protective Service (FPS) in accordance with the DOT Policy. FPS will then contact each Applicant with instructions for completing required forms and releases for the type of personnel investigation requested.

(e) Applicants will not be reinvestigated if a prior favorable adjudication is on file with FPS, OPM or DoD, there has been no break in service, and the position is identified at the same or lower risk level. Once a favorable FBI Criminal History Check (Fingerprint Check) has been returned, Applicants may receive a DOT identity credential (if required) and initial access to information systems holding DOT information.

(End of clause)

1252.239–86 Boundary Protection—Trusted Internet Connections.

As prescribed in 1239.7204(k), insert the clause as follows:

Boundary Protection—Trusted Internet Connections (NOV 2022)

The Contractor shall ensure that Federal information, other than non-sensitive information, being transmitted from Federal government entities to external entities using cloud services is inspected by Trusted internet Connections (TIC) processes or the Contractor shall route all external connections through a Trusted internet Connection (TIC).

(End of clause)

1252.239–87 Protection of Information at Rest.

As prescribed in 1239.7204(l), insert the clause as follows:

Protection of Information at Rest and in Transit (NOV 2022)

The Contractor shall provide security mechanisms for handling data at rest and in transit in accordance with FIPS 140–2 _____ [*Contracting officer insert encryption standard, based on NIST FIPS 199 categorization*].

(End of clause)

1252.239–88 Security Alerts, Advisories, and Directives.

As prescribed in 1239.7204(m), insert the clause as follows:

Security Alerts, Advisories, and Directives (NOV 2022)

The Contractor shall provide a list of its personnel, identified by name and role, who are assigned system administration, monitoring, and/or security responsibilities and who are designated to receive security alerts, advisories, and directives and individuals responsible for the implementation of remedial actions associated with them.

(End of clause)

1252.239–89 Technology Modernization.

As prescribed in 1239.7303(a), insert the following clause:

Technology Modernization (NOV 2022)

(a) *Modernization approach.* After issuance of the contract, the Government may solicit, and the Contractor is encouraged to propose independently, a modernization approach to the hardware, software, specifications, or other requirements of the contract. This modernization approach may be proposed to increase efficiencies (both system and process level), reduce costs, or strengthen the cyber security posture, or for any other purpose which presents an advantage to the Government. Furthermore, the modernization approach should, to the maximum extent practicable, align with how the commercial sector would solve the problem.

(b) *Proposal requirements.* As part of the proposed changes, the Contractor shall submit a price or cost proposal to the Contracting Officer for evaluation. Those proposed modernized improvements that are acceptable to the Government will be processed as modifications to the contract. At a minimum, the Contractor shall submit the following information with each proposal:

(1) A summary of how the modernized proposal aligns with the commercial sector approach and how the current approach is out of alignment/differs;

(2) A description of the difference between the existing contract requirement and the proposed change, and the comparative advantages and disadvantages of each;

(3) Itemized requirements of the contract that must be changed if the proposal is adopted and the proposed revision to the contract for each such change;

(4) An estimate of the changes in performance and price or cost, if any, that will result from adoption of the proposal;

(5) An evaluation of the effects the proposed changes would have on collateral costs to the Government, such as Government-furnished property costs, costs of related items, and costs of maintenance, operation and conversion (including Government application software);

(6) A statement of the schedule for contract modification adopting the proposal that maximizes benefits of the changes during the remainder of the contract, including supporting rationale; and

(7) Identification of impacts on contract cost and schedule. The Government is not liable for proposal preparation costs or for any delay in acting upon any proposal submitted pursuant to this clause.

(c) *Withdrawal.* The Contractor has a right to withdraw, in whole or in part, any proposal not adopted by contract modification within the period specified in the proposal. The decision of the Contracting Officer whether to accept any such proposal under this contract is final and not subject to the ''Disputes'' clause of this contract.

(d) *Product testing.* If the Government wishes to test and evaluate any item(s) proposed, the Contracting Officer will issue written directions to the Contractor specifying what item(s) will be tested, where and when the item(s) will be tested, to whom the item(s) is to be delivered, and the number of days (not to exceed 90 calendar days) that the item will be tested.

(e) *Contract modification.* The Contracting Officer may accept any proposal submitted pursuant to this clause by giving the Contractor written notice thereof. This written notice will be given by issuance of a modification to the contract. Until the Government issues a modification incorporating a proposal under this contract, the Contractor shall remain obligated to perform in accordance with the requirements, terms, and conditions of the existing contract.

(f) *Change orders.* If a proposal submitted pursuant to this clause is accepted and applied to this contract, the equitable adjustment increasing or decreasing the price or cost-plus-fixed-fee (CPFF) shall be in accordance with the procedures of the applicable ''Changes'' clause incorporated by reference in the contract. The resulting contract modification will state that it is made pursuant to this clause.

(End of clause)

1252.239–90 Technology Upgrades/ Refreshment.

As prescribed in 1239.7303(b), insert the following clause:

Technology Upgrades/Refreshment (NOV 2022)

(a) *Upgrade/refreshment approach.* After issuance of the contract, the Government may solicit, and the Contractor is encouraged to propose independently, technology improvements to the hardware, software, specifications, or other requirements of the contract. These improvements may be proposed to save money, to improve performance, to save energy, to satisfy increased data processing requirements, or for any other purpose that presents a technological advantage to the Government. As part of the proposed changes, the Contractor shall submit a price or cost proposal to the Contracting Officer for evaluation. Those proposed technology improvements that are acceptable to the Government will be processed as modifications to the contract. As a minimum, the following information shall be submitted by the Contractor with each proposal:

(1) A description of the difference between the existing contract requirement and the proposed change, and the comparative advantages and disadvantages of each;

(2) Itemized requirements of the contract that must be changed if the proposal is adopted, and the proposed revision to the contract for each such change;

(3) An estimate of the changes in performance and price or cost, if any, that will result from adoption of the proposal;

(4) An evaluation of the effects the proposed changes would have on collateral costs to the Government, such as Government-furnished property costs, costs of related items, and costs of maintenance, operation and conversion (including Government application software);

(5) A statement of the time by which the contract modification adopting the proposal must be issued so as to obtain the maximum benefits of the changes during the remainder of the contract including supporting rationale; and

(6) Identification of any impacts to contract completion time or delivery schedule. The Government is not liable for proposal preparation costs or for any delay in acting upon any proposal submitted pursuant to this clause. The Contractor has a right to withdraw, in whole or in part, any proposal not adopted by contract modification within the period specified in the proposal. The decision of the Contracting Officer whether to accept any such proposal under this contract is final and not subject to the ''Disputes'' clause of this contract.

(b) *Test and evaluation.* If the Government wishes to test and evaluate any item(s) proposed, the Contracting Officer will issue written directions to the Contractor specifying what item(s) will be tested, where and when the item(s) will be tested, to whom the item(s) is to be delivered, and the number of days (not to exceed 90 calendar days) that the item will be tested. The Contracting Officer may accept any proposal submitted pursuant to this clause by giving the Contractor written notice thereof. This written notice will be given by issuance of a modification to the contract. Unless and until a modification is executed to incorporate a proposal under this contract, the Contractor shall remain obligated to perform in accordance with the requirements, terms and conditions of the existing contract. If a proposal submitted pursuant to this clause is accepted and applied to this contract, the equitable adjustment increasing or decreasing the price or CPFF shall be in accordance with the procedures of the applicable ''Changes'' clause incorporated by reference in Section I of the contract. The resulting contract modification will state that it is made pursuant to this clause.

(End of clause)

1252.239–91 Records Management.

As prescribed in 1239.7403, insert the following clause:

Records Management (NOV 2022)

(a) *Definition.*

Federal record, as defined in 44 U.S.C. 3301, means all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them. The term Federal record:

(1) Includes all DOT records.

(2) Does not include personal materials.

(3) Applies to records created, received, or maintained by Contractors pursuant to a DOT contract.

(4) May include deliverables and documentation associated with deliverables.

(b) *Requirements.* (1) *Compliance.* Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to 44 U.S.C. chapters 21, 29, 31, and 33, NARA regulations at 36 CFR chapter XII, subchapter B, and those policies associated with the safeguarding of records covered by Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.

(2) *Applicability.* In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under, the legal control of the Government, are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended, and the Privacy Act of 1974 (5 U.S.C. 552a), as amended. Such Federal

records shall be managed and scheduled for disposition only as permitted by the Federal Records Act, other relevant statutes or regulations, and DOT Order 1351.28, Departmental Records Management Policy.

(3) *Records maintenance.* While DOT records are in the Contractor's custody, the Contractor is responsible for preventing the alienation or unauthorized destruction of DOT records, including all forms of mutilation. Records may not be removed from the legal custody of DOT or destroyed except in accordance with the provisions of the agency records schedules and with the written concurrence of the DOT or Component Records Officer, as appropriate. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, the Contractor must report the event to the Contracting Officer in accordance with 36 CFR part 1230, Unlawful or Accidental Removal, Defacing, Alteration, or Destruction of Records, for reporting to NARA.

(4) *Unauthorized disclosure.* The Contractor shall notify the Contracting Officer within two hours of discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the contract. The Contractor shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, documentary material, records and/or equipment. The Contractor shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Contracting Officer. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to DOT control or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or address prescribed in the contract. Destruction of records is expressly prohibited unless in accordance with the contract.

(c) *Non-public information.* The Contractor shall not create or maintain any records containing any non-public DOT information that are not specifically authorized by the contract.

(d) *Rights in data.* Rights in data under this contract are set forth in clauses prescribed by FAR part 27 and included in this contract, (*e.g.,* 52.227–14 Rights in Data—General). The Contractor must make any assertion of copyright in the data or other deliverables under this contract and substantiate such assertions. The Contractor must add or correct all limited rights, restricted rights, or copyright notices and take all other appropriate actions in accordance with the terms of this contract and the clauses included herein.

(e) *Notification of third-party access requests.* The Contractor shall notify the Contracting Officer promptly of any requests from a third party for access to Federal records, including any warrants, seizures, or subpoenas it receives, including those from another Federal, State, or local agency. The Contractor shall cooperate with the Contracting Officer to take all measures to protect Federal records, from any unauthorized disclosure.

(f) *Training.* All Contractor employees assigned to this contract who create, work with, or otherwise handle records are required to take DOT-provided records management training. The Contractor is responsible for confirming to the Contracting Officer that training, including initial training and any annual or refresher training, has been completed in accordance with agency policies.

(g) *Subcontract flowdown requirements.* (1) The Contractor shall incorporate the substance of this clause, its terms and requirements including this paragraph (g), in all subcontracts under this contract, and require written subcontractor acknowledgment of same.

(2) Violation by a subcontractor of any provision set forth in this clause will be attributed to the Contractor.

(End of clause)

1252.239–92 Information and Communication Technology Accessibility Notice.

As prescribed in 1239.203–70(a), insert the following provision:

Information and Communication Technology Accessibility Notice (NOV 2022)

(a) Any offeror responding to this solicitation must comply with established DOT Information and Communication Technology (ICT) (formerly known as Electronic and Information (EIT)) accessibility standards. Information about Section 508 is available at *https://www.section508.gov/.*

(b) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 1252.239–81, Information and Communication Technology Accessibility. In order to facilitate the Government's determination whether proposed ICT supplies and services meet applicable Section 508 accessibility standards, offerors must submit appropriate Section 508 Checklists, in accordance with the checklist completion instructions. The purpose of the checklists is to assist DOT acquisition and program officials in determining whether proposed ICT supplies or information, documentation and services support conform to applicable Section 508 accessibility standards. The checklists allow offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues.

(c) Respondents to this solicitation must identify any exception to Section 508 requirements. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, *i.e.,* after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

1252.239–93 Information and Communication Technology Accessibility.

As prescribed in 1239.203–70(b), insert the following clause:

Information and Communication Technology Accessibility (NOV 2022)

(a) All Information and Communication Technology (ICT) supplies, information, documentation and services support developed, acquired, maintained or delivered under this contract or order must comply with the Information and Communication Technology (ICT) Standards and Guidelines (*see* 36 CFR parts 1193 and 1194). Information about Section 508 is available at *https://www.section508.gov/.*

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Specification, Statement of Work, or Performance Work Statement. If it is determined by the Government that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) The Section 508 accessibility standards applicable to this contract are: _____ [*Contracting Officer inserts the applicable Section 508 accessibility standards*].

(d) In the event of a modification(s) to this contract or order, which adds new ICT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the Contractor submit a completed Section 508 Checklist and any other additional information necessary to assist the Government in determining that the ICT supplies or services conform to Section 508 accessibility standards. If the Government determines that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an indefinite-delivery type contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include ICT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed Section 508 Checklist and any other additional information necessary to assist the Government in determining that the ICT supplies or services conform to Section 508 accessibility standards. If it is determined by the

Government that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

1252.242–70 Dissemination of Information—Educational Institutions.

As prescribed in 1242.270(a), insert the following clause:

Dissemination of Information—Educational Institutions (NOV 2022)

(a) The Department of Transportation (DOT) desires widespread dissemination of the results of funded transportation research. The Contractor, therefore, may publish (subject to the provisions of the ''Data Rights'' and ''Patent Rights'' clauses of the contract) research results in professional journals, books, trade publications, or other appropriate media (a thesis or collection of theses should not be used to distribute results because dissemination will not be sufficiently widespread). All costs of publication pursuant to this clause shall be borne by the Contractor and shall not be charged to the Government under this or any other Federal contract.

(b) Any copy of material published under this clause must contain acknowledgment of DOT's sponsorship of the research effort and a disclaimer stating that the published material represents the position of the author(s) and not necessarily that of DOT. Articles for publication or papers to be presented to professional societies do not require the authorization of the Contracting Officer prior to release. However, two copies of each article shall be transmitted to the Contracting Officer at least two weeks prior to release or publication.

(c) Press releases concerning the results or conclusions from the research under this contract shall not be made or otherwise distributed to the public without prior written approval of the Contracting Officer.

(d) Publication under the terms of this clause does not release the Contractor from the obligation of preparing and submitting to the Contracting Officer a final report containing the findings and results of research, as set forth in the schedule of the contract.

(End of clause)

1252.242–71 Contractor Testimony.

As prescribed in 1242.270(b), insert the following clause:

Contractor Testimony (NOV 2022)

All requests for the testimony of the Contractor or its employees, and any intention to testify as an expert witness relating to: (a) any work required by, and/or performed under, this contract; or (b) any information provided by any party to assist the Contractor in the performance of this contract, shall be immediately reported to the Contracting Officer. Neither the Contractor nor its employees shall testify on a matter related to work performed or information provided under this contract, either voluntarily or pursuant to a request, in any judicial or administrative proceeding unless approved, in advance, by the Contracting Officer or required by a judge in a final court order.

(End of clause)

1252.242–72 Dissemination of Contract Information.

As prescribed in 1242.270(c), insert the following clause:

Dissemination of Contract Information (NOV 2022)

The Contractor shall not publish, permit to be published, or distribute for public consumption, any information, oral or written, concerning the results or conclusions made pursuant to the performance of this contract, without the prior written consent of the Contracting Officer. Two copies of any material proposed to be published or distributed shall be submitted to the Contracting Officer.

(End of clause)

1252.242–74 Contract Audit Support.

As prescribed in 1242.170, insert the following clause:

Contract Audit Support (NOV 2022)

The Government may at its sole discretion utilize certified public accountant(s) to provide contract audit services in lieu of the cognizant government audit agency to accomplish the contract administration requirements of FAR parts 32 and 42 under the terms and conditions of this contract. The audit services contractor reviewing the Contractor's accounting systems and data will perform this function in accordance with contract provisions which prohibit disclosure of proprietary financial data or use of such data for any purpose other than to perform the required audit services. The Contractor shall provide access to accounting systems, records, and data to the audit services contractor like that provided to the cognizant government auditor.

(End of clause)

Subpart 1252.3—Provision and Clause Matrix

1252.301 Solicitation provisions and contract clauses (matrix).

The TAR matrix is not published in the CFR. It is available on the *Acquisition.gov* website at *https://www.acquisition.gov/TAR.*

PART 1253—FORMS

Subpart 1253.2—Prescription of Forms

Subpart 1253.3—Forms Used in Acquisitions

Authority: 5 U.S.C. 301; 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 1253.2—Prescription of Forms

1253.204–70 Administrative matters—agency specified forms.

The following forms are prescribed for use in the closeout of applicable contracts, as specified in 1204.804–570:

(a) *Department of Transportation (DOT) Form DOT F 4220.4, Contractor's Release.* Form DOT F 4220.4 is authorized for local reproduction and a copy may be obtained at *https://www.transportation.gov/assistant-secretary-administration/procurement/tar-part-1253-forms.*

(b) *Form DOT F 4220.45, Contractor's Assignment of Refunds, Rebates, Credits, and Other Amounts.* Form DOT F 4220.45 is authorized for local reproduction and a copy may be obtained at *https://www.transportation.gov/assistant-secretary-administration/procurement/tar-part-1253-forms.*

(c) *Form DOT F 4220.46, Cumulative Claim and Reconciliation Statement.* Form DOT F 4220.46 is authorized for local reproduction and a copy may be obtained at *https://www.transportation.gov/assistant-secretary-administration/procurement/tar-part-1253-forms.*

(d) *Department of Defense DD Form 882, Report of Inventions and Subcontracts.* DD Form 882 can be found at *https://www.esd.whs.mil/Directives/forms/.*

1253.227 Patents, data, and copyrights.

1253.227–3 Patent rights under Government contracts.

The following form is prescribed as a means for contractors to report inventions made during contract performance, as specified in 1227.305–4: Department of Defense DD Form 882, Report of Inventions and Subcontracts. DD Form 882 can be found at *https://www.esd.whs.mil/Directives/forms/.*

Subpart 1253.3—Forms Used in Acquisitions

1253.300–70 DOT agency forms.

This subpart identifies, in numerical sequence, agency forms that are specified by the TAR for use in acquisitions. See table 1 to 1253.300–70. Forms are also accessible in Adobe PDF and Microsoft Word files on the DOT Office of Senior Procurement Executive website at *https://www.transportation.gov/assistant-secretary-administration/procurement/tar-part-1253-forms.*

TABLE 1 TO 1253.300–70—FORMS USED IN DOT ACQUISITIONS

Form name	Form No.
Contractor's Release Form	4220.4
Contractor's Assignment of Refunds, Rebates, Credits, and other Amounts.	4220.45
Cumulative Claim and Reconciliation Statement	4220.46

PARTS 1254–1299 [RESERVED]

[FR Doc. 2022–19907 Filed 10–6–22; 8:45 am]

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FEDERAL REGISTER

Vol. 87 Friday,
No. 194 October 7, 2022

Part III

The President

Proclamation 10466—German-American Day, 2022

Federal Register
Vol. 87, No. 194
Friday, October 7, 2022

Presidential Documents

Title 3—

The President

Proclamation 10466 of October 5, 2022

German-American Day, 2022

By the President of the United States of America

A Proclamation

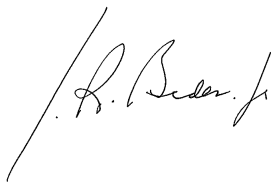
Since 1683, when thirteen families arrived in Philadelphia and founded the first German settlement in North America, generations of Germans have put their faith in the promises of this land and set down roots in communities across this country. On German-American Day, we honor the German immigrants who added their dreams to the American story, and we celebrate their descendants who continue to nurture and enrich the soul of this Nation.

From championing the anti-slavery movement to helping establish the freedom of the press, from introducing the concept of kindergarten to advocating for universal education, and from inspiring the music we love to influencing the food we eat and beer we drink—German-Americans have strengthened our Nation's character and sustained our progress and prosperity. Today, they are leaders in every industry and every community, spearheading innovation and making essential contributions to our Nation's success.

On German-American Day, let us also reaffirm the United States' vital alliance with Germany and our enduring bonds to its people. As the closest of friends, the most reliable of partners, and strong NATO Allies, our countries work together around the world to advance our shared commitment to democratic principles, human rights, and the rules-based international order. Together, we will continue to stand against authoritarianism and advance freedom and opportunity for all people.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim October 6, 2022, as German-American Day. I urge all Americans to celebrate the rich and varied history of German-Americans and remember the many contributions they have made to our Nation.

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



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FEDERAL REGISTER PAGES AND DATE, OCTOBER

CFR PARTS AFFECTED DURING OCTOBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *https://www.archives.gov/federal-register/laws/current.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text is available at *https://www.govinfo.gov/app/collection/plaw*. Some laws may not yet be available.

H.R. 5577/P.L. 117–184
To designate the facility of the United States Postal Service located at 3900 Crown Road Southwest in Atlanta, Georgia, as the ''John R. Lewis Post Office Building''. (Oct. 4, 2022; 136 Stat. 2196)

H.R. 6899/P.L. 117–185
Russia and Belarus SDR Exchange Prohibition Act of 2022 (Oct. 4, 2022; 136 Stat. 2197)

Last List October 4, 2022

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