



FEDERAL REGISTER

Vol. 90

Thursday,

No. 236

December 11, 2025

Pages 57351–57674

OFFICE OF THE FEDERAL REGISTER



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

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Rural Housing Service

Rural Business-Cooperative Service

7 CFR Part 5001

[Docket No. RUS–19–Agency–0030]

RIN 0572–AC63

OneRD Guaranteed Loan Regulation

AGENCY: Rural Business-Cooperative Service, Rural Housing Service, Rural Utilities Service, USDA.

ACTION: Final rule; technical amendments.

SUMMARY: On September 30, 2024, Rural Development’s Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service, agencies of the United States Department of Agriculture (USDA), published a final rule with comment for the OneRD Guarantee Loan Program (OneRD). The final rule made necessary revisions to the policy and procedures that strengthened the oversight and management of the growing Community Facilities, Water and Waste Disposal, Business and Industry, and Rural Energy for America guarantee portfolios. Following implementation of this final rule, the Agency found that corrections were necessary due to an incorrect definition of affiliate, and a section and sentence that were removed erroneously. This document corrects the final regulation.

DATES: This rule is effective December 11, 2025.

ADDRESSES: Address all comments concerning this correction to Crystal Pemberton, Regulations Management Division, Rural Development Innovation Center, U.S. Department of Agriculture, 1400 Independence Ave. SW, Stop 1522, Washington, DC 20250; telephone

(202) 260–8621; email Crystal.Pemberton@usda.gov.

FOR FURTHER INFORMATION CONTACT:

Crystal Pemberton, Regulations Management Division, Rural Development Innovation Center, U.S. Department of Agriculture, 1400 Independence Ave. SW, Stop 1522, Washington, DC 20250; telephone (202) 260–8621; email Crystal.Pemberton@usda.gov.

SUPPLEMENTARY INFORMATION: Rural Development’s Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service are issuing corrections to the final rule that published September 30, 2024, at 89 FR 79698.

The definition of “affiliate” has been modified to clarify that it means a person or entity that is closely attached or connected to another organization. For the purposes of program eligibility, the principles outlined in this regulation, and any successor regulation, are used to establish affiliation. Additionally, the Agency is adding the definition for “commercially available” as it was erroneously removed from the regulation previously.

List of Subjects in 7 CFR Part 5001

Business and industry, Community facility, Energy efficiency improvement, Loan programs, Renewable energy, Rural areas, Rural development, Water and waste disposal.

For the reasons discussed in the preamble, Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service amends 7 CFR part 5001 with the following technical amendments:

PART 5001—GUARANTEED LOANS

■ 1. The authority citation for part 5001 continues to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1926(a); 7 U.S.C. 1932(a); and 7 U.S.C. 8107.

■ 2. Amend § 5001.3 by revising the definition for “affiliate” and adding in alphabetical order the definition for “Commercially available” to read as follows:

§ 5001.3 Definitions.

* * * * *

Affiliate means a person or entity that is closely attached or connected to another person or entity. For the purposes of program eligibility, the

principles outlined in 13 CFR 121.301(f), and any successor regulation, are used to establish affiliation.

* * * * *

Commercially available means a system that meets the requirements of either paragraph (1) or (2) of this definition.

(1) A domestic or foreign system that:

(i) Has both a proven and reliable operating history and proven performance data for at least one year specific to the use and operation to the proposed application;

(ii) Is based on established design and installation procedures and practices and is replicable;

(iii) Has professional service providers, trades, large construction equipment providers, and labor who are familiar with installation procedures and practices;

(iv) Has proprietary and balance of system equipment and spare parts that are readily available;

(v) Has service that is readily available to properly maintain and operate the system; and

(vi) Has an existing established warranty that is valid in the United States for major parts and labor; or

(2) A domestic or foreign system that has been certified by a recognized industry organization whose certification standards are acceptable to the Agency.

* * * * *

■ 3. Amend § 5001.105 by revising paragraph (b)(7) to read as follows:

§ 5001.105 Eligible B&I projects and requirements.

* * * * *

(b) * * *

(7) Agricultural production, when not eligible for Farm Service Agency (FSA) farm loan programs assistance and when it is part of an integrated business also involved in the processing of agricultural products. Any agricultural production considered for guaranteed loan financing must be owned, operated, and maintained by the business receiving the guaranteed loan. Examples of potentially eligible agricultural production include but are not limited to an apple orchard in conjunction with a food processing plant; poultry buildings linked to a meat processing operation; or sugar beet production coupled with storage and processing.

(i) The agricultural production portion of any loan must not exceed 50 percent of the total loan or \$5 million, whichever is less.

(ii) The limitations in paragraph (b)(7)(i) do not apply to the following types of businesses:

(A) Commercial nurseries engaged in the production of ornamental plants, trees, and other nursery products, such as bulbs, flowers, shrubbery, flower and vegetable seeds, sod, and the growing of plants from seed to the transplant stage;

(B) Forestry, which includes businesses primarily engaged in the operation of timber tracts, tree farms, forest nurseries, harvesting of forest products, and related activities, such as reforestation;

(C) The growing or harvesting of mushrooms;

(D) The growing of hydroponics;

(E) The boarding and/or training of animals;

(F) Commercial fishing; and

(G) Production of algae and aquaculture, including conservation, development, and utilization of water for aquaculture.

* * * * *

■ 4. Amend § 5001.106 by revising the introductory paragraph to read as follows:

§ 5001.106 Eligible REAP—Renewable Energy System (RES) projects and requirements.

For a REAP RES project to be eligible for a loan guarantee under this part, it must meet the criteria specified in § 5001.102(a) through (c) and in paragraphs (a) through (e) of this section and be for a borrower eligible to submit an application for the project in accordance with § 5001.126. If taxable bonds are utilized as debt instruments the provisions of § 5001.105(b)(19) must be met.

* * * * *

Joe Gilson,

Chief of Staff, Rural Development.

[FR Doc. 2025–22567 Filed 12–10–25; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2025–1187; Airspace Docket No. 24–AWP–84]

RIN 2120–AA66

Modification and Revocation of Class E Airspace; Hawaiian Islands, HI; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule the FAA published in the **Federal Register** on November 26, 2025, that modified Class E airspace extending upward from 700 feet above the surface and the Class E airspace area designated as an extension to a Class D or Class E surface area at Ellison Onizuka Kona International at Keahole Airport (KOA), Kailua-Kona, HI. This action makes ministerial corrections to geographic coordinates.

DATES: The effective date of the final rule published in the **Federal Register** on November 26, 2025 (90 FR 54228) remains January 22, 2026, 0901 UTC. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11, Airspace Designations and Reporting Points, and publication of conforming amendments.

ADDRESSES: A copy of the notice of proposed rulemaking (NPRM), all comments received, the final rule, this final rule correction, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from www.federalregister.gov.

FAA Order JO 7400.11K, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Keith Adams, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S

216th Street, Des Moines, WA 98198; telephone (206) 231–2428.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (90 FR 54228; November 26, 2025), which modified the Class E airspace area extending upward from 700 feet or more above the surface and Class E airspace area designated as an extension to a Class D or Class E surface area at KOA. Subsequent to publication, and following a recent survey, the FAA amended the geographic coordinates for KOA. Accordingly, the updated geographic location will now serve as the point of origin from which the Class E airspace area boundaries are derived, no longer requiring reference to the Point in Space Alpha fix that appeared in the KOA’s airspace legal description in the final rule. This action is administrative only and corrects the coordinates.

Correction to the Final Rule

Accordingly, pursuant to the authority delegated to me, Modification and Revocation of Class E Airspace; Hawaiian Islands, HI, published in the **Federal Register** on November 26, 2025 (90 FR 54228), is corrected as follows:

§ 71.1 [Corrected]

■ 1. On page 54230, in the first column under the heading “AWP HI E4 Kailua-Kona, HI [Amended]”, the text is corrected to read as follows:

AWP HI E4 Kailua-Kona, HI [Amended]

Ellison Onizuka Kona International at Keahole Airport, HI

(Lat. 19°44′00″ N, long. 156°02′46″ W)

(Lat. 19°44′20″ N, long. 156°02′44″ W)

(Lat. 19°44′20″ N, long. 156°02′44″ W)

That airspace extending upward from the surface within 2.8 miles each side of the airport 186° bearing extending from the airport 4.3-mile radius to 5.7 miles south, and within 3.6 miles each side of the airport 002° bearing extending from the Point in Space Alpha 4.3-mile radius to 9.5 miles north.

■ 2. On page 54230, in the second column, under the heading “AWP HI E5 Kailua-Kona, HI, [Amended]”, the text is corrected to read as follows:

AWP HI E5 Kailua-Kona, HI [Amended]

Ellison Onizuka Kona International at Keahole Airport, HI

(Lat. 19°44′00″ N, long. 156°02′46″ W)

(Lat. 19°44′20″ N, long. 156°02′44″ W)

(Lat. 19°44′20″ N, long. 156°02′44″ W)

That airspace extending upward from 700 feet above the surface within a 7.4-mile radius of the airport, and within 4 miles each side of the airport 002° bearing extending from the 7.4-mile radius to 11 miles north;

and that airspace extending upward from 1,200 feet above the surface within 12 miles off the coastline of the Island of Hawaii.

Issued in Des Moines, Washington, on December 8, 2025.

B.G. Chew,

*Group Manager, Western Service Center,
Operations Support Group.*

[FR Doc. 2025–22501 Filed 12–10–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31638; Amdt. No. 4195]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 11, 2025. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 11, 2025.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Rune Duke, Manager (Acting), Standards Section, Flight Procedures and Airspace Group, Aviation Safety, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPs, Takeoff Minimums and/or ODPs. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The applicable FAA Forms are 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, pilots do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies

the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

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

amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on December 5, 2025.

Rune Duke,

Manager (Acting), Standards Section, Flight Procedures and Airspace Group, Flight Technologies & Procedures Division, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 22 January 2026

Dothan, AL, DHN, ILS OR LOC RWY 14, Amdt 2B
Dothan, AL, DHN, ILS OR LOC RWY 32, Amdt 10A
Dothan, AL, DHN, RNAV (GPS) RWY 14, Amdt 3A
Dothan, AL, DHN, RNAV (GPS) RWY 18, Amdt 3
Dothan, AL, DHN, VOR RWY 18, Amdt 4
West Palm Beach, FL, PBI, AHAB ONE, Graphic DP
West Palm Beach, FL, PBI, ILS OR LOC RWY 10L, Amdt 29
West Palm Beach, FL, PBI, RNAV (GPS) Y RWY 10L, Amdt 5
West Palm Beach, FL, PBI, Takeoff Minimums and Obstacle DP, Amdt 4
Newark, NJ, EWR, RNAV (GPS) W RWY 29, Orig-B
Newark, NJ, EWR, RNAV (RNP) Y RWY 29, Amdt 1F
Albany, NY, ALB, RNAV (GPS) RWY 28, Amdt 1
Ebensburg, PA, 9G8, RNAV (GPS) RWY 7, Orig-E
Nacogdoches, TX, OCH, ILS OR LOC RWY 36, Amdt 4
Nacogdoches, TX, OCH, RNAV (GPS) RWY 18, Amdt 1
Nacogdoches, TX, OCH, RNAV (GPS) RWY 36, Orig-E
Nacogdoches, TX, OCH, Takeoff Minimums and Obstacle DP, Amdt 3

Jackson, WY, JAC, VOR RWY 19, Amdt 1, CANCELED

[FR Doc. 2025–22511 Filed 12–10–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31639; Amdt. No. 4196]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 11, 2025. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 11, 2025.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Rune Duke, Manager (Acting), Standards Section, Flight Procedures and Airspace Group, Aviation Safety, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73099. Telephone (405) 954–1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, pilots do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C.

553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

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

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on December 5, 2025.

Rune Duke,

Manager (Acting), Standards Section, Flight Procedures and Airspace Group, Flight Technologies & Procedures Division, Federal Aviation Administration.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Procedure name
22-Jan-26 ...	NC	Louisburg	Triangle North Exec	5/7477	10/30/2025	ILS OR LOC RWY 5, Amdt 4C.
22-Jan-26 ...	NJ	Teterboro	Teterboro	5/7511	10/30/2025	RNAV (GPS) RWY 24, Orig.
22-Jan-26 ...	NJ	Teterboro	Teterboro	5/7524	10/30/2025	ILS OR LOC RWY 19, Amdt 1A.
22-Jan-26 ...	NJ	Teterboro	Teterboro	5/7525	10/30/2025	RNAV (GPS) X RWY 19, Orig.
22-Jan-26 ...	NJ	Teterboro	Teterboro	5/7529	10/30/2025	RNAV (GPS) X RWY 6, Amdt 3.
22-Jan-26 ...	NJ	Teterboro	Teterboro	5/7532	10/30/2025	RNAV (GPS) Y RWY 19, Amdt 1A.
22-Jan-26 ...	KS	Salina	Salina Rgnl	5/7707	10/30/2025	NDB RWY 35, Amdt 17C.

[FR Doc. 2025–22510 Filed 12–10–25; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION**17 CFR Part 249**

[Release No. 34–104349]

Technical Amendments to Commission Forms

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; technical amendments.

SUMMARY: The Securities and Exchange Commission (“Commission”) is adopting technical amendments to various forms under the Securities Exchange Act of 1934 (“Exchange Act”) to correct the address for the principal office of the Commission.

DATES: The amendments to the forms are effective December 11, 2025.

FOR FURTHER INFORMATION CONTACT: Justin Pica, Assistant Director, or Tyler

Raimo, Assistant Director, Office of Market Supervision, at (202) 551–5500, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is amending the following forms:

Commission reference	CFR citation (17 CFR)
<i>Forms, Securities Exchange Act of 1934:</i>	

Commission reference	CFR citation (17 CFR)
Form 1	§ 249.1
Form 1–N	§ 249.10
Form R31	§ 249.11
Form ATS	§ 249.637
Form ATS–R	§ 249.638
Form PILOT	§ 249.821

The amendments make technical corrections to certain Commission forms with respect to the Commission’s address in Washington DC, where the address appearing on a form was not updated when the Commission moved its principal office to 100 F Street NE, Washington, DC 20549. The text of these forms do not, and these amendments will not, appear in the Code of Federal Regulations.

Statutory Authority

We are adopting these technical amendments under the authority set forth in section 23(a) of the Exchange Act.

List of Subjects in 17 CFR Part 249

Brokers, Reporting and recordkeeping requirements, Securities.

Text of Amendments

For reasons set forth in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The authority for part 249 continues to read, in part, as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.*; 12 U.S.C. 5461 *et seq.*; 18 U.S.C. 1350; Sec. 953(b) Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3) Pub. L. 112–106, 126 Stat. 309 (2012), Sec. 107 Pub. L. 112–106, 126 Stat. 313 (2012), Sec. 72001 Pub. L. 114–94, 129 Stat. 1312 (2015), and secs. 2 and 3 Pub. L. 116–222, 134 Stat. 1063 (2020), unless otherwise noted.

* * * * *

■ 2. Amend Form 1 (referenced in § 249.1) by, in section A.8 of the instructions, removing the text “450 Fifth Street NW, Washington, DC 20549” and adding, in its place, the text “100 F Street NE, Washington, DC 20549”.

Note: Form 1 will not appear in the Code of Federal Regulations.

■ 3. Amend Form 1–N (referenced in § 249.10) by, in section A.8 of the instructions, removing the text “450 Fifth Street NW, Washington, DC 20549” and adding, in its place, the text “100 F Street NE, Washington, DC 20549”.

Note: Form 1–N will not appear in the Code of Federal Regulations.

■ 4. Amend Form R31 (referenced in § 249.11) by, in section B.8 of the instructions, removing the text “450 Fifth Street NW; Washington, DC 20549–1105” and adding, in its place, the text “100 F Street NE, Washington, DC 20549”.

Note: Form R31 will not appear in the Code of Federal Regulations.

■ 5. Amend Form ATS (referenced in § 249.637) and Form ATS–R (referenced in § 249.638) by, in section A.5 of the instructions, by removing the text “450 Fifth Street NW, Washington DC 20549–1002” and adding, in its place, the text “100 F Street NE, Washington, DC 20549”.

Note: Form ATS and Form ATS–R will not appear in the Code of Federal Regulations.

■ 6. Amend Form PILOT (referenced in § 249.821) by, in section A.5 of the instructions, removing the text “450 Fifth Street NW, Washington, DC 20549” and adding, in its place, the text “100 F Street NE, Washington, DC 20549”.

Note: Form PILOT will not appear in the Code of Federal Regulations.

Dated: December 9, 2025.

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2025–22583 Filed 12–10–25; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1356]

Schedules of Controlled Substances: Extension of Temporary Placement of MDMA-4en-PINACA in Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary scheduling order; extension.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to extend the temporary schedule I status of MDMA-4en-PINACA. The schedule I status of MDMA-4en-PINACA is in effect through December 12, 2025. This temporary order will extend the temporary scheduling of MDMA-4en-PINACA for one year, or until the permanent scheduling action for this substance is completed, whichever occurs first. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will continue to be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle MDMA-4en-PINACA.

DATES: This temporary scheduling order, which extends schedule I control of MDMA-4en-PINACA covered by an order (88 FR 86040, December 12, 2023), is effective December 12, 2025, and expires on December 12, 2026. If DEA publishes a final rule making this scheduling action permanent, this order will expire on the effective date of that rule, if the effective date is earlier than December 12, 2026.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: In this order, the Drug Enforcement Administration (DEA) extends the temporary scheduling of MDMA-4en-PINACA in schedule I of the Controlled Substances Act (CSA), including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- MDMA-4en-PINACA (methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3-carboxamido)butanoate).

Background and Legal Authority

On December 12, 2023, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the **Federal Register** temporarily placing MDMA-4en-PINACA in schedule I of the CSA based upon a finding that this substance poses an imminent hazard to the public safety.¹ That temporary order was effective upon the date of publication. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of a substance expires at the end of two years from the date of issuance of the scheduling order, except that DEA may extend temporary scheduling of that substance for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1) with the respect to the temporarily controlled substance. In this instance, the temporary scheduling of MDMA-4en-PINACA expires on December 12, 2025, unless extended.

Proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on her own motion, at the request of the Secretary of the Department of Health and Human Services (HHS), or on the petition of any interested party.² The Administrator of DEA, on his own motion pursuant to 21 U.S.C. 811(a), has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule MDMA-4en-PINACA. DEA is publishing a notice of proposed rulemaking elsewhere in this issue of the **Federal Register** for the permanent placement of MDMA-4en-PINACA in schedule I. If that proposed rule is finalized, DEA will publish a final rule in the FR to make permanent the schedule I status of this substance.

Pursuant to 21 U.S.C. 811(h)(2), the Administrator orders that the temporary scheduling of MDMA-4en-PINACA and

its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety.³ This provision of the CSA allows the Attorney General, by order, to temporarily place substances in schedule I.⁴ The same subsection also provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings to permanently schedule the substance under 21 U.S.C. 811(a)(1), extend the temporary scheduling for up to one year.

To the extent that 21 U.S.C. 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended, the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this extension of the temporary scheduling action. The APA expressly differentiates between orders and rules, as it defines an “order” to mean a “final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making.”⁵ This contrasts with permanent scheduling actions, which are subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” and final decisions that conclude the scheduling process and are subject to judicial review.⁶ The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an order instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking procedures for other kinds of scheduling actions,⁷ it is noteworthy that, in subsection 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even if this action were subject to 5 U.S.C. 553, the Administrator finds that there is good

cause to forgo the notice-and-comment requirements and the delayed effective date requirements of such section, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety that these substances would present if scheduling expired, for the reasons expressed in the temporary scheduling order.⁸

Further, DEA believes that this order extending the temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2) and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by the APA at 5 U.S.C. 553 or any other law to publish a general notice of proposed rulemaking. Therefore, in this instance, since DEA believes this temporary scheduling action is not a “rule,” it is not subject to the requirements of the RFA when issuing this temporary action.

In addition, in accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866, sec. 3(f), provides the definition of a “significant regulatory action,” requiring review by the Office of Management and Budget. Because this is not a rulemaking action, this is not a significant regulatory action as defined in subsection 3(f) of E.O. 12866. DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

This action will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the

¹ *Schedules of Controlled Substances: Temporary Placement of MDMA-4en-PINACA*, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I, 88 FR 86040 (Dec. 12, 2023).

² 21 U.S.C. 811(a). As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. *Memorandum of Understanding with the National Institute on Drug Abuse*, 50 FR 9518 (Mar. 8, 1985). Because the Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations, see *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91–513, As Amended; Delegation of Authority*, 58 FR 35460 (July 1, 1993), for purposes of this temporary order, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.”

³ 21 U.S.C. 811(h).

⁴ *Id.*

⁵ 5 U.S.C. 551(6) (emphasis added).

⁶ 21 U.S.C. 811(a) and 877.

⁷ See 21 U.S.C. 811(a).

⁸ See *Schedules of Controlled Substances: Temporary Placement of MDMA-4en-PINACA*, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I, 88 FR 86040 (Dec. 12, 2023).

distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, “any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.”⁹

It is in the public interest to maintain the temporary placement of MDMB-4en-PINACA, including its salts, isomers, and salts of isomers, in schedule I because it poses a public health risk. The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to keep this substance in schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Further, public notice and comment is impracticable in the amount of time remaining before expiration of the temporary scheduling order and considering the manifest urgency to avoid an imminent hazard to the public safety that this substance would present if scheduling expired, for the reasons expressed in the temporary scheduling order. Therefore, in accordance with subsection 808(2) of the CRA, this order extending the temporary scheduling order for MDMB-4en-PINACA, currently covered under the temporary order, shall take effect immediately upon its publication.

Nonetheless, DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 7, 2025, by Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–22540 Filed 12–10–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2025–0933]

Special Local Regulations; Marine Events Within the Coast Guard Southwest District

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce multiple special local regulations codified in federal regulations for recurring marine events taking place in December 2025 located in the Los Angeles-Long Beach Captain of the Port Zone. This action is necessary and intended to provide for the safety of life and property on navigable waterways during these events. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any official patrol vessel displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.1104 will be enforced for the times and locations described in event entries (5) through (16) in Table 1 to § 100.1104 during December 2025, according to the schedule listed in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kevin Kinsella, U.S. Coast

Guard Sector Los Angeles-Long Beach; telephone (310) 521–3860, email *D11-SMB-SectorLALB-WWM@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce multiple special local regulations for annual events in the Captain of the Port Los Angeles-Long Beach Zone listed in 33 CFR 100.1104 Table 1 to § 100.1104 for events occurring in the month of December as listed.

1. Entry (5) Morro Bay Holiday Boat Parade (also known as (a.k.a.) Morro Bay Lighted Boat Parade). From 5 p.m. to 9 p.m. on December 13, 2025.

2. Entry (6) Santa Barbara Holiday Boat Parade (a.k.a. Santa Barbara Annual Boat Parade of Lights). From 5 p.m. to 9:30 p.m. on December 14, 2025.

3. Entry (7) Ventura Harbor Holiday Boat Parade (a.k.a. Ventura Harbor Parade of Lights). From 6:30 p.m. to 8:30 p.m. daily on December 12 through December 13, 2025.

4. Entry (8) Channel Islands Harbor Holiday Boat Parade (a.k.a. Channel Islands Harbor Parade of Lights). From 7 p.m. to 9 p.m. on December 13, 2025.

5. Entry (9) Marina del Rey Holiday Boat Parade. From 5:55 p.m. to 8 p.m. on December 14, 2025.

6. Entry (10) King Harbor Holiday Boat Parade. From 5:30 p.m. to 8 p.m. on December 13, 2025.

7. Entry (11) Port of Los Angeles Holiday Boat Parade (a.k.a. LA Harbor Holiday Afloat Parade). From 5:30 p.m. to 9:30 p.m. on December 6, 2025.

8. Entry (12) Parade of 1,000 Lights (a.k.a. Shoreline Yacht Club Annual Christmas Boat Parade). From 5:30 p.m. to 7:30 p.m. on December 13, 2025.

9. Entry (13) Naples Island Holiday Boat Parade (a.k.a. Naples Boat Parade). From 5 p.m. to 9 p.m. on December 20, 2025.

10. Entry (14) Huntington Harbor Holiday Boat Parade (a.k.a. 62nd Annual Huntington Harbor Boat Parade). From 5 p.m. to 9 p.m. daily on December 13 through December 14, 2025.

11. Entry (15) Newport Beach Holiday Boat Parade (a.k.a. 126th Annual Christmas Boat Parade). From 6 p.m. to 10 p.m. daily on December 17 through December 21, 2025.

12. Entry (16) Dana Point Holiday in the Harbor (a.k.a. 49th Annual Dana Point Harbor Boat Parade of Lights). From 6:30 p.m. to 8:30 p.m. daily on December 12 through December 14, 2025.

Pursuant to 33 CFR 100.1104, all persons and vessels not registered with the sponsor as participants or as official patrol vessels are considered spectators. The “official patrol” consists of any

⁹ 5 U.S.C. 808(2).

Coast Guard; other Federal, state, or local law enforcement; and any public or sponsor-provided vessels assigned or approved by the cognizant Coast Guard Sector Commander to patrol each event. No spectator shall anchor, block, loiter, nor impede the through transit of participants or official patrol vessels in the regulated areas during all applicable effective dates and times unless cleared to do so by or through an official patrol vessel. When hailed and/or signaled by an official patrol vessel, any spectator located within a regulated area during all applicable effective dates and times shall come to an immediate stop. The Patrol Commander (PATCOM) is empowered to control the movement of all vessels in the regulated area or to restrict vessels from entering the regulated area. The Patrol Commander shall be designated by the cognizant Coast Guard Sector Commander; will be a U.S. Coast Guard commissioned officer, warrant officer, or petty officer to act as the Sector Commander's official representative; and will be located aboard the lead official patrol vessel. As the Sector Commander's representative, the PATCOM may terminate the event any time it is deemed necessary for the protection of life and property. PATCOM may be reached on VHF-FM Channel 13 (156.65MHz) or 16 (156.8MHz) when required, by the call sign "PATCOM." The Patrol Commander may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so. The Coast Guard may be assisted by other Federal, state, or local agencies.

This notice of enforcement is issued under authority of 33 CFR 100.1104 and 5 U.S.C. 552(a). In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via a Marine Safety Information Bulletin (MSIB) and a Broadcast Notice to Mariners (BNM). If the Captain of the Port Los Angeles-Long Beach determines that the Special Local Regulations need not to be enforced for the full duration stated in this notice, the Captain of the Port may use a Broadcast Notice to Mariners to reflect the change.

Stacey L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles-Long Beach.

[FR Doc. 2025-22558 Filed 12-10-25; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2025-1039]

RIN 1625-AA00

Safety Zone; Sandusky Bay, Sandusky, OH

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of Sandusky Bay within a 200-yard radius of 233 W Shoreline Drive, Sandusky, OH. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards during a fireworks event. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Detroit (COTP).

DATES: This rule is effective from 6 p.m. until 7 p.m. on December 13, 2025.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG-2025-1039.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST1 Cera Turner, Marine Safety Unit Toledo Waterways Management Division, U.S. Coast Guard; telephone 419-418-6050 or email D09-SMB-MSUToledo-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background and Authority

The Coast Guard received notification that fireworks will be launched from shore on Sandusky Bay near 233 W Shoreline Drive, Sandusky, OH on December 13, 2025. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port (COTP) Detroit has determined that potential hazards associated with fireworks are a safety concern for anyone within 200 yards of the

fireworks display. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

The Coast Guard is issuing this rule without prior notice and comment. As is authorized by 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 was notified of this event on October 31, 2025, but we must establish this safety zone by December 13, 2025, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reason, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a safety zone from 6 p.m. until 7 p.m. on December 13, 2025. The safety zone will cover all navigable waters of Sandusky Bay within 200 yards of the fireworks event. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or their designated representative.

IV. Regulatory Analyses

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

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business

Regulatory Fairness Boards by calling 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.

B. 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).

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This rule is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket.

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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; DHS Delegation No. 00170.1, Revision No. 01.4.

- 2. Add § 165.T09–1039 to read as follows:

§ 165.T09–1039 Safety Zone; Sandusky Bay, Sandusky, OH.

(a) *Location.* The following area is a safety zone: All waters of Sandusky Bay within a 200-yard radius of 233 W Shoreline Drive, Sandusky, OH.

(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 Sector Detroit (COTP) in the enforcement of the safety zone.

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

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

(d) *Enforcement period.* This section will be enforced from 6 p.m. to 7 p.m. on December 13, 2025.

Dated: December 5, 2025.

Richard P. Armstrong,

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

[FR Doc. 2025–22515 Filed 12–10–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0997]

RIN 1625–AA00

Safety Zone; Santa Barbara Harbor, Santa Barbara, CA

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable waters of Santa Barbara Harbor. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Los Angeles-Long Beach.

DATES: This rule is effective from 6:30 p.m. through 7:30 p.m. on December 14, 2025.

ADDRESSES: To view available documents, go to <https://www.regulations.gov> and search for USCG–2025–0997.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Commander Kevin Kinsella, U.S. Coast Guard Sector Los Angeles-Long Beach, Chief, Waterways Management Division; telephone (310) 521–3861, email D11-SMB-SectorLALB-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background and Authority

The Coast Guard received notification that fireworks will be launched from Santa Barbara Harbor's West Beach inside the jetties. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port (COTP) Los Angeles-Long Beach has determined that potential hazards associated with fireworks are a safety concern for anyone within the Santa Barbara Harbor channel entrance. Therefore, the COTP is issuing this rule

under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

The Coast Guard is issuing this rule without prior notice and comment. As is authorized by 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 the Coast Guard did not receive sufficient notice of this fireworks event in time to publish an NPRM. We must establish this safety zone by December 14, 2025 to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display.

Accordingly, it is impracticable to publish an NPRM because we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

For the same reasons, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a safety zone from 6:30 p.m. until 7:30 p.m. on December 14, 2025. The safety zone will cover all navigable waters within Santa Barbara Harbor channel entrance. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or their designated representative.

IV. Regulatory Analyses

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

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 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.

B. 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).

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This rule is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration

supporting this determination is available in the docket.

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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; DHS Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T11–218 to read as follows:

§ 165.T11–218 Safety Zone; Santa Barbara Harbor, Santa Barbara, CA.

(a) *Location.* The following area is a safety zone: All waters of Santa Barbara Harbor, from surface to bottom, encompassed by a line connecting the following points beginning at 34°24′26″ N, 119°41′27″ W, thence to 34°24′28″ N, 119°41′15″ W, thence to 34°24′17″ N, 119°41′15″ W, thence to 34°24′29″ N, 119°41′06″ W, thence to 34°24′40″ N, 119°41′17″ W and along the shoreline back to the beginning point. These coordinates are based on the World Geodetic System (WGS 84)/North American Datum 83 (NAD 83).

(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 Los Angeles-Long Beach (COTP) in the enforcement of the safety zone.

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

(2) To seek permission to enter, contact the COTP or the COTP's representative VHF–FM Channel 13 (156.65 MHz) or 16 (156.8MHz). Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 6:30 p.m. to 7:30 p.m. on December 14, 2025.

Stacey L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles-Long Beach.

[FR Doc. 2025–22559 Filed 12–10–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2025–0996]

Safety Zones: Los Angeles County Annual New Years Eve Fireworks Event

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Los Angeles County New Years Eve Fireworks from December 31, 2025 through January 1, 2026. This safety zone is to provide for the safety of life and property on the navigable waterways during these events. Our regulation for fireworks events within the Los Angeles Long Beach Captain of the Port Zone identifies the regulated areas for this fireworks event in Marina del Rey, CA. During the enforcement period, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 165.1125 will be enforced for the locations identified in Table 1 to § 165.1125 Item Number 15, from 8 p.m. on December 31, 2025, through 1 a.m. on January 1, 2026.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kevin Kinsella, U.S. Coast Guard; telephone 310–521–3860, email D11-SMB-SectorLALB-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.1125 for the Los Angeles County New Years Eve Fireworks regulated area in Item Number 15 of Table 1 to § 165.1125 from 8 p.m. on December 31, 2025, to 1 a.m. on January 1, 2026. This action will be taken to provide for the safety of life on navigable waterways during the event. Our regulation for fireworks events within the Los Angeles Long Beach Captain of the Port Zone, Table 1 to

§ 165.1125, Item Numbers 15, specifies the location of the regulated area for the Los Angeles County New Years Eve Fireworks display, which encompasses portions of Marina del Rey. During the enforcement period, § 165.1125 requires operators of a vessel in the regulated area to comply with directions from the Patrol Commander or Official Patrol, defined as any Coast Guard or other Federal, state, or local law enforcement assisting the Coast Guard in enforcing the regulated area.

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

Stacey L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles-Long Beach.

[FR Doc. 2025–22557 Filed 12–10–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–1045]

RIN 1625–AA00

Safety Zone; Patapsco River, Baltimore, MD

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 300 foot radius of a stationary barge in the Patapsco River, in Baltimore, MD. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Maryland—National Capital Region.

DATES: This rule is effective December 13, 2025, from 9:30 p.m., until 10:30 p.m.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG–2025–1045.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MST2 Natasha Hand, Sector

Maryland—National Capital Region (NCR) Waterways Management Division, U.S. Coast Guard; telephone 443–257–4011, or email D05-DG-SectorMD-NCR-Prevention-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR—Code of Federal Regulations

COTP—Captain of the Port, Sector

Maryland—National Capital Region

DHS—Department of Homeland Security

FR—Federal Register

NPRM—Notice of proposed rulemaking

§—Section

U.S.C.—United States Code

II. Background and Authority

The Coast Guard has received notification that there will be a fireworks display launched from a barge on the Patapsco River, in Baltimore's Inner Harbor. Hazards from fireworks displays include the chance of accidental discharges of fireworks, and the chance that people and vessels in the vicinity of the barge might be hit by dangerous projectiles, falling hot embers, or other debris. The Captain of the Port, Sector Maryland—NCR (COTP) has determined that these potential hazards present a safety concern for people and vessels within a 300-foot radius of the fireworks discharge site. Therefore, the COTP is issuing this rule under the authority of 46 U.S.C. 70034 to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

The Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds for good cause that notice of proposed rulemaking (NPRM) and public procedure thereon are impracticable with respect to this rule because there is insufficient time to provide notice, accept comments, respond to comments, and publish a final rule by December 13, 2025, when it must be in place to protect personnel, vessels, and the marine environment.

The Coast Guard also finds there is insufficient time to delay the effective date for 30 days after publication in the **Federal Register**, as would normally be required under 5 U.S.C. 553(d). The Coast Guard has therefore determined, as provided under 5 U.S.C. 553(d)(3), that good cause exists for finding it is impracticable to delay the effective date of this rule for 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a safety zone from 9:30 p.m. until 10:30 p.m. on December 13, 2025. The safety zone will

cover all navigable waters within 300-foot radius of the fireworks discharge site, a barge which will be located in the Patapsco River, in Baltimore's Inner Harbor. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or their designated representative.

IV. Regulatory Analyses

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

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 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.

B. 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).

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

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.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of \$100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This rule is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; DHS Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T05–1045 to read as follows:

§ 165.T05–1045 Safety Zone; Patapsco River, Baltimore, MD.

(a) *Location.* The following area is a temporary safety zone: All navigable waters within a 300 foot radius of a barge in the approximate location of 39°17'3.37" N, 076°36'35.93" W.

(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, Sector Maryland—NCR (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative. (2) To seek permission to enter, contact the COTP or the COTP's representative on VHF–FM channel 16 or by telephone, at (410) 576–2693. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 9:30 p.m. to 10:30 p.m. on December 13, 2025.

Dated: December 5, 2025.

Patrick C. Burkett,

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

[FR Doc. 2025–22518 Filed 12–10–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2025–1040]

Safety Zones; Annual Events in the Captain of the Port Detroit Zone—Sandusky New Years Eve Fireworks

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the Sandusky New Years Eve Celebration Fireworks. The safety zone is necessary to protect the safety of life and property on Sandusky Bay immediately prior to, during, and immediately after the event. During the enforcement period, no person or vessel may enter the safety zone without permission of the Captain of the Port Detroit or a designated representative.

DATES: The regulations in 33 CFR 165.941 will be enforced for the Sandusky New Years Eve Celebration Fireworks listed in item 51 in Table 1 to § 165.941, from 6 p.m. to 7 p.m. on December 31, 2025, and from 12 p.m. to 1 a.m. on January 1, 2026.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or

email MST1 Cera Turner, MSU Toledo, Waterways Management Division, U.S. Coast Guard; telephone 419-418-6050, email d09-smb-msutoledo-wwm@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone regulation in 33 CFR 165.941 for the Sandusky New Years Eve Celebration Fireworks listed in item 51 in Table 1 to § 165.941, from 6 p.m. to 7 p.m. on December 31, 2025, and from 12 p.m. to 1 a.m. on January 1, 2026. This action is being taken to provide for the safety of life and property on the Maumee River during the event. The regulation for reoccurring marine events within Sector Detroit Marine Safety Unit Toledo, Table 1 to § 165.941, item 51, specifies the location of the regulated area for the event. During the enforcement period, no person or vessel may enter the safety zone without permission of the Captain of the Port Detroit or an on-scene representative.

In addition to this notification or enforcement in the **Federal Register**, the Coast Guard will provide notification of this enforcement period via Broadcast Notice to Mariners.

Dated: December 5, 2025.

Richard P. Armstrong,
Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2025-22516 Filed 12-10-25; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2025-0199; FRL-12749-02-R9]

Air Plan Approval; California; South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP) concerning a rule submitted to address section 185 of the Clean Air Act (CAA or “Act”) with respect to the 1997 and 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or “standard”).

DATES: This rule is effective January 12, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R09-OAR-2025-0199. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Doris Lo, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; telephone number: (415) 972-3959; email address: lo.doris@epa.gov.

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

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Proposed Action

On July 31, 2025 (90 FR 36003), the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
SCAQMD	317.1	Clean Air Act Nonattainment Fees For 8-Hour Ozone Standards	06/07/24	08/13/24

We proposed to approve this rule because we determined that it complies with the relevant CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments and EPA Responses

The EPA’s proposed action provided a 30-day public comment period. During this period, we received three comments, two of which expressed support for the EPA’s proposed rule. The third comment, which focused primarily on the impact of carbon dioxide emissions, is outside the scope of this rulemaking.

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is

approving this rule into the California SIP.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of SCAQMD Rule 317.1, Clean Air Act Nonattainment Fees for 8-Hour Ozone Standards, adopted on June 7, 2024, which addresses CAA section 185 fee program requirements. The EPA has made, and will continue to make, these documents available through <https://www.regulations.gov> and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025)

because SIP actions are exempt from review under Executive Order 12866;

- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it proposes to approve a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by [insert date 60 days after date of publication in the **Federal Register**]. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: November 25, 2025.

Michael Martucci,

Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

- 2. Section 52.220 is amended by adding paragraph (c)(629) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(629) The following rule was submitted electronically on August 13, 2024, by the Governor’s designee as an attachment to a letter dated August 9, 2024.

(i) *Incorporation by reference.* (A) South Coast Air Quality Management District.

(1) Rule 317.1, “Clean Air Act Nonattainment Fees For 8-Hour Ozone Standards,” adopted June 7, 2024.

(2) [Reserved]

(B) [Reserved]

(ii) [Reserved]

[FR Doc. 2025–22584 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2025–1113; FRL–12927–02–R9]

Approval of Air Quality Implementation Plans; Arizona; Arizona Department of Environmental Quality; Stationary Source Permits; West Pinal County; PM₁₀

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to fully approve the Arizona Department of Environmental Quality’s (ADEQ or “State”) portion of the Arizona State Implementation Plan (SIP) under the Clean Air Act (CAA or “the Act”) that addresses Nonattainment New Source Review (NNSR) permitting for precursor emissions from major stationary sources for purposes of the 1987 PM₁₀ National Ambient Air Quality Standards (NAAQS or standard) in the West Pinal PM₁₀ nonattainment area.

DATES: This action is effective January 12, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2025–1113. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Rebecca Newhouse, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; telephone number: (415) 972–3936; email address: newhouse.rebecca@epa.gov.

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

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- I. Proposed Action
- II. Public Comment and EPA Response
- III. EPA Action
- IV. Statutory and Executive Order Reviews

I. Proposed Action

On September 11, 2025 (90 FR 43980), the EPA proposed to fully approve ADEQ’s NNSR permitting program for precursor emissions from major stationary sources for the 1987 PM₁₀ NAAQS in the West Pinal PM₁₀ nonattainment area because we determined that it fulfills the relevant CAA requirements.

As described in our proposal, the EPA issued a final rule in November 2015, taking action on a comprehensive 2012 NSR SIP submittal from the ADEQ that constituted a major update to the ADEQ's NSR program ("2015 NSR action"). 80 FR 67319 (Nov. 2, 2015). The EPA's 2015 NSR action also included a separate limited approval of the ADEQ's NNSR program for PM₁₀ only with respect to the West Pinal PM₁₀ nonattainment area, based on the requirements of section 189(e) of the Act, without an accompanying limited disapproval. 80 FR 67319, 67332; see also 80 FR 14044, 14058, 14060 (Mar. 18, 2015) (proposed rulemaking for the 2015 NSR action). In the proposal for that action, the EPA observed that while the 2015 NSR action was generally SIP strengthening, CAA section 189(e) requires that the ADEQ's NNSR program for PM₁₀ nonattainment areas apply to major stationary sources of PM₁₀ precursors unless the EPA determines that such sources do not contribute significantly to PM₁₀ levels which exceed the standard in the area. The NSR program did not apply to all precursors, and at that time, the EPA did not have the state's PM₁₀ precursor analysis before us, and we could therefore not fully approve the 2012 NSR SIP submittal as complying with the CAA. 80 FR 14044, 14058.

On December 15, 2023, the ADEQ submitted the "2023 Five Percent Particulate Plan for PM-10 for the West Pinal County Nonattainment Area" ("2023 PM₁₀ Plan") as a revision to the Arizona SIP, which includes a discussion of PM₁₀ formation in the West Pinal PM₁₀ nonattainment area and summarizes the State's PM₁₀ precursor evaluation and determination that precursors do not contribute significantly to PM₁₀ levels that exceed the NAAQS in the West Pinal PM₁₀ nonattainment area. The EPA evaluated the State's PM₁₀ precursor determination and concurred with the State's evaluation. Our proposal and TSD provide a more detailed discussion of our analysis supporting this determination.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received one comment.¹

The commenter stated, "I believe the proposal should not be approved, because public health surveys were not

conducted." The commenter stated that while the evidence in the State's PM₁₀ precursor analysis "seems substantial," a survey of citizens within the nonattainment area to address health concerns related to PM pollution should be conducted to allow citizens within the nonattainment area to express their concerns. The commenter noted that while the proposal was open to public comments, many citizens are not able to accurately express their concerns.

The EPA acknowledges the commenter's concerns regarding health input from the public. This issue is outside the scope of the present rulemaking, and the EPA does not have the authority to compel such a survey in this context. In the SIP framework established under Title I of the CAA, health impacts are evaluated in the process of setting the NAAQS. The states then choose how to regulate sources such that the NAAQS are attained. Section 109 of the CAA specifies that the primary NAAQS are set at a level "requisite to protect the public health" with "an adequate margin of safety." The PM₁₀ NAAQS at issue in this rulemaking was established in 1987 (52 FR 24634, July 1, 1987), and has been evaluated and retained multiple times since then. See 71 FR 61144 (Oct. 17, 2006), 78 FR 3085 (Jan 15, 2013), 85 FR 82684 (Dec. 18, 2020), 89 FR 16202 (Mar. 6, 2024). Once the NAAQS has been established and the states are tasked with regulating sources to ensure attainment of the NAAQS, states are generally not required to re-evaluate the health impacts of NAAQS pollutants.

Under section 110(k)(3) "the Administrator shall approve" a complete SIP submittal "if it meets all of the applicable requirements of [the Act]." As explained in our proposal and TSD, the applicable Clean Air Act requirement for the purposes of this action is the section 189(e) requirement that "control requirements applicable under plans in effect under this part for major stationary sources of PM-10 shall also apply to major stationary sources of PM-10 precursors, except where the Administrator determines that such sources do not contribute significantly to PM-10 levels which exceed the standard in the area." As outlined in the proposal and TSD, the EPA evaluated the State's precursor analysis and found their evidence and arguments sufficient to conclude that, for the purposes of NNSR permitting, precursors do not significantly contribute to PM₁₀ formation in the West Pinal nonattainment area. The comment does not indicate that precursors contribute significantly to PM₁₀ formation in West

Pinal, and it is not clear how public survey information would assist in the EPA's section 189(e) determination regarding whether precursors contribute significantly to PM₁₀ levels which exceed the standard in the area. Lastly, as noted by the commenter, all members of the public, including those in the West Pinal nonattainment area, were afforded the opportunity to comment on our proposal within the 30-day comment period. See CAA section 307(h). The public also had the opportunity to comment on the EPA's NAAQS evaluation actions. Although both the State and the EPA are free to conduct additional public engagement, the EPA may not condition its approval of a SIP submission on such additional public engagement.

III. EPA Action

No comments were submitted that change our assessment as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving the portion of the Arizona SIP under the Act that addresses NNSR permitting for precursor emissions from major stationary sources for purposes of the 1987 PM₁₀ NAAQS in the West Pinal PM₁₀ nonattainment area. As noted in our proposal, this resolves the issue that led the EPA to issue a limited approval in the 2015 NSR action, and this was the only remaining issue to be resolved regarding the full approvability of the ADEQ's NNSR program for PM₁₀ in the West Pinal nonattainment area.

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions

¹ The comment was received on October 14, 2025, from a member of the public, and is available at www.regulations.gov under docket number EPA-R09-OAR-2025-1113.

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 subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 9, 2026. Filing a petition for reconsideration by the Administrator of this final action does not affect the finality of this action for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: November 27, 2025.

Michael Martucci,

Acting Regional Administrator, Region IX.

[FR Doc. 2025-22582 Filed 12-10-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2019-0308; FRL-10404-02-R4]

Air Plan Approval; Tennessee; Second Period Regional Haze Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a regional haze State Implementation Plan (SIP) revision submitted by Tennessee Department of Environmental Conservation (TDEC), dated February 23, 2022, (“Haze Plan” or “2022 Plan”), as satisfying applicable requirements under the Clean Air Act (CAA or Act) and EPA’s Regional Haze Rule (RHR) for the regional haze program’s second planning period. Tennessee’s SIP submission addresses the requirement that states must periodically revise their long-term strategies (LTSs) for making reasonable progress toward the national goal of preventing any future, and remedying any existing, anthropogenic impairment of visibility, including regional haze, in mandatory Class I Federal areas (hereinafter referred to as “Class I areas”). The SIP submission also addresses other applicable requirements for the second planning period of the regional haze program. EPA is taking this action pursuant to sections 110 and 169A of the Act.

DATES: This rule is effective January 12, 2026.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA-R04-OAR-2019-0308. All documents in the docket are listed on the [regulations.gov](https://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:

Estelle Bae, Air Permitting Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303-8960. The telephone number is (404) 562-9143. Ms. Bae can also be reached via electronic mail at bae.estelle@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On February 23, 2022, TDEC submitted a revision to its SIP to address regional haze for the second planning period.¹ TDEC made this SIP submission to satisfy the requirements of the CAA’s regional haze program pursuant to CAA sections 169A and 169B and 40 Code of Federal Regulations (CFR) 51.308. The 2022 Plan includes measures at Eastman Chemical Company (Eastman) that Tennessee identified as necessary for reasonable progress for the second planning period. These measures include the permanent shutdown of Boilers 18–20,² as well as a combined sulfur dioxide (SO₂) emissions limit of 1,396 tons per year for Boilers 23 and 24 during any period of 12 consecutive months, along with associated monitoring, recordkeeping, and reporting, contained in Tennessee Operating Permit 079592. As discussed in further detail in the August 19, 2025, notice of proposed rulemaking (NPRM) (90 FR 40272), this notice of final rulemaking, and the accompanying Response to Comments document, EPA has determined that the Tennessee regional haze SIP submission for the second planning period meets the applicable statutory and regulatory

¹ The February 23, 2022, SIP submission, with exception of the supporting modeling files and Confidential Business Information, is included in the docket for this rulemaking.

² On June 6, 2025, TDEC informed EPA that Eastman completed the planned shutdown of Boilers 18, 19, and 20, on February 24, 2025, October 21, 2024, and May 20, 2025, respectively. These three boilers have been replaced with natural gas boilers. Based on information received from Tennessee, the three natural gas boilers have begun operation.

requirements and is thus approving Tennessee's submission.

On February 9, 2023, Tennessee separately submitted a SIP revision regarding the SO₂ attainment demonstration for Sullivan County, Tennessee, which provides source-specific SO₂ emission limits for Eastman and associated compliance parameters for incorporation into Tennessee's SIP.³ This submittal is referred to throughout this Notice as the "2023 Plan." On December 20, 2024, Tennessee submitted a letter to EPA asking the Agency to incorporate certain permit conditions from the 2023 Plan to generally strengthen Tennessee's SIP.

In the August 19, 2025, NPRM, EPA proposed to approve Tennessee's Haze Plan as satisfying the regional haze requirements for the second planning period contained in the CAA and 40 CFR 51.308. EPA also proposed to incorporate into Tennessee's SIP, as SIP strengthening measures, portions of the 2023 Plan. EPA described its rationale for these proposed approvals in the NPRM. Comments on the NPRM were due on or before October 20, 2025.

II. Response to Comments

EPA's August 19, 2025, proposal provided a 60-day public comment period that ended on October 20, 2025. EPA received five sets of adverse comments during the comment period: one set of comments from the National Parks Conservation Association (NPCA), Sierra Club, the Coalition to Protect America's National Parks, and Tennessee Citizens for Wilderness Planning (hereinafter "Conservation Groups"); one set of comments from the Mid-Atlantic/Northeast Visibility Union (MANE-VU); one set of comments from Coalition to Protect America's National Parks, Elders Climate Coalition for Climate Action, NAACP Nashville Branch, National Parks Conservation Association, Sierra Club Tennessee Chapter, Tennessee Citizens for Wilderness Planning, Tennessee Interfaith Power and Light, and Third Act Tennessee; and sets of comments from two individuals. EPA has responded to these comments in the Response to Comments document included in the docket for this rulemaking. EPA also received one comment in support of EPA's proposed approval from the state of Tennessee, which is included in the docket.

III. 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 discussed in Sections I and II of this preamble, EPA is finalizing the incorporation by reference into Tennessee's SIP of Operating Permit Number 079592 (State effective February 9, 2022) for Eastman. EPA is also finalizing the incorporation by reference into Tennessee's SIP of that portion of Condition 1 of Tennessee Operating Permit Number 080222 (State effective March 1, 2023) containing the 30-day rolling average SO₂ emission limit of 1,248 pounds per hour (lb/hr) for Eastman Boilers 18 through 24, 30, and 31; all of Condition 2 of Tennessee Operating Permit Number 080222 (State effective March 1, 2023); that portion of Condition 3 of Tennessee Operating Permit Number 080222 (State effective March 1, 2023) containing the supporting monitoring, recordkeeping, and reporting requirements for the 1,248 lb/hr SO₂ limit; and Attachment A to Tennessee Operating Permit Number 080222 (State effective March 1, 2023). EPA is further finalizing the incorporation by reference into Tennessee's SIP of Conditions E3–8 and E3–9 of Tennessee Operating Permit Number 576501 (State effective October 1, 2021), which include the 317 lb/hr and 293 lb/hr SO₂ limits applicable to Boilers 30 and 31; Condition E3–20; and Attachment 3 to this permit. 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.⁴

IV. Final Action

EPA is approving Tennessee's February 23, 2022, SIP revision as satisfying the regional haze requirements for the second planning period contained in 40 CFR 51.308(f). EPA is also incorporating into Tennessee's SIP, as SIP strengthening measures, those portions of Tennessee's February 9, 2023, SIP submission discussed above in Section III (entitled Incorporation by Reference). Thus, EPA is adopting into Tennessee's SIP the

permit conditions identified in Section III above.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 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 that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
 - Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
 - Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
 - Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
 - Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
 - Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
 - Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
 - Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
 - Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.
- In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

³ The February 9, 2023, SIP submission is included in the docket for this rulemaking.

⁴ See 62 FR 27968 (May 22, 1997).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 9, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to

enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Particulate matter, Sulfur oxides.

Dated: December 2, 2025.

Kevin McOmber,
Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart RR—Tennessee

■ 2. In § 52.2220:

■ a. In paragraph (d), amend the table by adding three entries for “Eastman Chemical Company” at the end of the table; and

■ b. In paragraph (e), amend the table by adding an entry for “Regional Haze Plan—Second Planning Period” at the end of the table.

The additions read as follows:

§ 52.2220 Identification of plan.

* * * * *

(d) * * *

EPA-APPROVED TENNESSEE SOURCE-SPECIFIC REQUIREMENTS

Name of source	Permit No.	State effective date	EPA approval date	Explanation
* * *	* * *	* * *	* * *	* * *
Eastman Chemical Company.	079592	2/9/2022	12/11/2025, 90 FR [Insert Federal Register page where the document begins].	
Eastman Chemical Company.	080222	3/1/2023	12/11/2025, 90 FR [Insert Federal Register page where the document begins].	That portion of Condition 1 containing the 30-day rolling average 1,248 lb/hr SO ₂ emission limit for Boilers 18 through 24, 30, and 31; Condition 2; that portion of Condition 3 containing the monitoring, recordkeeping, and reporting requirements for the 1,248 lb/hr SO ₂ emission limit; and Attachment A.
Eastman Chemical Company.	576501	10/1/2021	12/11/2025, 90 FR [Insert Federal Register page where the document begins].	Condition E3–8 and E3–9 containing the SO ₂ emission limits for Boilers 30 and 31; Condition E3–20; and Attachment 3.

(e) * * *

EPA-APPROVED TENNESSEE NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State effective date	EPA approval date	Explanation
* * *	* * *	* * *	* * *	* * *
Regional Haze Plan—Second Planning Period.	Tennessee	2/23/2022	12/11/2025, 90 FR [Insert Federal Register page where the document begins].	

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–R09–OAR–2025–0317, EPA–R09–OAR–2025–0321, EPA–R09–OAR–2025–0458; FRL–12915–02–R9]

Air Plan Approval; Arizona; Maricopa County Air Quality Department; Volatile Organic Compounds and Particulate Matter; Solvent Cleaning; Architectural Coatings; Incinerators, Burn-Off Ovens, and Crematories

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Maricopa County Air Quality Department (MCAQD) portion of the Arizona State Implementation Plan (SIP). These revisions concern emissions of volatile organic compounds (VOC) from solvent cleaning activities and architectural coatings and emissions of particulate matter (PM) from incinerators, burn-off ovens, and crematories. We are

approving local rules that regulate these emission sources under the Clean Air Act (CAA or “Act”).

DATES: This rule is effective January 12, 2026.

ADDRESSES: The EPA has established dockets for this action. Docket ID No. EPA–R09–OAR–2025–0317 pertains to Architectural Coatings, Docket ID No. EPA–R09–OAR–2025–0321 pertains to Solvent Cleaning, and Docket ID No. EPA–R09–OAR–2025–0458 pertains to Incinerators, Burn-Off Ovens, and Crematories. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If

you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT:

Allison Kawasaki, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; telephone number: (415) 972–3922; email address: kawasaki.allison@epa.gov.

SUPPLEMENTARY INFORMATION:

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

Table of Contents

- I. Proposed Action
- II. Public Comments and EPA Responses
- III. EPA Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Proposed Action

On September 11, 2025 (90 FR 43952, 90 FR 43955, and 90 FR 43983), the EPA proposed to approve the rules listed in table 1 into the Arizona SIP. We also proposed to rescind or replace the rules listed in table 2 from the Arizona SIP.

TABLE 1—SUBMITTED RULE(S)

Local agency	Rule No.	Rule title	Revised	Submitted
MCAQD	313	Incinerators, Burn-Off Ovens, and Crematories	December 11, 2024 ...	December 23, 2024.
MCAQD	331	Solvent Cleaning	September 25, 2024 ..	October 3, 2024.
MCAQD	335	Architectural Coatings	September 25, 2013 ..	September 8, 2017.
MCAQD	335	Architectural Coatings	December 11, 2024 ...	December 23, 2024.

TABLE 2—RULES REQUESTED TO BE RESCINDED OR REPLACED

Local agency	Rule No.	Rule title	Local revision date	SIP approved date	FR citation
MCAQD	34—Paragraphs F, G, H, I, J, K.	Organic Solvents—Volatile Organic Compounds (VOC).	June 23, 1980	May 5, 1982	47 FR 19326.
MCAQD	35	Incinerators	August 12, 1971	July 27, 1972	37 FR 15080.
MCAQD	331	Solvent Cleaning	April 21, 2004	December 21, 2004	69 FR 76417.
MCAQD	335	Architectural Coatings	July 13, 1988	January 6, 1992	57 FR 354.

We proposed to approve these rules and rule rescissions because we determined that they comply with the relevant CAA requirements. Our proposed actions contain more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA’s proposed actions provided a 30-day public comment period. During this period, we received one comment pertaining to MCAQD Rule 313, “Incinerators, Burn-Off Ovens, and Crematories,” revised December 11, 2024 (Rule 313), and five comments

pertaining to our proposed approval of MCAQD Rule 331, “Solvent Cleaning,” revised September 25, 2024, (“Rule 331”) and rescission of Paragraphs F, G, H, I, J, K from MCAAQD Rule 34, “Organic Solvents—Volatile Organic Compounds (VOC),” revised June 23, 1980, (Rule 34). No comments were received on our proposal to approve the September 25, 2013 and December 11, 2024 versions of MCAQD Rule 335, “Architectural Coatings” (Rule 335). The full text of these comments is available in the rulemaking dockets. We have summarized these comments and included our responses below.

A. Comments Received on Rule 313

Comment: For Rule 313, the commenter notes that the proposed rule revisions are only relevant to particulate matter and asserts that the incineration process potentially involves the generation and emission of toxic substances such as polyfluoroalkyl (PFA) compounds, dioxins, and heavy metals. The commenter recommends that, to improve overall health for the community, the MCAQD should consider regulating these pollutants from incineration activities in addition to just particulate matter and opacity. The comment also states that

“preventative measures must be made to create lasting change in air quality.” Further, the commenter states that the air plan revisions should be used to make “more baseline laws” to stop larger scale pollutants.

Response: The comment is a recommendation for how the MCAQD should revise Rule 313, or local laws, to address other pollutants and not a comment for the EPA on our proposed approval of Rule 313 into the Arizona SIP. The EPA is not able to address a recommendation for MCAQD in our action. In the future, we suggest that the commenter use MCAQD’s local rulemaking process for providing these types of recommendations. Further, the EPA’s authority for approving SIPs under CAA section 110 is limited to the implementation, maintenance, and attainment of the national ambient air quality standards (NAAQS). The regulation of pollutants that do not pertain to a NAAQS, as the commenter recommends, would be outside the EPA’s legal authority for approving SIP revisions. There are federal regulations that further regulate air pollutants emitted by incinerators, including some of the pollutants identified by the commenter, but those regulations are developed under separate CAA authority and do not pertain to SIPs. Our Technical Support Document and MCAQD’s submittal discussed these other regulations and are available in the docket for Rule 313 (Docket ID No. EPA–R09–OAR–2025–0458). It is unclear what types of “preventative measures” or “baseline laws” the commenter is recommending, but we understand this comment to be related to the pollutants of concern identified by the commenter and not related to the pollutant regulated by Rule 313, particulate matter.

B. Comments Received on Rule 331 and Rule 34

Four comments of the five comments received on Rules 331 and 34 were supportive of the EPA’s September 11, 2025 proposal. We thank the commenters for their support. The fifth comment pertained to a recent Pima County, Arizona, permitting action that is not germane to this rulemaking.

III. EPA Action

No comments were submitted that change our assessment of the rules as described in our proposed actions. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving the rules listed in table 1 into the Arizona SIP and rescinding or replacing the rules in table 2. The December 11, 2024 version of Rule 313

will replace MCAQD Rule 35, “Incinerators,” revised August 12, 1971, in the SIP. The September 25, 2024 version of Rule 331 will replace the previously approved version of this rule in the SIP and Rule 34. The September 25, 2013 version of Rule 335 will replace the previously approved version of this rule in the SIP.

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of four Maricopa County Air Quality District Rules:

MCAQD Rule 313—Incinerators, Burn-Off Ovens, and Crematories revised on December 11, 2024, which regulates emissions of particulate matter from incinerators, burn-off ovens, and crematories; MCAQD Rule 331—Solvent Cleaning, revised on September 25, 2024, which regulates emissions of VOC from solvent cleaning and metal degreasing activities; MCAQD Rule 335—Architectural Coatings, revised on September 25, 2013; and Rule 335—Architectural Coatings, revised on December 11, 2024, which regulates emissions of VOC from architectural coatings. In addition, the EPA is finalizing the rescission of the incorporation by reference of MCAQD Rule 35—Incinerators and MCAQD Rule 34—Solvent Cleaning, which were previously incorporated by reference into the applicable Arizona SIP. Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the 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 the EPA’s approval, and will be incorporated by reference in the next update to the SIP compilation.¹ The EPA has made, and will continue to make, these documents available through <https://www.regulations.gov> and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the

EPA’s role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

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

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

¹ 62 FR 27968 (May 22, 1997).

circuit by February 9, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: November 25, 2025.
Michael Martucci,
Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, EPA amends part 52, chapter I, Title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart D—Arizona

- 2. In § 52.120, in table 4 to paragraph (c):
 - a. Remove the table headings “Pre-July 1988 Rule Codification”, “Regulation II—Permits” and

- “Regulation III—Control of Air Contaminants”;
- b. Remove the entries for “Rule 34 (paragraphs F, G, H, I, J and K only)” and “Rule 35”;
- c. Remove the table headings “Regulation IV—Production of Records; Monitoring; Testing and Sampling Facilities”, “Regulation VII—Emergency Procedures”, and “Post-July 1988 Rule Codification”;
- d. Revise the entries for “Rule 313” and “Rule 331”;
- e. Remove the entry for “Rule 335”; and
- f. Add the entries for “Rule 335 (v. 2013)” and “Rule 335 (v. 2024)” in numerical order.

The revisions and additions read as follows:

§ 52.120 Identification of plan.
* * * * *
(c) * * *

TABLE 4 TO PARAGRAPH (c)—EPA-APPROVED MARICOPA COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Regulation III—Control of Air Contaminants				
Rule 313	Incinerators, Burn-Off Ovens, and Crematories.	December 11, 2024 ...	December 11, 2025, 90 FR [insert Federal Register page where the document begins].	Submitted on December 23, 2024.
Rule 331	Solvent Cleaning.	September 25, 2024 ..	December 11, 2025, 90 FR [insert Federal Register page where the document begins].	Submitted electronically on October 3, 2024, as an attachment to a letter dated October 1, 2024. The September 25, 2024 version of Rule 331 replaces the April 21, 2004 version that was approved on December 21, 2004 (69 FR 76417).
Rule 335 (v. 2013)	Architectural Coatings.	September 25, 2013 ..	December 11, 2025, 90 FR [insert Federal Register page where the document begins].	Submitted electronically on September 8, 2017.
Rule 335 (v. 2024)	Architectural Coatings.	December 11, 2024 ...	December 11, 2025, 90 FR [insert Federal Register page where the document begins].	Submitted electronically on December 23, 2024. The VOC content limits in table 335–1 of Rule 335 will only become applicable upon a determination by the EPA that either the Phoenix-Mesa nonattainment area failed to attain the 2015 ozone NAAQS by the attainment date or failed to make reasonable further progress. Until such time, the requirements in the September 25, 2013 version of Rule 335 remain applicable.
*	*	*	*	*

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52****[EPA–R01–OAR–2016–0168; FRL–13109–01–R1]****Air Plan Approval; Connecticut; Plan Submittals for the 2008 Ozone National Ambient Air Quality Standard****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule; correcting amendment.

SUMMARY: The Environmental Protection Agency (EPA) previously approved State Implementation Plan (SIP) revisions submitted by the State of Connecticut under the Clean Air Act (CAA) to address moderate area nonattainment requirements for the 2008 ozone standard for the Greater Connecticut and the Connecticut portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT moderate ozone nonattainment areas. This rule does not change those previous EPA approvals; it merely corrects an error inadvertently introduced in a November 30, 2022, final rule by reinserting reference to EPA's previous approval of Connecticut's motor vehicle inspection and maintenance program certifications.

DATES: This rule is effective on December 11, 2025.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2016–0168. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection.

FOR FURTHER INFORMATION CONTACT: Patrick Lillis, Air and Radiation Division, Environmental Protection Agency, Region 1, 5 Post Office Square—Suite 100, Boston, MA 02109, (617) 917–1067, lillis.patrick@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever

“we,” “us,” or “our” is used, we mean EPA.

Table of Contents

- I. Background and Purpose
- II. Final Action
- III. Statutory and Executive Order Reviews

I. Background and Purpose

EPA has identified the need for a typographical correction to the regulatory text approved into the Code of Federal Regulations (CFR) on November 30, 2022, by FR Rule Doc. 2022–26016. The typographical error appears on page 73471, in the first column, in § 52.377, in amendment 2, within the revised paragraph (t).

II. Final Action

The EPA is revising a final rule published in the **Federal Register** on November 30, 2022, that corrected an earlier typographical error in 40 CFR 52.377(t) but inadvertently introduced a new one. In an October 1, 2018, final rule, EPA approved SIP revisions submitted by the State of Connecticut to meet moderate area nonattainment requirements for the 2008 ozone standard. The SIP revisions were for the Greater Connecticut and the Connecticut portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT moderate ozone nonattainment areas, and included these areas' 2011 base year emissions inventories, an emissions statement certification, RFP demonstrations, RACM analyses, motor vehicle emissions budgets, and contingency measures (See 83 FR 49297). In the regulatory text added to 40 FR 52.377(t) by the October 1, 2018, final rule, EPA incorrectly cited to CAA § 182(c)(9) for the contingency measure requirements (See 83 FR 49298). The correct citation for contingency measure requirements for moderate ozone nonattainment areas is CAA § 172(c)(9). In addition, in a separate March 29, 2019, final rule, EPA approved motor vehicle inspection and maintenance (I/M) program certifications submitted by Connecticut for the same ozone nonattainment areas (See 84 FR 11884). In the March 29, 2019, final rule, EPA revised 40 CFR 52.377(t) to reflect EPA approval of the I/M program certifications but continued the incorrect citation to CAA § 182(c)(9) for the contingency measure requirements (See 84 FR 11885). Finally, on November 30, 2022, EPA published a document that corrected the citation for moderate area contingency measures to CAA § 172(c)(9) but inadvertently deleted the reference to EPA's approval of Connecticut's I/M program certifications from 40 CFR 52.377(t).

This revision does not change EPA's October 1, 2018, and March 29, 2019, approvals, but rather corrects 40 CFR 52.377(t) to reinsert reference to EPA's approval of Connecticut's I/M program certifications that was mistakenly deleted in the November 30, 2022, final rule. We have determined that there is good cause for making this rule final without prior proposal and opportunity for comment because we are merely correcting an inadvertent deletion made in a previous action. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B).

III. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National

Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

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

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).

List of Subjects in 40 CFR Part 52

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

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

Dated: December 4, 2025.

Mark Sanborn,

Regional Administrator, EPA Region 1.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is 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 (t) to read as follows:

§ 52.377 Control strategy: Ozone.

* * * * *

(t) *Approval.* Revisions to the State Implementation Plan submitted by the Connecticut Department of Energy and Environmental Protection on January 17, 2017, September 5, 2017, and August 8, 2017, to meet, in part, requirements of the 2008 ozone NAAQS. These revisions satisfy the rate of progress requirement of section 182(b) through 2017, the motor vehicle inspection and maintenance requirements of section 182(b), the contingency measure requirements of section 172(c)(9), the emission statement requirements of section 182(a)(3)(B), and the reasonably available control measure requirement of section 172(c)(1) for the Connecticut portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT area, and the Greater Connecticut moderate ozone nonattainment areas. The January 17, 2017, revision establishes motor vehicle emissions budgets for 2017 of 15.9 tons per day of VOC and 22.2 tons per day of NO_x to be used in transportation conformity in the Greater Connecticut moderate ozone nonattainment area. The August 8, 2017, revision establishes motor vehicle emissions budgets for 2017 of 17.6 tons per day of VOC and 24.6 tons per day of NO_x to be used in transportation conformity in the Connecticut portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT moderate ozone nonattainment area.

* * * * *

[FR Doc. 2025–22595 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2024–0549; FRL–12784–02–R5]

Air Plan Approval; Ohio; Carmeuse Lime, Inc. SO₂

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving new emissions limits for the Carmeuse Lime Maple Grove, Inc. facility into the Ohio State Implementation Plan (SIP) for the National Ambient Air Quality Standard (NAAQS) for sulfur dioxide (SO₂). The Ohio Environmental Protection Agency (Ohio EPA) submitted Director’s Findings and Orders that establish a new emission limit for SO₂ emissions from two rotary lime kilns at the Carmeuse Lime Maple Grove, Inc.

facility (hereafter referred to as Carmeuse Lime) in Seneca County, Ohio. EPA proposed to approve this action on August 7, 2025.

DATES: This final rule is effective on January 12, 2026.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2024–0549. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through <https://www.regulations.gov> or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Cecilia Magos, at (312) 886–7336 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Cecilia Magos, Air and Radiation Division (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7336, magos.cecilia@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

I. Background Information

On August 21, 2015 (80 FR 51052), EPA finalized the Data Requirements Rule (DRR), which required State air agencies to characterize ambient SO₂ levels in areas with large sources of SO₂ emissions to identify sources that may be causing air quality problems. Under the DRR (40 CFR 51.1205), for any area where modeling of actual SO₂ emissions served as a basis for designating such area as attainment for the 2010 SO₂ NAAQS, the State air agency shall submit to EPA an annual SO₂ emissions report of applicable sources by July 1 of each year, including an assessment of the cause of any emission increases from the previous year and a recommendation regarding the need for additional dispersion modeling to determine if an area is still meeting the 2010 SO₂ NAAQS.

In August 2023, in preparation for Ohio's 2024 Annual SO Emissions Review, Ohio EPA conducted new modeling for Carmeuse Lime due to increased emissions at the facility. This new modeling showed violations of the SO₂ NAAQS near the facility. In response, Ohio EPA conducted additional modeling to determine what allowable emissions limit to adopt at the Carmeuse Lime facility, that would model compliance with the 2010 SO₂ NAAQS in the area.

On November 13, 2024, Ohio EPA submitted a request to EPA to incorporate DFFOs that establish a new allowable 30-day rolling average SO₂ emissions limit of 1,170 pounds per hour (lbs/hr) for the combined lime kiln stack shared by two rotary lime kilns. On August 7, 2025 (90 FR 38093), EPA proposed to approve Ohio EPA's DFFOs to ensure continued attainment of the NAAQS. An explanation of the Clean Air Act (CAA) requirements, a detailed analysis of the revisions, and EPA's reasons for proposing approval were provided in the notice of proposed rulemaking (NPRM) and will not be restated here. The public comment period for this proposed rule ended on September 8, 2025.

II. EPA's Response to Comments

During the comment period, EPA received one comment expressing general concerns over increased SO₂ emissions. The comment did not specify a source with increased emissions or the area being impacted. In response, EPA clarifies that the addition of the limit in the DFFOs being approved in this action establishes a new emission limit at the facility and will reduce emissions at Carmeuse Lime. The new limit will allow the area around the facility to show modeled compliance with the NAAQS and is protective of the environment and human health. EPA does not consider the comment to be germane or relevant to this action and is therefore, finalizing the action as proposed. The comment on the proposed rule is included in the docket for this action.

III. Final Action

EPA is approving Ohio EPA's DFFOs issued to the Carmeuse Lime facility submitted on November 13, 2024, into the Ohio 2010 SO₂ NAAQS SIP. The DFFOs establish a new SO₂ emissions limit of 1,170 lbs/hr for the combined lime kiln stack that receives and emits SO₂ emissions from two rotary kilns, ensuring continued attainment of the 2010 SO₂ NAAQS.

IV. Incorporation by Reference

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

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described

in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

This rule is exempt from the Congressional Review Act because it is a rule of particular applicability.

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 February 9, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: December 5, 2025.

Cheryl Newton,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, title 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

¹ 62 FR 27968 (May 22, 1997).

Authority: 42 U.S.C. 7401 *et seq.*
■ 2. In § 52.1870, the table in paragraph (d) is amended by adding an entry for

“Carmeuse Lime, Inc. Maple Grove” after the entry for “Cardinal Power Plant” to read as follows:

§ 52.1870 Identification of plan.
* * * * *
(d) * * *

EPA—APPROVED OHIO SOURCE-SPECIFIC PROVISIONS

Name of source	Number	Ohio effective date	EPA approval date	Comments
* * * * *				
Carmeuse Lime, Inc. Maple Grove.	DFFO	11/8/2024	12/11/2025, 90 FR [Insert Federal Register page where the document begins].	*
* * * * *				

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[FR Doc. 2025–22562 Filed 12–10–25; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648
[Docket No. 251208–0181]
RIN 0648–BN40

Magnuson-Stevens Act Provisions; Fisheries of the Northeastern United States; Fisheries of the Northeastern United States; 2025–2027 Atlantic Herring Fishery Specifications

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

SUMMARY: NMFS approves and implements 2025–2027 specifications and river herring and shad catch caps for the Atlantic herring fishery, as recommended by the New England Fishery Management Council. This action also updates the target rebuilding date for Atlantic herring. This action is necessary to respond to updated scientific information from a 2024 Atlantic herring management track assessment and to achieve the objectives of the Atlantic Herring Fishery Management Plan, including preventing overfishing, helping rebuild an overfished stock, and achieving optimum yield on a continuing basis.
DATES: Effective December 11, 2025.
ADDRESSES: Copies of the 2025–2027 herring specifications action, including the Supplemental Information Report (SIR) and the Regulatory Impact Review (RIR) prepared by the New England Fishery Management Council in support of this action, are available from Dr.

Cate O’Keefe, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. These documents are also accessible via the internet at <https://www.nefmc.org/management-plans/herring>.
Copies of the small entity compliance guide are available from Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930–2298, or available on the internet at <https://www.greateratlantic.fisheries.noaa.gov>.
FOR FURTHER INFORMATION CONTACT: Carrie Nordeen, Fishery Policy Analyst, 978–281–9272.

SUPPLEMENTARY INFORMATION:
Background

NMFS and the New England Fishery Management Council (Council) manage the Atlantic herring fishery pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the Atlantic Herring Fishery Management Plan (FMP), and regulations implementing the FMP located at 50 CFR part 648, subpart K.
This action relieves a restriction by increasing herring annual catch limits (ACL) by 68 percent for 2025 and by 237 percent for 2026 and 2027, compared to the current 2025 ACL. In 2023, the most recent year for which complete data are available, the herring fishery generated \$5.61 million in revenue. This action projects up to an additional \$1.56 million in revenue available for 2025 and an additional \$5.25 million in revenue available for both 2026 and 2027, compared to revenue associated with the current 2025 herring ACL.
The regulatory process to propose, approve, and implement herring specifications is described at § 648.200. First, the Council recommends herring specifications to NMFS for its review, including: The overfishing limit (OFL);

acceptable biological catch (ABC); ACL; optimum yield (OY); domestic annual harvest; domestic annual processing; U.S. at-sea processing; border transfer; management area sub-ACLs, including seasonal periods as allowed by § 648.201(d) and modifications to sub-ACLs as allowed by § 648.201(f); the amount of research and fixed gear set aside; and river herring and shad catch caps. Next, NMFS reviews the Council’s recommended specifications and publishes proposed specifications in the Federal Register, describing its evaluation of the specifications and whether or not the proposed specifications are consistent with the Council’s recommendations. During this time, NMFS seeks public comment on the proposed herring specifications and whether they are consistent with the FMP, the Magnuson-Stevens Act and its National Standards, and other applicable law. Following the close of the comment period on the proposed specifications, NMFS evaluates the public comments and determines whether to approve the proposed specifications. Lastly, NMFS implements the approved specifications, as well as any changes to the proposed specifications, by publishing them in the Federal Register.
A 2024 herring management track stock assessment (2024 stock assessment) was completed in June 2024. According to the results of the 2024 stock assessment, the stock continues to be overfished with overfishing not occurring. Retrospective pattern adjustments were necessary because the model overestimated biomass and underestimated mortality. The adjusted spawning stock biomass was estimated to be 26 percent (47,955 metric tons (mt)) of the biomass (B) to support maximum sustainable yield (B_{MSY}) (186,367 mt) and the adjusted fishing mortality rate (F) was estimated to be 58 percent (0.263) of the overfishing threshold (F_{MSY} equals

0.45). The 2024 stock assessment was unable to explain a cause for the stock's historic and continued low recruitment and projected that continued poor recruitment of herring would likely result in a substantial decline in biomass.

Original catch projections from the 2024 stock assessment indicated the need for an almost 90-percent reduction from the previously projected 2025 ACL (23,961 mt) (88 FR 17397; March 23, 2023) to an updated 2025 ACL (2,710 mt). The Council acknowledged that herring harvest needed to be reduced to prevent overfishing and rebuild the stock and, at its September 2024 meeting, requested NMFS use its in-season adjustment authority described in the herring regulations at § 648.200(e) to reduce the 2025 specifications before the start of the fishing year on January 1 to prevent catch from exceeding new, lower limits. NMFS concurred with the Council's request to reduce herring harvest to prevent overfishing and rebuild the stock and, therefore, published 2025 in-season changes on December 19, 2024 (89 FR 103695), that implemented the reduced 2025 specifications.

Original catch projections from the 2024 stock assessment were based on the assumption that the 2024 ABC (23,409 mt) would be fully harvested. However, in January 2025, preliminary 2024 herring catch data became available indicating that the amount of herring harvested in 2024 was much lower than what was assumed in the original projections. Based on preliminary herring catch, NMFS

estimated only 51 percent of the 2024 herring ACL (10,315 mt of 20,141 mt) was harvested. Updated catch projections from the 2024 stock assessment indicated that less catch in 2024 allows for higher catch limits in 2025 and beyond, while still achieving the FMP's goals of preventing overfishing and rebuilding the stock.

At its April 2025 meeting, the Council reviewed and adopted its Scientific and Statistical Committee's (SSC's) OFL and ABC recommendations for 2025–2027 based on the updated catch projections from the 2024 stock assessment, with one exception. In response to the uncertainty around catch projection increases, especially in 2027, the Council recommended that the projected 2027 OFL remain consistent with catch projections, but that all other projected specification values for 2027 be held constant at 2026 levels. The Council also noted that the 2027 specifications would likely be replaced following the next management track stock assessment currently scheduled for 2026. The Council's approach uses the most recent and best scientific information available, while acknowledging the uncertainty around catch projection increases.

After carefully considering the Council's recommendations for 2025–2027 specifications for the herring fishery, NMFS preliminary determined it concurred with the Council's recommendations pending public comment. NMFS published the proposed specifications in the **Federal Register** on June 25, 2025 (90 FR 26955), and solicited public input on whether

the proposed specifications were consistent with the FMP, the Magnuson-Stevens Act and its National Standards, and other applicable law. Following the close of the public comment period on July 10, 2025, NMFS reviewed all public comments and concluded that the proposed herring specifications are consistent with the FMP and all applicable law. Through this final rule, NMFS approves and implements the Council's recommended new 2025 herring specifications and projected specifications for 2026–2027 pursuant to section 305(d) of the Magnuson-Stevens Act, which authorizes the Secretary of Commerce to implement management measures necessary to carry out an approved FMP.

Approved Specifications

This action sets new 2025 herring specifications and projects herring specifications for 2026–2027 based on the ABC control rule developed in Amendment 8 to the FMP (86 FR 1810; January 11, 2021). These specifications are consistent with recommendations by the Council, based on the best scientific information available, and intended to achieve the objectives of the FMP, including preventing overfishing, helping rebuild an overfished stock, and achieving OY on a continuing basis. As specified at § 648.200(a)(2), the Council may annually review these specifications and recommend adjustments if necessary. The current, new, and projected specifications are shown in table 1.

TABLE 1—CURRENT, NEW, AND PROJECTED ATLANTIC HERRING SPECIFICATIONS

Specifications	Current (mt)	New (mt)	Projected (mt)	
	2025	2025	2026	2027
Overfishing Limit	18,273	20,802	23,491	31,075
Acceptable Biological Catch	6,741	8,587	13,165	13,165
Management Uncertainty *	** 4,031	** 4,031	4,031	4,031
Annual Catch Limit/Optimum Yield *	** 2,710	** 4,556	9,134	9,134
Domestic Annual Harvest	2,710	4,556	9,134	9,134
Border Transfer	0	0	0	0
Domestic Annual Processing	2,710	4,556	9,134	9,134
US At-Sea Processing	0	0	0	0
Area 1A Sub-ACL (28.9%) *	** 783	** 1,317	2,640	2,640
Area 1B Sub-ACL (4.3%)	117	196	393	393
Area 2 Sub-ACL (27.8%)	753	1,267	2,539	2,539
Area 3 Sub-ACL (39%)	1,057	1,777	3,562	3,562
Fixed Gear Set-Aside	30	30	30	30
Research Set-Aside	0%	0%	0%	0%

* If New Brunswick weir landings are less than 2,600 mt through October 1, then 1,000 mt will be subtracted from the management uncertainty and reallocated to the Area 1A sub-ACL and the ACL.

** In 2025, NMFS determined that New Brunswick weir landings were less than 2,600 mt through October 1. Therefore, effective November 17, 2025, NMFS subtracted 1,000 mt from the "current" 2025 management uncertainty and reallocated it to the "current" 2025 Area 1A sub-ACL and ACL (90 FR 51570; November 18, 2025). The resulting effect on the "current" 2025 specifications was as follows, the management uncertainty equaled 3,031 mt, the Area 1A sub-ACL equaled 1,783 mt, and the ACL equaled 3,710 mt. Additionally, the effect of this change as applied to the "new" 2025 specifications is as follows, the management uncertainty equals 3,031 mt, the Area 1A sub-ACL equals 2,317 mt, and the ACL equals 5,556 mt.

Status of Rebuilding Plan

This action revises the target rebuilding date for Atlantic herring from 2028 to 2031. Framework 9 to the FMP (87 FR 42962; July 19, 2022) established a rebuilding plan for herring that became effective in August 2022. The rebuilding plan was expected to rebuild the stock by 2026; however, the target rebuilding date was extended from 5 years (2026) to 7 years (2028) with implementation of the 2023–2025 herring specifications (88 FR 17397; March 23, 2023). Both the original and

updated projections from the 2024 stock assessment indicate the herring stock is no longer likely to rebuild by 2028, but it could rebuild by 2031. The revised target rebuilding date for herring reflects the results of the 2024 stock assessment and falls within the 10-year rebuilding period required under the Magnuson-Stevens Act.

Approved River Herring and Shad Catch Caps

This action maintains the current river herring and shad catch caps for 2025 and projects the current catch caps

for 2026–2027. Herring regulations at § 648.200(b)(6) provide for river herring and shad catch caps by gear and area. Catch caps are intended to provide an incentive for the herring fleet to continue to avoid river herring and shad catch, while allowing the fleet to fully harvest the Atlantic herring OY. The Council is reconsidering river herring and shad management in Amendment 10 to the FMP; therefore, this action maintains the current catch caps during its reconsideration. The current and projected river herring and shad catch caps are shown in table 2.

TABLE 2—MAINTAINING CURRENT RIVER HERRING AND SHAD CATCH CAPS

Catch cap	Current (mt)	Projected (mt)	
	2025	2026	2027
Gulf of Maine Midwater Trawl	76.7	76.7	76.7
Cape Cod Midwater Trawl	32.4	32.4	32.4
Southern New England Midwater Trawl	129.6	129.6	129.6
Southern New England Bottom Trawl	122.3	122.3	122.3

Comments and Responses

NMFS received eight comment letters in response to the proposed rule seeking public comment on the proposed 2025–2027 herring specifications including letters from members of the general public, a letter from a member of the herring fishing industry, a letter from the Wampanoag Tribe of Gay Head (Aquinnah) (hereinafter Tribe), and a joint letter from several non-government organizations (NGOs) (i.e., Conservation Law Foundation, Earthjustice, National Resources Defense Council, Oceana). Comments related to other fishery management actions or general fishery management practices are not addressed here.

A summary of comments and NMFS responses is presented below:

Comment 1: Two commenters support the proposed 2025–2027 herring specifications because they believe the proposed specifications reflect a careful, science-based approach that balances ecological sustainability of the stock with the economic needs of Northeast fishing communities. One commenter stated that the proposed specifications are informed by the most recent stock assessments, help ensure the long-term health of the herring population while allowing for a sustainable harvest, and recognize herring’s important ecosystem role as forage. One commenter noted herring catch limits are reduced from limits in past years because the size of the herring stock is only about 25 percent of size needed to support MSY and no action could lead to a closed

fishery and economic hardship. One commenter explained that the new and projected harvest limits are aligned with conservation needs, but also provide important revenue for New England commercial fisheries and coastal fishing communities. Additionally, both commenters support the revised Atlantic herring target rebuilding date of 2031, because it is supported by science and aligned with management objectives, and one commenter noted that the revised target rebuilding date is consistent with Magnuson-Stevens Act timeline requirements.

Response: NMFS agrees with the commenters and is implementing the proposed 2025–2027 herring specifications and revised Atlantic herring rebuilding timeline without any changes.

Comment 2: A commenter supports maintaining the current river herring and shad catch caps for the herring fishery because they believe the catch caps are vital for protecting river herring and shad. The commenter asserted that river herring and shad populations are vulnerable and that they experience pressure from habitat loss and climate change. By enforcing the catch caps, the commenter explained that NMFS supports biodiversity and prevents the unintended harvest of non-target species.

Response: River herring and shad catch caps are intended to provide an incentive for the herring fleet to continue to avoid and minimize river herring and shad incidental catch and

bycatch, while allowing the fleet to fully harvest the Atlantic herring OY. The catch caps help minimize the unintended harvest of non-target species to the extent practicable and, therefore, the specifications maintain the current river herring and shad catch caps for 2025–2027.

Comment 3: A commenter expressed concern that inserting a carryover ban in § 648.201 that references only the 2025 and 2026 fishing years creates confusion regarding overage and carryover rules. The commenter explained it is unclear whether carryover automatically resumes in 2027 or stays suspended indefinitely. Additionally, the commenter contended that because existing regulations for administering overages and carryover are not revised for 2025 and 2026, stakeholders are forced to navigate multiple subparagraphs (they cite § 648.201(g)(1) and (g)(3)–(5)) to understand the 2025 and 2026 provisions.

Response: NMFS disagrees that the specific references to the 2025 and 2026 fishing years is confusing. A general rule applies unless there is an express exception or it is otherwise withdrawn or replaced. The current carryover provision, described at § 648.201(g)(1), generally requires carryover of unharvested catch in any appropriate subsequent year as instructed in the rule without a reference to any particular calendar year. This ensures that in the absence of a specific exception, carryover of unharvested catch will be applied in any year consistent with

§ 648.201(g)(1)'s general mandate. In other words, the general rule will be applied as instructed, unless there is an express exception, or the rule is otherwise withdrawn by a future action.

In this action, NMFS added an express exception to the general requirement that applies only to the 2025 and 2026 fishing years, as recommended by the Council and stated in the rule. The proposed rule explained that carryover had the potential to increase the 2025 and 2026 sub-ACLs up to an additional 20 percent. In an effort to better support the FMP's conservation and management objectives, the Council recommended that no unharvested catch should be carried over and added to any management area sub-ACL for 2025 and 2026, and NMFS concurred.

To help simplify and streamline the herring regulations, NMFS added the new carryover exception at paragraph (g)(2) so it is in the same paragraph as the current carryover provisions. Paragraphs (g)(3)–(5) described by the commenter do not exist. Stakeholders looking for carryover requirements are able to find all the carryover provision in § 648.201(g)(1)–(2). Additionally, NMFS listed only 2025 and 2026 in the regulatory text to clearly specify that the carryover exception applies only to those years. Unless revised in a subsequent action, NMFS would resume administering the carryover of unharvested catch for 2027 and beyond.

The commenter expressed concern that existing regulations for administering overages were not revised for 2025 and 2026, making it difficult to understand overage rules for 2025 and 2026. As described in the proposed rule, catch overages in prior years (*i.e.*, 2023 and 2024) were not large enough to require deductions in 2025 or 2026. This action does not affect or revise any aspect of how NMFS administers overages, for 2025, 2026, or any year; therefore, the regulations regarding overages at § 648.201(a)(3) were not revised as part of this action.

Comment 4: A commenter raised issues relating to the provision at § 648.201(h) specifying that if NMFS determines that the New Brunswick weir fishery landed less than 2,600 mt of herring through October 1, NMFS will subtract 1,000 mt from management uncertainty and reallocate that 1,000 mt to the ACL and Area 1A sub-ACL. The provision also specifies that NMFS will notify the Council of the management uncertainty adjustment and publish the adjustment in the **Federal Register**. The commenter asserted that because the provision does not specify a calendar or fishing year, that harvesters and

regulators are left guessing about the time period for the reallocation of quota to the ACL and Area 1 sub-ACL. The commenter also contended the provision should specify a firm **Federal Register** publication timeline to anchor industry planning. Lastly, the commenter expressed concern that the term “management uncertainty” is defined only in the preamble to the proposed rule and that in the absence of a regulatory definition, there may be conflicting interpretations about the origin and purpose of the deduction.

Response: This action sets new 2025 herring specifications and projects herring specifications for 2026–2027. The herring fishing year mirrors the calendar year, beginning on January 1 and ending on December 31; herring specifications apply for the duration of each year, unless subsequently adjusted. As described in the proposed rule, the ACL is set by reducing the ABC by management uncertainty. Management uncertainty, defined at § 648.200(b)(3), includes, but is not limited to, expected catch of herring in the New Brunswick weir fishery and the uncertainty around discard estimates of herring caught in Federal and state waters. Management uncertainty and the provision at § 648.201(h), which conditionally adjusts management uncertainty, also apply for the duration of each year. Because this provision currently applies to every year, its regulatory text does not specify a particular year or years, otherwise the regulatory text describing a specific year would need to be continually updated. Table 1 in this final rule provides a summary of the herring specifications for 2025–2027, including the provision to adjust management uncertainty across the bottom of the table as a helpful reminder to stakeholders that this provision applies to 2025–2027.

The provision at § 648.201(h) specifies NMFS will notify the Council if it adjusts management uncertainty and will publish the adjustment in the **Federal Register**. The regulation intentionally does not specify a timeframe for publication or implementation because NMFS has no certainty of when it will receive the necessary data or when it will publish the notice adjusting management uncertainty. NMFS uses New Brunswick weir data from January 1 through October 1 to determine if landings are below the specified threshold to reduce management uncertainty and reallocate that quota to the ACL and Area 1A sub-ACL. NMFS obtains New Brunswick weir data from Canada's Department of Fisheries and Oceans (DFO). NMFS does not have any control over DFO or

its data, and the timing of receiving DFO data can be uncertain. Once NMFS determines if catch is low enough to reduce and reallocate management uncertainty, the timing around drafting a notice, getting agency review and clearance, and getting the notice published in the **Federal Register** is also uncertain. The process for NMFS to evaluate and adjust management uncertainty, if warranted, has become a routine, expected aspect of the herring fishery for industry members and communities that rely on herring. For these reasons, NMFS works closely with management partners and stakeholders to publish the notice in the **Federal Register** as soon after October 1 as possible, but it does not codify a timeframe in regulation.

Comment 5: One member of the herring fishing industry urged the Council to research the latest data and reports from fishermen about the increased amounts of herring they are seeing and revisit the sub-ACL for Area 1A in 2025. The commenter explained how the recent gradually-increasing catch limits have allowed the herring stock to rebuild, they described increased herring sightings along the coast of Maine, and advocated for raising 2025 herring catch limits higher than 2024 catch limits.

Response: This action is necessary to respond to updated scientific information from a 2024 stock assessment and to prevent overfishing and help rebuild the overfished stock. As described in the proposed rule, the herring biomass was estimated to be much lower in the 2024 stock assessment than it was in the 2022 assessment (47,955 mt and 79,231 mt, respectively). In December 2024, in response to catch projections from the 2024 stock assessment and at the request of the Council, NMFS used its in-season adjustment authority to reduce the 2025 ACL by almost 90 percent from the previously projected 2025 ACL (23,961 mt reduced to 2,710 mt) to prevent overfishing and help rebuild the stock. While this action increases the 2025 herring ACL (2,710 mt to 4,556 mt) based on updated catch projections, the new 2025 ACL is substantially lower than the 2024 ACL (20,141 mt) in order to prevent overfishing and help rebuild the stock. As specified at § 648.200(a)(2), the Council may annually review these specifications and recommend adjustments if necessary. The next herring stock assessment is currently scheduled for 2026.

Comment 6: A commenter noted that there was a typographical error in the proposed regulations at § 648.201(g)(2).

Specifically, that there was an extra period after paragraph (g)(2).

Response: NMFS corrects that typographical error in this final rule.

Comment 7: A commenter asserted that the proposed specifications do not seem to align with reported data since 2023, they stated more research is needed to confirm the data and determine if actionable metrics are required, and they recommended considering data and fishery specifications for future research and development.

Response: NMFS is unclear which data and metrics the commenter is referencing, but because the herring specifications are based on the best available scientific data and the herring stock assessments continue to consider a wide range of data and metrics, NMFS does not think any action is necessary at this time.

Comment 8: The comment letter from the Tribe stated it was prudent to extend the herring target rebuilding date from 2028 to 2031 and prohibit the carryover of unharvested catch in 2025 and 2026.

Response: NMFS concurs.

Comment 9: Comment letters from the Tribe and the NGOs both expressed concern with the proposed river herring and shad catch caps. The Tribe contended that the large caps for Southern New England (*i.e.*, over 120 mt for both bottom and midwater trawl) are ineffective and recommended maintaining the current 2025 sub-ACLs for Areas 2 and 3 during 2025–2027 to minimize river herring catch. The NGOs cautioned that implementing flawed catch caps will not provide the necessary incentive for the herring industry to avoid river herring and shad or minimize bycatch consistent with National Standard 9. They asserted that river herring and shad have been mismanaged in the past five years, highlighting a perceived mismatch between Atlantic herring ACLs and river herring and shad catch caps because catch cap values have not been reduced in tandem with herring ACLs. Additionally, the NGOs stated that without stringent catch caps, the decline of river herring and shad is exacerbated and efforts to rebuild their population undermined.

Response: NMFS disagrees with these comments. River herring and shad are typically caught incidentally and retained in the Atlantic herring fishery, rather than discarded as bycatch. River herring and shad catch caps were established in Framework 3 to the FMP (79 FR 71960; December 4, 2014) as a means to control and/or limit river herring and shad catch in the Atlantic herring fishery. Catch cap values are

based on historical catch of river herring and shad before the implementation of catch caps. Catch cap values were not designed to fluctuate up and down with the herring ACL. A new method to determine catch caps values would need to be developed, if the values are intended to fluctuate with the Atlantic herring ACL. The catch caps provide an incentive for the fishing industry to continue to avoid river herring and shad interactions, and they are a proactive measure intended to manage and minimize river herring and shad catch, to the extent practicable, while allowing the Atlantic herring fishery to fully utilize the OY, if river herring and shad can be avoided.

Atlantic herring ACLs, as well as the associated fishing effort and catch, are historically low, reducing the likelihood of incidentally catching river herring and shad. In the past 5 years, the average Atlantic herring ACL was about 11,000 mt and the average fishery utilization of the ACL was less than 80 percent. Additionally, the average fishery utilization of the sub-ACL in Area 2 during that time, an area that corresponds to the Southern New England catch caps, was even lower at an average of only 14 percent. Despite low ACLs, river herring and shad catch triggered closures for midwater trawl vessels fishing off Cape Cod in April 2023 and January 2024. These closures suggest that catch caps are still operating as intended and that catch caps are effective tools to help minimize the incidental catch of river herring and shad, which is consistent with National Standard 9. The Council is considering management measures to address the catch of river herring and shad in the Atlantic herring fishery, including catch caps and/or closed areas, in Amendment 10 to the FMP. Work on Amendment 10 has been temporarily paused for 2025, but Amendment 10 is currently on the Council's list of work priorities for 2026. For all the reasons described, it is appropriate for NMFS to maintain the current river herring and shad catch caps, especially given the Council's ongoing consideration of river herring and shad management.

Comment 10: The comment letter from the NGOs encouraged NMFS to disapprove the 2025–2027 herring specifications because otherwise NMFS risks further depleting the herring stock and jeopardizing the broader marine ecosystem that relies on herring as forage. The NGOs also contended that increasing the ACL for 2025 decreased the likelihood that the stock will rebuild by 2031. Additionally, the NGOs asserted that the probability the herring stock will rebuild by 2031 barely meets

minimum rebuilding requirements and extending the target rebuilding date to 2031 is inconsistent with the Magnuson-Stevens Act requirement to rebuild a stock within a timeframe as short as possible.

Response: NMFS disagrees with these comments. According to catch projections from the 2024 stock assessment, increasing the ACL for 2025 has no meaningful impact on rebuilding by 2031. There is only a 0.1 percent decrease in the probability of rebuilding by 2031 under the new 2025 ACL (50.7 percent), compared to the probability of rebuilding under the current 2025 ACL (50.8 percent). The National Standard 1 guidelines explain that rebuilding means at least a 50-percent probability of attaining B_{MSY} . The year 2031 is the earliest year, according to catch projections from the 2024 stock assessment, for which the probability of rebuilding exceeds 50 percent. Therefore, referencing the 50.7-percent probability that the herring stock will rebuild by 2031 is consistent with rebuilding guidelines.

The Atlantic herring rebuilding plan was implemented in Framework 9 with an effective date of August 2022. Even though this action extends the target rebuilding date to 2031, the rebuilding period is still within the 10-year rebuilding timeframe specified in the Magnuson-Stevens Act. One of the factors to be considered during rebuilding is the needs of fishing communities. This action projects up to an additional \$1.56 million in revenue available for 2025 and up to an additional \$5.25 million in revenue available for 2026 and 2027, compared to revenue associated with the current 2025 ACL. This additional revenue is vital to support the fishing industries and fishing communities that rely on herring, consistent with National Standard 1.

NMFS approves and implements the Council's recommended new 2025 herring specifications and projected specifications for 2026–2027 because NMFS determined they represent the most recent and best scientific information available and are consistent with the FMP and applicable law. These specifications respond to updated scientific information from the 2024 Atlantic herring management track assessment in order to achieve the objectives of the FMP, including preventing overfishing, helping rebuild an overfished stock, and achieving OY on a continuing basis. These specifications are based on the ABC control rule developed in Amendment 8, one specifically designed to account for herring's role as forage in the

ecosystem, and on recommendations by the Council's SSC. These herring specifications balance ecological and economic needs to support the goal of the FMP, managing the fishery at long-term sustainable levels.

Changes From the Proposed Rule

One of the comment letters noted a typographical error in the proposed regulations at § 648.201(g)(2). Specifically, that there was an extra period after paragraph (g)(2). NMFS corrects that typographical error in this final rule.

Classification

NMFS is issuing this rule pursuant to section 305(d) of the Magnuson-Stevens Act. In a previous action taken pursuant to section 304(b), the regulations at 50 CFR 648.200 provide the procedures by which NMFS takes this action under Magnuson-Stevens Act section 305(d). The NMFS Assistant Administrator has determined that this final rule is consistent with the Atlantic Herring FMP, National Standards and other provisions of the Magnuson-Stevens Act, and other applicable law. This action relieves a restriction by increasing the 2025 herring ACL by 68 percent compared to the current ACL and, therefore, it is not subject to the 30-day delayed effectiveness provision of the Administrative Procedure Act pursuant to 5 U.S.C. 553(d)(1). NMFS reduced the 2025 herring specifications in December 2024 (89 FR 103695; December 19, 2024) to prevent overfishing and help rebuild the stock based on catch projections from the 2024 stock assessment. However, the original 2024 stock assessment catch projections were based on the

assumption that the 2024 herring ABC (23,409 mt) would be fully harvested and preliminary 2024 catch data available in January 2025 indicated only 51 percent of the 2024 herring ACL (10,315 mt of 20,141 mt) was harvested. Updated catch projections from the 2024 stock assessment indicated that less catch in 2024 allows for higher catch limits in 2025 and beyond, while still achieving the FMP's goals of preventing overfishing and rebuilding the stock. The summer herring fishery in Management Area 1A typically begins in July. Any delay in implementing this action past the summer fishery may hinder the fishing industry's ability to fully harvest the higher 2025 OY, potentially causing the fishing industry to forgo the additional \$1.56 million in revenue associated with the higher OY. Further, the fishing industry does not need a 30-day delay in effectiveness to prepare for and respond to the increased ACL, instead the industry would simply continue its 2025 fishing operations.

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

This final rule is not an Executive Order 14192 regulatory action because this final rule is not significant under Executive Order 12866.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

A final regulatory flexibility analysis (FRFA) was prepared. The FRFA incorporates the initial regulatory flexibility analysis (IRFA), a summary of the significant issues raised by the public comments in response to the

IRFA, NMFS responses to those comments, and a summary of the analyses completed to support the action. A summary of the analysis follows. A copy of this analysis is available from the Council (see **ADDRESSES**).

A Summary of the Significant Issues Raised by the Public in Response to the IRFA, a Summary of the Agency's Assessment of Such Issues, and a Statement of Any Changes Made in the Final Rule as a Result of Such Comments

NMFS received eight comment letters on the proposed rule. Those comments, and NMFS' responses, are contained in the Comments and Responses section of this final rule and are not repeated here. None of the comments addressed the IRFA, and NMFS did not make any substantive changes in the final rule based on public comment.

Description and Estimate of Number of Small Entities to Which This Final Rule Would Apply

The directly-regulated entities are the firms that currently hold at least one Atlantic herring permit (*i.e.*, Categories A, B, C, D, or E). The RFA recognizes three kinds of small entities: small businesses; small organizations; and small governmental jurisdictions. Herring-permitted vessels may hold permits for several fisheries, harvesting species of fish that are regulated by several different fishery management plans, even beyond those affected by the proposed action. Furthermore, multiple permitted vessels and/or permits may be owned by entities with various personal and business affiliations.

TABLE 3—NUMBER AND CHARACTERIZATION OF DIRECTLY-REGULATED ENTITIES AND AVERAGE REVENUE FROM 2019–2023

Size	Type	Firms	Vessels	Average gross receipts	Average herring receipts
Small	Fishing	739	1,174	\$831,00	\$7,000
Small	For Hire	138	178	215,000	0
Large	Fishing	10	135	19,094,000	98,000

Source: NMFS.

Table 3 indicates there are many small firms with herring permits, but that revenue from herring is only a small percentage of their total revenue. This may be because these firms hold

only a Category D open access permit with a low herring possession limit (6,600 lb (3,000 kg)) or that these firms are not active in the herring fishery. The herring fishery has had historically low

ACLs since 2018. Some firms have stopped participating in the fishery, but continue to hold herring permits to preserve the option to fish.

TABLE 4—NUMBER AND CHARACTERIZATION OF DIRECTLY-REGULATED, SMALL ENTITIES ACTIVE IN THE ATLANTIC HERRING FISHERY AND AVERAGE REVENUE FROM 2019–2023

Size	Type	Firms	Vessels	Average gross receipts	Average herring receipts
Small	Fishing	29	61	\$1,510,000	\$171,000

Source: NMFS.

Table 4 describes a subset of the directly-regulated, small entities that hold a Limited Access Permit (*i.e.*, Categories A, B, C) or an Open Access Areas $\frac{2}{3}$ Permit (*i.e.*, Category E) and participated in the herring fishery between 2019 and 2023. The small firms identified in table 4 are the firms most likely to be affected by this final rule. Because there are fewer than three directly-regulated, large entities, data confidentiality requirements prevent those data from being included.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

This final rule does not introduce any new reporting, recordkeeping, or other compliance requirements.

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

The 2025–2027 herring specifications implemented with this final rule relieve

a restriction by increasing the herring ACL compared to the current 2025 ACL. The current 2025 ACL (2,710 mt) is the lowest ACL on record for the herring fishery. In comparison, the new ACL for 2025 (4,556 mt) is 68-percent higher than the current ACL and the projected ACLs for 2026–2027 (9,134 mt) are 237-percent higher than the current ACL. The 2025–2027 herring specifications implemented in this final rule are consistent with applicable statutes and minimize any significant economic impact on small entities.

TABLE 5—PROJECTED LANDINGS, PRICES, AND REVENUE FOR 2025–2027

Year	Landings (mt)	Price *	Revenue **	
			Proposed ACL	Amount of increase compared to current ACL
2025	4,556	\$862	\$3,925,000	\$1,560,000
2026	9,134	834	7,618,000	5,253,000
2027	9,134	834	7,618,000	5,253,000

* Price is based on real 2023 US dollars per mt.
** Revenue is based on real 2023 US dollars.
Source: NMFS.

Table 5 projects an additional \$1.56 million in revenue available for 2025 and an additional \$5.25 million in revenue available for 2026 and 2027, compared to revenue associated with the current 2025 ACL. As described previously, it is likely that the projected 2027 specifications would be replaced following the 2026 stock assessment.

Despite increases to the ACLs, the SIR for the 2025–2027 herring specifications concluded the impacts of this action on herring fishery-related businesses and communities would likely remain negative. Despite moderate ACL increases, this action would continue the period of substantially reduced catch limits implemented in 2019. The low ACL and corresponding sub-ACLs would likely lead to continued low fishing effort, which could have negative social and economic impacts in fishing communities and for stakeholders directly or indirectly reliant on the herring fishery. Users of fresh herring as bait may need to switch to an alternative supply (*e.g.*, frozen herring bait or menhaden). Additionally, this action could prevent

larger vessels from participating in the fishery altogether, resulting in a potential loss of jobs for crew and adverse community impacts (*e.g.*, reduced spending on ice, fuel, cold storage, other supplies). There is no significant alternative to this action that accomplishes the objectives of applicable statutes and minimizes any significant economic impact on small entities.

For the 2025–2027 river herring and shad catch caps, this action maintains the values, gears, and areas for the catch caps that were originally implemented in 2016. There is no significant alternative to this action that accomplishes the objectives of applicable statutes and minimizes any significant economic impact on small entities.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such

publications as “small entity compliance guides.” The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a bulletin to permit holders that also serves as small entity compliance guide was prepared. This final rule and the guide (*i.e.*, bulletin) will be sent via email to the Greater Atlantic Regional Fisheries Office Atlantic herring email list and are available on the website at: <https://www.fisheries.noaa.gov/species/atlantic-herring/management>. Hard copies of the guide and this final rule will be available upon request (see ADDRESSES).

NMFS has determined that this action would not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes; therefore, consultation with Tribal officials under E.O. 13175 is not required, and the requirements of

sections (5)(b) and (5)(c) of E.O. 13175 also do not apply. A Tribal summary impact statement under section (5)(b)(2)(B) and section (5)(c)(2)(B) of E.O. 13175 is not required and has not been prepared.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: December 8, 2025.

Samuel D. Rauch III,

*Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.*

For the reasons set out in the preamble, NMFS amends 50 CFR part 648 as follows:

**PART 648—FISHERIES OF THE
NORTHEASTERN UNITED STATES**

- 1. The authority citation for part 648 continues to read as follows:

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

- 2. In § 648.201, add paragraph (g)(2) and revise paragraph (h) to read as follows:

§ 648.201 AMs and harvest controls.

* * * * *

(g) * * *

(2) No unharvested catch will be carried over and added to any management area sub-ACL for the 2025 and 2026 fishing years.

(h) If NMFS determines that the New Brunswick weir fishery landed less than 2,600 mt of herring through October 1, NMFS will subtract 1,000 mt from management uncertainty and reallocate that 1,000 mt to the ACL and Area 1A sub-ACL. NMFS will notify the Council of this adjustment and publish the adjustment in the **Federal Register**.

[FR Doc. 2025–22545 Filed 12–10–25; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 90, No. 236

Thursday, December 11, 2025

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 AGRICULTURE

Agricultural Marketing Service

7 CFR Part 989

[Docket No. AMS–SC–23–0039]

Raisins Produced From Grapes Grown in California; Secretary's Decision and Referendum Order on Proposed Amendments to Marketing Order No. 989

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and referendum order.

SUMMARY: This decision proposes amendments to Marketing Order No. 989 (Order), which regulates the handling of raisins produced from grapes grown in California and provides producers with the opportunity to vote in a referendum to determine if they favor the proposed changes. The Raisin Administrative Committee, which locally administers the Order, recommended amendments that would reduce Committee size, eliminate the designated cooperative bargaining association member seat, lower quorum requirements, remove producer district representation, remove the requirement for separate member and alternate nominations for independent and small cooperative producers, remove factors for establishing marketing policy, add language to clarify the quality of reconditioned raisins, add authority to accept voluntary contributions, and add language regarding ownership of intellectual property. In addition, the Agricultural Marketing Service proposed to make any such changes to the Order as may be necessary to conform to any amendment that may result from the hearing.

DATES: The referendum will be conducted from January 12, 2026, through January 30, 2026. The representative period for the purpose of the referendum is August 1, 2024, through July 31, 2025.

ADDRESSES: Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237.

FOR FURTHER INFORMATION CONTACT:

Christy Pankey, Marketing Specialist, or Matthew Pavone, Chief, Rulemaking Services Branch, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085, or Email: Christy.Pankey@usda.gov or Matthew.Pavone@usda.gov.

Small businesses may request information on this proceeding by contacting Antoinette Carter, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085, or Email: antoinette.carter@usda.gov.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of Hearing published in the January 12, 2024, issue of the **Federal Register** (89 FR 2178) and a Recommended Decision and Opportunity to File Written Exceptions published in the September 13, 2024, issue of the **Federal Register** (89 FR 74851).

This action is governed by the provisions of sections 556 and 557 of title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Orders 12866 and 13563.

Notice of this rulemaking action was provided to Tribal governments through the Department of Agriculture's (USDA) Office of Tribal Relations.

Preliminary Statement

This decision is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act,” and the applicable rules of practice and procedure governing the formulation and amendment of marketing agreements and orders (7 CFR part 900).

The proposed amendments in this decision are based on the record of a public hearing on February 13 and 14, 2024, at the office of the Raisin Administrative Committee, 2445 Capitol Street, Suite 200, Fresno, California 93721. Notice of this hearing was published in the **Federal Register** on

January 12, 2024 (89 FR 2178). The notice of hearing contained four proposals submitted to the Agricultural Marketing Service (AMS) by the Raisin Administrative Committee (Committee). AMS also proposed to make conforming changes as may be necessary to conform to any amendments, and to correct minor inconsistencies and typographical errors. The Recommended Decision notes that the Committee has struggled to fill vacancies and secure member attendance at meetings, largely because the California raisin industry has significantly declined and that volume regulation authority was removed from the Order in 2018. In response to these challenges, the Committee proposed several changes:

Under Proposal No. 1, the Committee membership size would be reduced from 47 to 21 members and alternates. Specifically, Proposal No. 1 would decrease producer member seats (from 35 to 12) and handler member seats (from 10 to 8), eliminate the designated cooperative bargaining association member seat, remove producer district representation, and would add a designated seat for an unaffiliated independent producer member. The quorum requirements would also be reduced from 25 to 14 members.

Additionally, the Committee recommended eliminating separate nomination procedures for small cooperative and independent producers (Proposal No. 2); removing two factors no longer relevant to the development of their annual marketing policy and clarifying language regarding the quality of reconditioned raisins (Proposal No. 3); and adding authority to accept voluntary contributions as well as to develop and use intellectual property (Proposal No. 4).

Witnesses testified on the record that the proposed amendments would help reduce Committee vacancies, improve attendance, generate cost savings, enhance administrative efficiency, ensure fair representation, and align Committee membership with the overall size of the California raisin industry. As outlined in the Recommended Decision, the Committee believes that reducing its size from 47 to 21 members and alternates would make it easier to manage and fill Committee positions, thus improving attendance and lessening the likelihood of prolonged

vacancies. This amendment, along with the other amendments under Proposal No. 1, would ensure that the size and composition of the Committee aligns with the size and structure of the industry, and that different stakeholders within the industry have a fair and equitable level of representation on the Committee. Further, with lower quorum requirements, the Committee can make decisions more easily, reduce meeting delays and the number of rescheduled meetings caused by low attendance, improve administrative efficiency and generate a cost savings for the Committee.

Eliminating separate nomination procedures for small cooperative and independent producers under Proposal No. 2, would also enhance administrative efficiency by reducing administrative burden and streamlining the nomination process.

Removing factors for establishing marketing policy under Proposal No. 3 would improve administrative efficiency by removing unnecessary and outdated considerations and allow the Committee to focus on more relevant matters. Further, the amendment to clarify the quality of reconditioned raisins under Proposal No. 3 would dispel negative impressions stemming from misconceptions and clarify the quality of reconditioned fruit, streamlining sales and contribute to improving administrative efficiencies.

Lastly, the addition of voluntary contribution authority and intellectual property language under Proposal No. 4 would generate a costs savings because voluntary contributions and revenue from intellectual property can provide additional funding, aside from assessments, that the Committee may use for other activities approved under the Order, such as research and promotion.

After thorough consideration of the hearing record, USDA has determined that the proposed amendments would tend to effectuate the declared policy of the Act.

Additionally, USDA proposed to make any such changes as may be necessary to the Order to conform to any amendment that may be adopted, or to correct minor inconsistencies and typographical errors. Accordingly, USDA recommended the following change in the Recommended Decision: revise § 989.129 to replace the word “ballot” with “vote.” This conforming change aligns with the Committee’s proposal to remove separate nomination procedures, reverting the regulatory text to its original form prior to the 2018 amendment. Witnesses at the hearing testified in support of the removal of

separate nominations for small cooperative and independent producers, as separate nomination procedures had been shown to discourage participation and would not be needed with a smaller Committee.

Comments and Exceptions

Upon the basis of evidence introduced at the hearing and the record thereof, the Administrator of AMS on September 16, 2024, filed with the Hearing Clerk, USDA, a Recommended Decision and Opportunity to File Written Exceptions thereto by October 15, 2024. USDA received three comments opposing the removal of the designated cooperative bargaining association seat from the Committee membership. Accordingly, three exceptions were filed.

All three comments proposed establishing a Committee size of 22 members, instead of the 21-member structure as proposed by the Committee, and retaining the designated cooperative bargaining association seat. The relevant issues raised by commenters suggest that under the structure proposed by the Committee, Sun-Maid Growers (Sun-Maid), a cooperative marketing association, would control 50 percent of the Committee’s representation, giving it dominance in decision-making, and that the removal of the cooperative bargaining association seat would disenfranchise workers and weaken the Raisin Bargaining Association (RBA). We address these points, as well as the alternate proposal, below:

Alternate Proposal

USDA considered but rejected the proposal to increase the proposed Committee size to 22 members because record evidence does not support this proposal. Rather, the record evidence shows that the justification for the extra seat no longer applies. Adding the seat to the proposed 21-member Committee structure would give the RBA disproportionate representation, as the extra seat is not allocated on proportional shares and would be unfair to other industry groups, such as independent producers, who do not have a dedicated seat.

Sun-Maid’s Influence on the Committee

Two of the three comments raised concerns about Sun-Maid gaining more influence on the Committee, asserting that it would control 50 percent of the Committee’s seats under the proposed structure, which could negatively impact small producers. Under the proposed Committee membership structure, Sun-Maid would hold eight seats—five for producers and three for

handlers—representing approximately 38 percent of the Committee, not the 50 percent asserted by the commenters. Further, the number of seats allocated to Sun-Maid aligns with its share of industry volume. While this would give Sun-Maid some level of influence, there would still be 10 seats reserved for independents—five independent producers and five independent handlers—which would help to ensure that no single entity can dominate decisions without the support of other Committee members.

Record evidence shows that the Committee has been considering a reduction in size for many years and has explored various alternatives, ultimately recommending the proposed amendments. The addition of the unaffiliated independent producer member seat would help to reduce the marginalization of small producers. The unaffiliated seat would most likely be filled by a small producer, ensuring representation of producers not affiliated with handlers on the Committee. Furthermore, small independent producers testified in favor of the changes, including the elimination of the designated cooperative bargaining association seat, indicating that they are comfortable with Sun-Maid’s level of representation within the proposed Committee structure. Lastly, under the proposed Committee structure, the majority of Committee seats would be allocated to producers ensuring that there would not be disproportionate handler representation and that the Committee is producer-focused.

RBA’s Reduced Representation

Commenters also suggested that removing the cooperative bargaining association seat would disenfranchise workers by eliminating a seat designated for industry workers, thereby reducing diversity, and further weakening the RBA, as well as hindering new member recruitment and disrupting the worker/manufacturer relationship. Record evidence shows that the RBA’s diminished representation and the Committee’s proposal to remove the designated seat are the result of a significant decline in RBA’s membership and total raisin acquisitions over time, as well as the removal of volume control authority under the Order.

As noted above in the alternate proposal discussion, if the designated seat were to remain on the Committee, the seat would grant the RBA disproportionate representation on the Committee, which would be unfair to other industry producers. While the

designated seat's removal may be perceived to further contribute to the RBA's decline, the sustainability and continuity of such organizations ultimately depends on the evolving needs and preferences of the industry. Therefore, new member recruitment to the RBA and the maintenance of a good working relationship between such workers and manufacturers falls under the RBA's purview, and not the Committee, as the Committee does not have authority over the RBA or any other organization representing industry regarding such matters.

Record evidence further indicates that the RBA's role has changed over time. Historically, the RBA played a vital role in the establishment of volume regulation, which helped to address pricing contracts. However, raisin growers voted through referendum in 2017 to remove volume regulation authority from the Order. Furthermore, the Committee's primary authorities are to recommend regulations related to quality control and research and promotion. Since the Committee no longer has authority to implement volume control, it does not make decisions that directly affect surplus raisins and, consequently, pricing. Therefore, the RBA's function of bargaining for commodity prices falls outside the current scope of the Order. Without this authority, the Committee no longer views the RBA-designated seat as necessary. RBA would still have Committee representation that is proportional to its raisin acquisitions, so if the RBA experiences future growth in acquisitions, its representation on the Committee would change accordingly. The opportunity for RBA members to serve directly on the Committee as producers would remain.

For these reasons, no changes have been made to the amendment under Proposal No. 1 related to the reduction of Committee membership to 21 members or the elimination of the cooperative bargaining association seat.

Initial Regulatory Flexibility Analysis

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

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be unduly or disproportionately burdened. Marketing orders and amendments issued pursuant to the Act, and the rules issued thereunder, are unique in that

they are normally brought about through group action of essentially small entities acting on their own behalf.

According to the hearing transcript, there are approximately 1,500 producers of California raisins. According to the National Agricultural Statistical Service (NASS) data presented at the hearing, the total value of production for the 2022–2023 crop year of raisins was \$381,780,000. Taking the total value of production for raisins and dividing it by the total number of raisin producers provides a return per producer of \$254,520. Small agricultural producers of raisins are defined by the Small Business Administration (SBA) as those having annual receipts equal to or less than \$4.0 million (NAICS code 111332, Grape Vineyards) (13 CFR 121.201). Therefore, a majority of raisin producers would be considered small entities under SBA's standards.

According to the record, there were 17 handlers for the 2022–2023 crop year. Small agricultural service firms are defined as those whose annual receipts are equal to or less than \$34.0 million (NAICS code 115114, Postharvest Crop Activities) (13 CFR 121.201). To make a similar computation for handlers, the first step is to estimate a representative handler price received per pound for packaged raisins. Recent USDA purchases under the Commodity Procurement Program provide such an estimate. For the most recent raisin crop year used by the Committee (August 2022–July 2023), the average price paid for packaged raisins purchased by the USDA for food assistance programs was \$1.56 per pound. The annual receipts for handlers can be calculated by taking the USDA average purchase price and multiplying it by the total number of shipments as reported by the Committee for the 2022–2023 crop year ($\$1.56 \times 414,898,000 \text{ LB}$) which equals \$647,240,880. Taking the calculation for the annual receipts by handlers and dividing by the number of handlers provides an estimated annual receipt per handler ($\$647,240,880 \text{ divided by } 17$), which equals \$38,072,993. Based on the SBA definition of an agricultural service firm having less than \$34 million in annual receipts, there is a mix of both large and small raisin handlers.

The production area regulated under the Order covers the State of California. Acreage devoted to raisin production in the production area has declined in recent years. According to data presented at the hearing, bearing acreage for raisins reached a high of 280,000 acres during the 2000–2001 crop year. Since then, bearing acreage for raisins has decreased almost 53 percent to

133,000 acres in 2021–2022. Total production of raisins reached a high during the 2000–2001 crop year of 2,921,000 tons (green tons) but has decreased 65 percent to a total production of raisins of 1,010,000 tons in 2021–2022.

During the hearing held on February 13 and 14, 2024, interested persons were invited to present evidence at the hearing on the probable regulatory and informational impact of the proposed amendments to the Order on small businesses. The evidence presented at the hearing shows that none of the proposed amendments would have any burdensome effects on small agricultural producers or firms.

Estimated Economic Impact of Amending Committee Membership Size and Composition

Proposal No. 1 would remove producer district representation in § 989.26(c) and add an unaffiliated independent producer member seat to § 989.126(a)(1). Corresponding changes would also remove §§ 989.22 and 989.122 and references to producer districts in §§ 989.29(b)(2), 989.126(a), and 989.129. In addition, Proposal No. 1 would eliminate the designated cooperative bargaining association seat in § 989.26. Corresponding changes would also remove the reference to the cooperative bargaining association position in § 989.30. Lastly, Proposal No. 1 would amend § 989.38 by lowering the quorum requirement from 25 to 14.

Most witnesses supported this proposal and stated that reducing the size of the Committee would make conducting business more efficient. These witnesses' statements are supported by the data collected by NASS showing that bearing acreage for raisins has decreased almost 53 percent since the 2000–2001 season.

Currently, the Committee structure consists of 47 members and 47 alternates, where quorum is met when at least 25 members are in attendance. A witness testified that, from April 2019 through June 2023, Committee meeting participation averaged only 33 out of the 47 members in attendance. Further, witnesses testified that the number of raisin producers has declined from approximately 3,500 during the 2000–2001 season to approximately 1,500 during the 2022–2023 season. Reducing the number of members on the Committee would bring representation into balance with the overall size of the industry.

For the reasons described above, it is determined that the proposed amendment would benefit industry

participants and improve administration of the Order. The costs of implementing this proposal would be minimal, if any, and may even create efficiencies that would reduce administrative costs.

Estimated Economic Impact of Removing Separate Nomination Procedures

Proposal No. 2 would amend § 989.29 to eliminate the requirement for separate nominations for independent producers or producers affiliated with small cooperative marketing associations.

Currently, the Committee has difficulty filling Committee seats designated for independent producer members and independent producer alternate members. Independent producer alternate member seats have gone unfilled for several consecutive years.

According to witness testimony, the purpose of the proposal is to eliminate the requirements for separate nominations for independent producers and create greater competition for all Committee positions. When the raisin industry had more producers, the Committee believed designating separate nominations for independent producers ensured that independent producers' concerns were part of Committee discussions. As the raisin industry has evolved, separate nominations for independent producers have resulted in low attendance rates and absenteeism at Committee meetings.

In conclusion, it is determined that the benefits of eliminating the requirements for separate nominations for independent producers would outweigh any costs associated with the implementation of the proposed amendment.

Estimated Economic Impact of Updating Marketing Policy and Quality Standards for Reconditioned Raisins

Proposal No. 3 would modify § 989.54(a) by removing factor number 4 "An estimated desirable carryout at the end of the crop year;" and the last part of factor number 5, "considering the estimated world raisin supply and demand situation". Proposal No. 3 would also amend §§ 989.24 and 989.58 by adding language to clarify that the quality of reconditioned raisins is the same as other "standard raisins."

Currently, many customers believe reconditioned raisins differ from raisins that were not reconditioned, even though both raisins have been inspected and met the same quality standard. The Committee believes that there is an impression in the raisin market that the quality level of reconditioned raisins is

lower than other standard raisins. Clarifying that "standard raisins" shall be defined as any raisins that have been inspected and meet the Order's minimum requirements, regardless of whether the fruit has been reconditioned or not, would remove the negative quality association customers may have with reconditioned raisins.

According to a witness, the proposed amendment would streamline the sales process and would have a positive impact for raisin handlers and producers. Currently, USDA does not distinguish between reconditioned or standard raisins when purchasing for feeding programs.

It is determined that the benefits gained from implementing this proposal would outweigh additional implementation costs incurred, if any.

Estimated Economic Impact of Adding Contribution Authority and Patent/Trademark Authority

Proposal No. 4 would add § 989.63 to establish the authority to accept voluntary contributions; add § 989.64 to establish authority related to ownership of, and rights to, intellectual property; and add authority for the collection of rents/royalties from the same.

The Order does not currently allow for the Committee to accept voluntary contributions or have ownership of, and rights to, intellectual property. This proposal would allow for the Committee to generate additional income outside the collection of handler assessments.

According to a witness, the Committee has been approached recently with the opportunity to generate revenue from "The California Raisins," the trademarked animated rhythm and blues music group created by the raisin industry. Adding the authority to own, and to exercise the rights of, intellectual property would allow the Committee to receive income from patents, copyrights, trademarks, inventions, publications, or product formulations. Such authority would allow the Committee to collect additional income from "The California Raisins" and any other intellectual property owned or controlled by the Committee. The additional income could benefit the raisin industry by, for instance, supporting future production research as determined by the Committee.

For the reasons described above, it is determined that any additional costs incurred as a result of this proposal would be outweighed by the increased flexibility for the industry to respond to a changing global marketplace.

USDA has not identified any relevant Federal rules that duplicate, overlap or

conflict with this proposed rule. These amendments are intended to improve the operation and administration of the Order and to assist in the marketing of California raisins.

Committee meetings regarding these proposals, as well as the hearing date and location, were widely publicized throughout the California raisin industry, and all interested persons were invited to attend the meetings and the hearing to participate in Committee deliberations on all issues. All Committee meetings, and the hearing, were public forums, and all entities, both large and small, were able to express views on these issues.

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

Paperwork Reduction Act

Current information collection requirements that are part of the Federal marketing order for California raisins (7 CFR part 984) are approved under OMB No. 0581-0178 Vegetables and Specialty Crops. Some changes in those requirements are anticipated as a result of this proceeding. Such changes would be submitted to OMB for approval.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

Civil Justice Reform

The amendments to the Order proposed herein have been reviewed under Executive Order 12988, Civil Justice Reform. They are not intended to have retroactive effect. If adopted, the proposed amendments would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this proposal.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under § 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which

the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed no later than 20 days after the date of entry of the ruling.

Findings and Conclusions

The findings and conclusions, rulings, and general findings and determinations included in the Recommended Decision and Opportunity to File Written Exceptions set forth in the September 13, 2024, issue of the **Federal Register** (89 FR 74851), are hereby approved and adopted.

Marketing Order

Annexed hereto and made a part hereof is the document entitled "Order Amending the Order Regulating the Handling of Raisin Produced from Grapes Grown in California." This document has been decided upon as the detailed and appropriate means of effectuating the foregoing findings and conclusions.

It is hereby ordered, that this entire decision be published in the **Federal Register**.

Referendum Order

It is hereby directed that a referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR 900.400 through 900.407). To determine whether the annexed order amending the order regulating the handling of raisins produced from grapes grown in California is approved or favored by growers, as defined under the terms of the Order, who during the representative period were engaged in the production of raisins produced from grapes in the production area.

The representative period for the conduct of such referendum is hereby determined to be August 1, 2024, through July 31, 2025.

The agents of the Secretary to conduct such referendum are hereby designated to be Peter Sommers, Marketing Specialist, and Abigail Maharaj, Branch Chief, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487-5905, or Email: peterr.sommers@usda.gov or abigail.maharaj@usda.gov.

Order Amending the Order Regulating the Handling Raisins Produced From Grapes Grown in California¹

Findings and Determinations

The findings and determinations hereinafter set forth are supplementary

to the findings and determinations that were previously made in connection with the issuance of the marketing order, and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) Findings and Determinations Upon the Basis of the Hearing Record

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and the applicable rules of practice and procedure effective thereunder (7 CFR part 900), a public hearing was held upon proposed further amendment of Marketing Order No. 989, regulating the handling of raisins produced from grapes grown in California.

Upon the basis of the record, it is found that:

(1) The marketing order, as amended, and as hereby proposed to be further amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

(2) The marketing order, as amended, and as hereby proposed to be further amended, regulates the handling of raisins produced from grapes grown in the production area in the same manner as, and is applicable only to, persons in the respective classes of commercial and industrial activity specified in the marketing order upon which a hearing has been held;

(3) The marketing order, as amended, and as hereby proposed to be further amended, is limited in its application to the smallest regional production area that is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

(4) The marketing order, as amended, and as hereby proposed to be further amended, prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of raisin produced from grapes grown in California; and

(5) All handling of raisins produced from grapes grown in the production area, as defined in the marketing order, is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

formulate marketing agreements and marketing orders have been met.

Order Relative to Handling

It is therefore ordered, that on and after the effective date hereof, all handling of raisins produced from grapes grown in California shall be in conformity to, and in compliance with, the terms and conditions of the said Order as hereby proposed to be amended as follows:

The provisions of the proposed marketing order amending the Order contained in the Recommended Decision and Opportunity to File Written Exceptions published in the September 13, 2024, issue of the **Federal Register** (89 FR 74851), and in this Secretary's Decision and Referendum Order, will be and are the terms and provisions of this order amending the Order and are set forth in full herein.

List of Subjects in 7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

Recommended Further Amendment of the Marketing Order

For the reasons set out in the preamble, 7 CFR part 989 is proposed to be amended as follows:

PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

■ 1. The authority citation for part 989 continues to read as follows:

Authority: 7 U.S.C. 601-674.

§ 989.22 [Removed and Reserved]

■ 2. Remove and reserve § 989.22.

■ 3. Amend § 989.24 by revising paragraph (b) to read as follows:

§ 989.24 Standard raisins, off-grade raisins, other failing raisins, and raisin residual material.

* * * * *

(b) *Off-grade raisins* means raisins which do not meet the then effective minimum grade and condition standards for natural condition raisins: *Provided*, That raisins which are certified as off-grade raisins shall continue to be such until successfully reconditioned as standard raisins or become "other failing raisins."

* * * * *

■ 4. Revise § 989.26 to read as follows:

§ 989.26 Establishment and membership.

A Raisin Administrative Committee is hereby established consisting of 21 members of whom 12 shall represent producers, 8 shall represent handlers and 1 shall be a public member.

(a) The producer members shall be selected as follows:

¹ This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to

(1) Producer members representing the cooperative marketing association(s) shall be members of such association(s) engaged in the handling of raisins, each of which acquired not less than 10 percent of the total raisin acquisitions during the preceding crop year, and those members shall be equal to the product, rounded to the nearest whole number, obtained by multiplying 12 by the ratio the cooperative marketing association(s) raisin acquisitions are to the acquisitions of all handlers during the preceding crop year.

(2) Producer members representing cooperative bargaining association(s) shall be members of such association(s), and the number of those members shall be equal to the product, rounded to the nearest whole number, obtained by multiplying 12 by the ratio the raisins acquired by handlers from bargaining association members are to the total acquisitions of all handlers during the preceding crop year.

(3) All other producer members, who shall not be members of a cooperative bargaining association(s), cooperative marketing association(s) engaged in the handling of raisins which acquired 10 percent or more of the total acquisitions during the preceding crop year, nor sold for cash to cooperative marketing association(s), shall represent all producers not defined in paragraphs (a)(1) or (a)(2) of this section and shall be selected as designated in the rules and regulations.

(b) The handler members shall be divided into two groups and include the following:

(1) Handler members shall be selected from and represent cooperative marketing association(s) engaged in the handling of raisins each of which acquired not less than 10 percent of the total raisin acquisitions during the preceding crop year, and the number of those members shall be equal to the product, rounded to the nearest whole number, obtained by multiplying 8 by the ratio of the cooperative marketing association(s) raisin acquisitions are to the total acquisitions of all handlers during the preceding crop year.

(2) The remaining handler members shall be selected from and represent all other handlers, which would include all independent handlers and small cooperative marketing association(s) who acquired less than 10 percent of the total raisin acquisitions during the preceding crop year. Handler nominees for this group shall be nominated by all handlers in the group in a manner determined by the Committee, with the approval of the Secretary, and specified in the rules and regulations.

(c) The public member shall be nominated by the Committee and selected by the Secretary as public member.

(d) For each member of the Committee there shall be an alternate member who shall have the same qualifications as the member for whom they are an alternate.

■ 5. Amend § 989.29 by revising paragraphs (a) and (b) (1) and (2) to read as follows:

§ 989.29 Initial members and nomination of successor members.

(a) *Initial members.* Members and alternate members of the Committee serving immediately prior to the effective date of this amended subpart shall, if thereafter they are eligible, serve on the Committee until April 30, 2026, and until their respective successors have been selected and qualified.

(b) * * *

(1) The Committee shall notify the cooperative marketing association(s) engaged in handling not less than 10 percent of the total raisin acquisitions during the preceding crop year, and cooperative bargaining association(s), of the date by which nominations to fill member and alternate member positions shall be made. The Committee shall give reasonable publicity of a meeting or meetings of producers who are not members of cooperative bargaining association(s), or cooperative marketing association(s) which handled 10 percent or more of the total raisin acquisitions during the preceding crop year, and of independent handlers and cooperative marketing association(s) who handled less than 10 percent of the total raisin acquisitions during the preceding crop year, for the purpose of making nominations to fill the member and alternate member positions prescribed in § 989.26 (a)(3) and (b): *Provided*, That member and alternate member nominations by independent handlers and cooperative marketing association(s) who acquired less than 10 percent of the total raisin acquisitions during the preceding crop year may be made to the Committee by mail in lieu of meetings.

(2)(i) Any producer representing independent producers and producers who are affiliated with cooperative marketing association(s) handling less than 10 percent of the total raisin acquisitions during the preceding crop year must have produced grapes which were made into raisins.

(ii) Each such producer whose name is offered in nomination to represent on the Committee independent producers or producers who are affiliated with cooperative marketing association(s) handling less than 10 percent of the

total raisin acquisitions during the preceding crop year shall be given the opportunity to provide the Committee a short statement outlining qualifications and desire to serve if selected. These brief statements, together with a ballot and voting instructions, shall be mailed to all independent producers and producers who are affiliated with cooperative marketing associations handling less than 10 percent of the total raisin acquisitions during the preceding crop year of record with the Committee. The producer candidate receiving the highest number of votes shall be designated as the first member nominee for a member position in which they qualify, the second highest shall be designated as the second member nominee for a member position which they qualify, until nominees for all producer member positions have been filled. Similarly, after all producer member positions have been filled, the producer candidate receiving the highest number of votes shall be designated as the first alternate member nominee for a member position in which they qualify, the second highest shall be designated as the second alternate member nominee for a member position in which they qualify, until nominees for all alternate member positions have been filled.

(iii) In the event there are no qualified candidates for any designated producer member or alternate member positions, such positions may be filled by other producer candidates not otherwise nominated for a position.

(iv) Each independent producer or producer affiliated with cooperative marketing association(s) handling less than 10 percent of the total raisin acquisitions during the preceding crop year shall cast only one vote with respect to each position for which nominations are to be made. Write-in candidates shall be accepted. The person receiving the most votes with respect to each position to be filled, in accordance with paragraph (b)(2)(ii) and (iii) of this section, shall be the person to be certified to the Secretary as the nominee. The Committee may, subject to the approval of the Secretary, establish rules and regulations to effectuate this section.

* * * * *

■ 6. Revise § 989.30 to read as follows:

§ 989.30 Selection.

The Secretary shall select producer, handler, and public members and alternate members in the number specified in § 989.26, as applicable, and with the qualifications specified in § 989.27. Such selections may be made from nominations certified pursuant to

§ 989.29 or from other eligible producers, or handlers.

§ 989.38 [Amended]

■ 7. Amend § 989.38 by removing the numeral “25” and adding in its place the numeral “14”.

§ 989.54 [Amended]

■ 8. Amend § 989.54 by:

■ a. Removing paragraph (a)(4);
 ■ b. Redesignating paragraphs (a)(5) through (9) as paragraphs (a)(4) through (8), respectively; and

■ c. Removing in newly redesignated paragraph (a)(4), removing the text “, considering the estimated world raisin supply and demand situation”.

■ 9. Amend § 989.58 by adding paragraph (g) to read as follows:

§ 989.58 Natural condition raisins.

* * * * *

(g) *Quality reconditioned raisins.* All raisins which have been inspected and certified as meeting the minimum grade, quality, and condition standards established pursuant to this section, whether upon incoming inspection or upon later inspection after reconditioning, shall be determined to be standard raisins, labelled accordingly, and shall be eligible for commercial disposition as natural condition raisins or packed raisins in normal outlets.

■ 10. Add § 989.63 to read as follows:

§ 989.63 Contributions.

The Committee may accept voluntary contributions: *Provided*, That such contributions shall only be used to pay expenses authorized under § 989.79. Furthermore, contributions shall be free from any encumbrances by the donor and the Committee shall retain complete control of their use.

■ 11. Add § 989.64 to read as follows:

§ 989.64 Patents, copyrights, trademarks, inventions, product formulations, and publications.

(a) Any patents, copyrights, trademarks, inventions, product formulations, and publications developed through the use of funds received by the Committee under this subpart shall be the property of the U.S. Government, as represented by the Committee, and shall, along with any rents, royalties, residual payments, or other income from the rental, sales, leasing, franchising, or other uses of such patents, copyrights, trademarks, inventions, product formulations, or publications, inure to the benefit of the Committee; shall be considered income subject to the same fiscal, budget, and audit controls as other funds of the

Committee; and may be licensed subject to approval by the Secretary.

(b) Upon termination of this subpart, § 989.92 shall apply to determine disposition of any property, including patents, copyrights, trademarks, inventions, product formulations, and publications developed through the use of funds received by the Committee under this subpart.

(c) Should patents, copyrights, trademarks, inventions, product formulations, or publications be developed through the use of funds collected by the Committee under this subpart and funds contributed by another organization or person, ownership and related rights to such patents, copyrights, trademarks, inventions, product formulations, or publications shall be determined by agreement between the Committee and the person or organization contributing funds towards the development of such patents, copyrights, inventions, trademarks, product formulations, or publications in a manner consistent with paragraph (a) of this section.

(d) Should any patents, copyrights, trademarks, inventions, product formulations, or publications, be licensed to the Committee by another person or organization, the rights and obligations regarding such licensed patents, copyrights, trademarks, inventions, product formulations, or publications shall be determined by agreement between the Committee and the person or organization permitting licensure in a manner consistent with paragraph (a) of this section.

§ 989.122 [Removed and Reserved]

■ 12. Remove and reserve § 989.122.

■ 13. Revise § 989.126 to read as follows:

§ 989.126 Representation of the Committee.

(a) Pursuant to § 989.26(a)(3), and commencing with the term of office beginning May 1, 2026, apportionment of independent and small cooperative producers shall be:

(1) One producer member, selected from and representing all producers, who is unaffiliated with any handler (including, but not limited to, ownership, employment, or agent of any handler, and whose family members are similarly unaffiliated with any handler); and

(2) The remaining producer member(s) selected from and representing all other independent and small cooperative producers.

(b) Pursuant to section § 989.26(b)(2), and commencing with the term of office beginning May 1, 2026, apportionment

of the independent and small cooperative marketing association handlers shall be:

(1) Two members selected from and representing the four handler(s) other than major cooperative marketing association handler(s) who acquired the largest percentage of the total raisin acquisitions during the preceding crop year; and

(2) The remaining member(s) selected from and representing all other handlers, including small cooperative marketing association handler(s) and all processors.

■ 13. Revise § 989.129 to read as follows:

§ 989.129 Voting at nomination meetings.

Any person (defined in § 989.3 as an individual, partnership, corporation, association, or any other business unit) who is engaged, in a proprietary capacity, in the production of grapes which are sun-dried or dehydrated by artificial means to produce raisins and who qualifies under the provisions of § 989.29(b)(2) shall be eligible to cast one vote for a nominee for each producer member position and one vote for a nominee for each producer alternate member position on the Committee which is to be filled. Such person must be the one who or which: Owns and farms land resulting in his or its ownership of such grapes produced thereon; rents and farms land, resulting in his or its ownership of all or a portion of such grapes produced thereon; or owns land which he or it does not farm and, as rental for such land, obtains the ownership of a portion of such grapes or the raisins. In this connection, a partnership shall be deemed to include two or more persons (including a husband and wife) with respect to land the title to which, or leasehold interest in which, is vested in them as tenants in common, joint tenants, or under community property laws, as community property. In a landlord-tenant relationship, wherein each of the parties is a producer, each such producer shall be entitled to one vote for a nominee for each producer member position and one vote for each producer alternate member position. Hence, where two persons operate land as landlord and tenant on a share-crop basis, each person is entitled to one vote for each such position to be filled. Where land is leased on a cash rental basis, only the person who is the tenant or cash renter (producer) is entitled to vote. A partnership or corporation, when eligible, is entitled to cast only

one vote for a nominee for each producer position to be filled.

Erin Morris,

Administrator, Agricultural Marketing Service.

[FR Doc. 2025–22596 Filed 12–10–25; 8:45 am]

BILLING CODE P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 704

RIN 3133–AF73

Corporate Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is proposing to amend its regulations for corporate credit unions by removing the requirement that a corporate credit union's asset and liability management committee (ALCO) must have at least one member who is also a member of the corporate credit union's board of directors. The proposed rule would also remove filing requirements related to a corporate credit union's annual report and any management letter or other report issued by its independent public accountant. The intended effect is to reduce unnecessary regulatory burden and provide corporate credit unions with greater flexibility.

DATES: Comments must be received by February 9, 2026.

ADDRESSES: Comments may be submitted in one of the following ways. (*Please send comments by one method only*):

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. The docket number for this proposed rule is NCUA–2025–1302. Follow the “Submit a comment” instructions. If you are reading this document on [federalregister.gov](https://www.federalregister.gov), you may use the green “SUBMIT A PUBLIC COMMENT” button beneath this rulemaking's title to submit a comment to the [regulations.gov](https://www.regulations.gov) docket. A plain language summary of the proposed rule is also available on the docket website.

- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

- *Hand Delivery/Courier:* Same as mailing address.

Mailed and hand-delivered comments must be received by the close of the comment period.

Public inspection: Please follow the search instructions on <https://www.regulations.gov> to view the public comments. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously. If you are unable to access public comments on the internet, you may contact the NCUA for alternative access by calling (703) 518–6540 or emailing OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT:

Rachel Ackmann, Senior Attorney, Office of General Counsel, at (703) 518–6540 or at 1775 Duke Street, Alexandria, VA 22314

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

In 2010, the Board comprehensively revised the regulations governing corporate credit unions to provide longer-term structural enhancements to the corporate system in response to the financial crisis of 2007–2009.¹ The provisions of the 2010 rule were intended to stabilize the corporate system and improved corporate credit unions' ability to function and provide services to natural person credit unions without undue risk. Since 2010, and as part of the Board's continuous reevaluation of its regulation of corporate credit unions, the Board has amended part 704 on several occasions.²

In 2017, the Board amended corporate credit union capital standards to change the calculation of capital after a consolidation and to set a retained earnings ratio target.³ In October 2020, the Board issued a final rule to amend several provisions relating to corporate credit union investments in credit union service organizations (CUSOs) and other provisions relating to corporate credit union governance.⁴ Finally, in 2021, the Board amended part 704 to clarify that corporate credit unions may purchase subordinated debt instruments issued by consumer credit unions.⁵

B. Legal Authority

The Board is issuing this proposed rule pursuant to its authority under the

Federal Credit Union Act (FCU Act).⁶ Under the FCU Act, the NCUA is the chartering and supervisory authority for federal credit unions (FCUs) and the federal supervisory authority for federally insured credit unions (FICUs). The FCU Act grants the NCUA a broad mandate to issue regulations governing both FCUs and FICUs. Section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe regulations for the administration of the FCU Act.⁷ Section 209 of the FCU Act is a plenary grant of regulatory authority to the NCUA to issue regulations necessary or appropriate to carry out its role as share insurer for all FICUs.⁸ The FCU Act also includes an express grant of authority for the Board to subject federally chartered central, or corporate, credit unions to such rules, regulations, and orders as the Board deems appropriate.⁹ Part 704 of the NCUA's regulations implements the requirements of the FCU Act regarding corporate credit unions.¹⁰

II. Proposed Rule

A. ALCO Committee Representation

Before the financial crisis of 2007–2009, the Board comprehensively revised part 704 (1997 final rule).¹¹ The 1997 final rule required that corporate credit unions operate according to a written asset and liability management policy. Additionally, the 1997 final rule required that each corporate credit union's ALCO have at least one member who is also a member of the board of directors. The board member requirement has not been amended since 1997.

The Board now proposes to rescind the requirement for each corporate credit union's ALCO to have at least one member who is also a member of the board of directors. After careful review, the Board believes that this prescriptive approach is unnecessary. The Board's primary policy rationale for this proposed elimination is that this requirement is overly prescriptive and inflexible, and corporate credit union boards should have discretion to determine their ALCO membership.

B. Filing Requirements for a Corporate Credit Union's Annual Report

The 1997 final rule also required that a corporate credit union's supervisory committee get an annual opinion audit

¹ 75 FR 64786 (Oct. 20, 2010).

² See e.g., 80 FR 25932 (May 6, 2015) and 80 FR 57283 (Sept. 23, 2015).

³ 82 FR 55497 (Nov. 22, 2017).

⁴ 85 FR 17288 (Mar. 27, 2020).

⁵ 86 FR 10729 (Feb. 23, 2021).

⁶ 12 U.S.C. 1751 *et seq.*

⁷ 12 U.S.C. 1766(a).

⁸ 12 U.S.C. 1789.

⁹ 12 U.S.C. 1766(a).

¹⁰ 12 CFR part 704.

¹¹ 62 FR 12938 (Mar. 19, 1997).

of the corporate credit union's financial statements. The supervisory committee was required to submit the audit report to the board of directors. In addition, the supervisory committee had to submit a copy of the audit report and copies of all communications provided to the corporate credit union by the external auditor to the NCUA within 30 calendar days after receipt by the board of directors.¹²

In 2010, the Board amended corporate credit union audit requirements by adding additional auditing, reporting, and supervisory committee requirements.¹³ For consistent application of the requirement, the Board required that a corporate credit union file a copy of its annual report with the NCUA within 180 days following the end of the calendar year.¹⁴ The Board also provided that the NCUA would make a corporate credit union's annual report available for public inspection and that, consistent with good corporate governance, a corporate credit union was required to give the NCUA a copy of any management letter or report issued by its independent public accountant.¹⁵ Finally, the Board required corporate credit unions to notify the NCUA when filing the annual report late.¹⁶

The Board now proposes to remove several of its filing requirements related to a corporate credit union's annual report. The proposed rule would rescind the requirement to file a copy of an annual report and any management letter or other report issued by its independent public accountant with the NCUA within 180 days after the end of the calendar year. The proposed rule would also rescind the requirement for the NCUA to make the annual report available for public inspection. Along with the proposed removal of these filing requirements, the Board would rescind requirements related to untimely filings.

The Board is proposing to eliminate these filing requirements because the section imposes an unnecessary and undue compliance burden on corporate credit unions that is disproportionate to its limited public benefit. The NCUA has access to corporate credit union records and audit reports through its

examination authority.¹⁷ The proposed amendments only remove the requirements for the corporate credit union to file the documents with the NCUA and does not limit the NCUA's access to the information. NCUA examiners will continue to review these materials through the examination process. The intended effect of the proposed amendment is to reduce unnecessary regulatory burden without affecting corporate credit union safety and soundness.

The Board notes that other aspects of the NCUA's filing requirements will remain unchanged. Corporate credit unions will continue to be required to notify the NCUA within 15 days of losing an independent public accounting through dismissal or resignation. The proposed rule would remove the requirement to report the engagement of an independent public accountant. The Board is more concerned with prompt notification for the dismissal or resignation of an accountant than about notification of the initial engagement. The NCUA would have access to the engagement letter if necessary and does not need prompt notification. Additionally, a corporate credit union must submit a preliminary annual report to the corporate credit union's membership at its next calendar year's annual meeting.

The Board solicits comments on all aspects of the proposed rule.

III. Regulatory Procedures

A. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (5 U.S.C. 553(b)(4)) (Act) requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as *regulations.gov*).

The Board is proposing to amend its regulations for corporate credit unions by removing the requirement that a corporate credit union's ALCO must have at least one member who is also a member of the corporate credit union's board of directors. The proposed rule would also remove filing requirements related to a corporate credit union's annual report and any management letter or other report issued by its independent public accountant. The intended effect is to reduce unnecessary

regulatory burden and provide corporate credit unions with greater flexibility.

The proposal and the required summary can be found at <https://www.regulations.gov>.

B. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 ("Regulatory Planning and Review"), as amended by Executive Order 14215, a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the Executive Order.¹⁸ Executive Order 13563 ("Improving Regulation and Regulatory Review") supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.¹⁹ This proposed rule was drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. OMB has determined that this proposed rule is not a "significant regulatory action" as defined in section 3(f)(1) of Executive Order 12866. Further, this proposed rule will reduce the burden of filing certain reports with the NCUA and increase flexibility for corporate credit union boards to determine ALCO members and is consistent with Executive Order 13563.

Executive Order 14192 ("Unleashing Prosperity Through Deregulation") requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.²⁰ This proposed rule is expected to be a deregulatory action for purposes of Executive Order 14192.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act²¹ generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the agency makes such a certification, it must publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.²² For purposes of this analysis, the NCUA

¹² 62 FR 12929 (Mar. 19, 1997). See 12 CFR 704.15(a).

¹³ 75 FR 73000 (Nov. 29, 2010).

¹⁴ 12 CFR 704.15(c)(1). The report must contain the audited comparative financial statements, the independent public accountant's report on those statements, a management report, and, if applicable, the independent public accountant's attestation report on management's assessment of internal control over financial reporting.

¹⁵ 12 CFR 704.15(c)(2) and (c)(3).

¹⁶ 12 CFR 704.15(c)(5).

¹⁷ 12 U.S.C. 1784.

¹⁸ 58 FR 51735 (Oct. 4, 1993).

¹⁹ 76 FR 3821 (Jan. 21, 2011).

²⁰ 90 FR 9065 (Feb. 6, 2025).

²¹ 5 U.S.C. 601 *et seq.*

²² 5 U.S.C. 605(b).

considers small credit unions to be those having under \$100 million in assets.²³ The Board fully considered the potential economic impacts of the regulatory amendments on small credit unions. There are no corporate credit unions under \$100 million in assets. Accordingly, the NCUA certifies the proposed rule would not have a significant economic impact on a substantial number of small credit unions.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency may not conduct or sponsor, and not withstanding any other provision of law, a person is not required to respond to, a collection of information, unless it displays a currently valid Office of Management and Budget control number. The PRA applies to rulemakings in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information-collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. The NCUA has determined that the changes addressed in this notice do not create a new information collection or revise an existing information collection as defined by the PRA.

E. Executive Order 13132 on Federalism

Executive Order 13132 encourages certain regulatory agencies to consider the impact of their actions on state and local interests. The NCUA, an agency as defined in 44 U.S.C. 3502(5), complies with the executive order to adhere to fundamental federalism principles. This proposed rule would apply to all FICUs, including state-chartered credit unions. The NCUA expects that any effect on states or on the distribution of power and responsibilities among the various levels of government will be minor. The proposed changes would remove existing federal filing requirements for state-chartered corporate credit unions and do not negatively affect the division of responsibilities between the NCUA and state regulatory authorities with oversight of federally insured, state-chartered corporate credit unions. The NCUA welcomes comments on ways to eliminate, or at least minimize, any potential impact in this area.

F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of

section 654 of the Treasury and General Government Appropriations Act, 1999.²⁴ The proposed rescission is exclusively concerned with corporate credit union governance and filing requirements. The proposed rule is intended to reduce regulatory burden while maintaining a strong corporate system to support consumer credit unions in their provision of financial services to members. The potential positive effect on family well-being, including financial well-being is, at most, indirect.

List of in Subjects 12 CFR Part 704

Credit unions, Reporting and recordkeeping requirements, Surety bonds.

By the National Credit Union Administration Board, this 8th day of December 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons stated in the preamble, the NCUA Board proposes to amend 12 CFR part 704 as follows:

PART 704—CORPORATE CREDIT UNIONS

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

Authority: 12 U.S.C. 1766(a), 1781, 1789.

- 2. Revise section 704.8(b) to read as follows:

§ 704.8 Asset and liability management.

* * * * *

(b) *Asset and liability management committee (ALCO).* The ALCO must review asset and liability management reports on at least a monthly basis. These reports must address compliance with Federal Credit Union Act, NCUA Rules and Regulations (12 CFR chapter VII), and all related risk management policies.

* * * * *

- 3. Revise § 704.15(c) to read as follows:

§ 704.15 Audit and reporting requirements.

* * * * *

(c) *Filing and notice requirements—*
(1) *Notice of dismissal or resignation of accountants.* Each corporate credit union that loses an independent public accountant through dismissal or resignation, must notify the NCUA within 15 days after the dismissal, or resignation. The corporate credit union must include with the notice a reasonably detailed statement of the reasons for any dismissal or resignation. The corporate credit union must also

provide a copy of the notice to the independent public accountant at the same time the notice is filed with the NCUA.

(2) *Report to Members.* A corporate credit union must submit a preliminary Annual Report to the membership at the next calendar year's annual meeting.

* * * * *

[FR Doc. 2025–22487 Filed 12–10–25; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 715

RIN 3133–AF74

Supervisory Committee Audits and Verifications

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board is proposing to amend its regulations governing supervisory committee audits to eliminate unnecessary, redundant, and overly prescriptive provisions. This action is necessary to reduce regulatory burden, increase operational flexibility for credit unions, and streamline the rules by removing requirements that are outdated or duplicative of other authorities. The intended effect of this proposal is to simplify compliance for credit unions without compromising the integrity of the audit process.

DATES: Comments must be received by February 9, 2026.

ADDRESSES: Comments may be submitted in one of the following ways. (*Please send comments by one method only*):

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. The docket number for this proposed rule is NCUA–2025–1303. Follow the “Submit a comment” instructions. If you are reading this document on [federalregister.gov](https://www.federalregister.gov), you may use the green “SUBMIT A PUBLIC COMMENT” button beneath this rulemaking’s title to submit a comment to the [regulations.gov](https://www.regulations.gov) docket. A plain language summary of the proposed rule is also available on the docket website.

- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

- *Hand Delivery/Courier:* Same as mailing address.

Mailed and hand-delivered comments must be received by the close of the comment period.

²³ 80 FR 57512 (Sept. 24, 2015).

²⁴ Public Law 105–277, 112 Stat. 2681 (1998).

Public inspection: Please follow the search instructions on <https://www.regulations.gov> to view the public comments. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously. If you are unable to access public comments on the internet, you may contact the NCUA for alternative access by calling (703) 518–6540 or emailing OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Ian Marenga, Associate General Counsel, Office of General Counsel, at (703) 518–6540 or at 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

The NCUA Board proposes to amend its regulations at 12 CFR part 715, which govern the supervisory committee audit and verification responsibilities for federally insured credit unions (FICUs). The primary purpose of this regulation is to ensure that FICUs meet required financial reporting objectives and establish practices and procedures sufficient to safeguard members' assets from error, conflicts of interest, self-dealing, and fraud.

The current proposal seeks to partially or wholly eliminate several sections of this part. The following is a description of the purpose and function of those sections as they currently exist.

Section 715.2 defines key terms used throughout the part. It establishes the meaning of technical terms such as *financial statements*, *financial statement audit*, *GAAP*, and *GAAS*. It also defines terms specific to the rule's framework, such as *compensated person*, which refers to an accounting or auditing professional compensated for performing more than one supervisory committee audit per year, and *working papers*, which are the records supporting the auditor's findings. This section distinguishes a formal *financial statement audit* from the broader *supervisory committee audit* responsibility, which can be fulfilled through several alternative engagements.

Section 715.8 sets forth the requirements for the verification of member accounts. This requirement is derived from 12 U.S.C. 1761d and

obligates the supervisory committee to verify members' passbooks and accounts against the credit union's records at least once every two years. The regulation permits several methods for this verification, including a 100 percent controlled verification of all member share and loan accounts, a statistical sampling method, or a non-statistical sampling method consistent with GAAS when performed by a state-licensed independent person.

Section 715.9 governs the engagement of an outside, compensated person to assist the supervisory committee. To ensure auditor independence, the section prohibits such a person from being related by blood or marriage to any management employee or official of the credit union. It also mandates that the engagement be formalized through a written engagement letter contracted directly with the supervisory committee. This letter must specify the terms, conditions, objectives, and compensation for the engagement; identify the basis of accounting to be used; and set a target date for the delivery of the written audit report. The engagement letter must also certify that regulators will be provided unconditional access to the complete set of original working papers and acknowledge that these papers will be retained for at least three years.

Section 715.10 outlines the supervisory committee's responsibilities for the audit report and working papers. Upon receiving a written audit report, the committee must submit it to the board of directors and provide a summary of the audit to the members at the next annual meeting. If a member requests it, the committee must provide access to the full audit report. This section also holds the supervisory committee responsible for maintaining a complete set of original working papers for each audit and for providing the NCUA with unconditional access to these papers upon request.

Section 715.12 provides statutory remedies for the NCUA Board to address non-compliance by a federal credit union (FCU). The Board may compel a credit union to obtain a supervisory committee audit performed by an independent, state-licensed person if the credit union's supervisory committee fails to obtain a required annual audit or obtains one that does not meet the requirements of part 715. The Board may also compel a full financial statement audit if the credit union has experienced "serious and persistent recordkeeping deficiencies." The rule defines a deficiency as "serious" if financial reporting objectives are not met and member

assets are not safeguarded, and "persistent" if it continues beyond a reasonable period.

Section 741.202 applies supervisory committee audit and verification and other requirements of part 715 to all FICUs, which extends coverage to federally insured, state-chartered credit unions.

The reasons for the proposed changes are discussed in the preamble, under the heading "Discussion."

B. Legal Authority

Sections 115 and 202(a)(6) of the FCU Act set forth provisions addressing auditing and accounting requirements.¹ Section 115 of the FCU Act requires a FCU's supervisory committee to make an annual audit and submit a report of that audit to the FCU's board of directors and a summary of that report to the FCU's members at the next annual meeting.² Further, the supervisory committee is required to make supplemental reports as it deems necessary.

Section 202(a)(6)(A) of the FCU Act is a general grant of authority to the Board to prescribe audit standards that require an outside, independent audit by a certified public accountant for any fiscal year for which a FCU has not conducted an annual supervisory committee audit, has not received a complete and satisfactory supervisory committee audit, or during which the FCU has experienced persistent or serious recordkeeping deficiencies.³

Section 202(a)(6)(C) of the FCU Act generally requires FICUs having assets of \$10 million or more to use accounting principles consistent with GAAP in all reports or statements required to be filed with the Board. The Board, and state credit union supervisors under applicable state law, may require credit unions having less than \$10 million in assets to follow GAAP.

Section 202(a)(6)(D) of the FCU Act imposes audit requirements for larger FICUs. Specifically, a FCU having assets of \$500 million or more is required to obtain an annual independent audit of its financial statements performed in accordance with GAAS, hereafter referred to as a "financial statement audit." That audit must be performed by an independent certified public accountant or public accountant licensed to do so by an appropriate state or jurisdiction.⁴

Additionally, if an FCU having total assets of less than \$500 million but

¹ 12 U.S.C. 1761d; 12 U.S.C. 1782(a)(6).

² 12 U.S.C. 1761d.

³ 12 U.S.C. 1782(a)(6)(C).

⁴ 12 U.S.C. 1782(a)(6)(D).

more than \$10 million elects to obtain a financial statement audit, the audit must be performed consistent with the accountancy laws of the appropriate state or jurisdiction.⁵

II. Proposed Rule

The Board is proposing several amendments to 12 CFR part 715 to reduce regulatory burden, eliminate unnecessary and redundant provisions, and increase flexibility for FICUs. These changes are consistent with the Board's ongoing efforts to modernize its regulations and ensure they remain effective and efficient without imposing undue burdens. The proposed changes are discussed in detail below.

A. Elimination of Unnecessary and Prescriptive Requirements

The Board proposes to eliminate several provisions that are overly prescriptive, unnecessarily rigid, or redundant of existing statutory duties. These changes are intended to provide FICUs with greater flexibility in meeting their audit compliance obligations while maintaining the integrity of the audit and verification process.

1. Section 715.2

The Board is proposing to amend § 715.2(h), which defines “Internal control” for part 715. The current definition defines this term as the process designed by a FICU's board, officers, and employees to provide reasonable assurance of reliable financial reporting and safeguarding of assets against unauthorized acquisition, use, or disposition. The definition also describes internal control components in detail, specifying five components and describing reliable financial reporting. The second sentence of the paragraph, which enumerates the five components of an internal control structure, is overly prescriptive and risks becoming obsolete. This list is derived from a specific framework that may evolve over time. Removing this static definition would make the regulation more durable and allow FICUs and auditors to apply current, industry-accepted frameworks for evaluating internal controls. The third sentence, which defines reliable financial reporting by referencing only the preparation of Call Reports, is unduly narrow and is also proposed for removal to provide a more comprehensive understanding of the term.

2. Section 715.8

The Board is proposing to amend § 715.8(a), which details specific methods for the verification of member accounts. The FCU Act, at 12 U.S.C. 1761d, imposes a clear and self-executing duty on the supervisory committee to verify member accounts at least once every 2 years. The regulation requires members' accounts to be verified against the records of the treasurer of the credit union. The Board proposes to amend this requirement to state more generally that members' accounts must be verified against the credit union's records. The Board notes that the treasurer's records belong to the credit union. Thus, while the treasurer must maintain the records under the FCU Act, the supervisory committee is responsible for checking these records against members' account records.

3. Section 715.9

The Board is proposing to amend § 715.9(b), which provides details on engagement letters with outside, compensated auditors. The current provision requires the scope of work to be documented in an engagement letter contracted with the supervisory committee. The provision also details how the engagement letter must be signed by both parties. The Board finds this additional detail and prescription unnecessary. Without this description, the provision is clear that the supervisory committee must enter into a contract with the outside, compensated auditor. Prescribing this process in greater detail adds to the body of regulations that FICUs must follow without any clear benefit. Therefore, the Board proposes to remove the final sentence of this provision.

4. Section 715.10

The Board is also proposing to amend § 715.10(a) by removing the sentence that requires a supervisory committee to provide the NCUA with a copy of audit reports upon request. This provision is entirely redundant of the Board's existing authority. The Board has broad statutory power under the FCU Act to access all books and records of any FICU during its examination and supervision activities.⁶ This inherent authority includes the power to obtain audit reports, which are records of the credit union. Eliminating this duplicative regulatory language streamlines the rule without in any way diminishing the agency's access to information or its oversight capabilities.

5. Section 715.12

Finally, the Board proposes to remove two sentences from § 715.12(b). This provision currently describes the objective of a financial statement audit compelled by the NCUA and states that an “adverse opinion or disclaimer of opinion should be the exception rather than the norm.” This language is unnecessary because GAAS already establishes the objectives of a financial statement audit. This commentary in the regulation is best read as guidance and could cause confusion if auditing standards evolve to provide different objectives or expectations for financial statement audits. Therefore, the Board proposes to remove the final two sentences of this provision to reduce potential confusion.

The Board requests public comment on all of these proposed changes. Commenters are also invited to address whether the removal of prescriptive language in §§ 715.9(b) and 715.12(b) achieves the goal of reducing administrative burden without compromising audit integrity.

III. Regulatory Procedures

A. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (5 U.S.C. 553(b)(4)) (Act) requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as *regulations.gov*). The Act, under its terms, applies to notices of proposed rulemaking and does not expressly include other types of documents that the Board publishes voluntarily for public comment, such as notices and interim-final rules that request comment despite invoking “good cause” to forgo such notice and public procedure. The Board, however, has elected to address the Act's requirement in these types of documents in the interests of administrative consistency and transparency.

In summary, the Board is proposing to amend its regulations governing supervisory committee audits to eliminate unnecessary, redundant, and overly prescriptive provisions. This action is necessary to reduce regulatory burden, increase operational flexibility for credit unions, and streamline the rules by removing requirements that are outdated or duplicative of other authorities. The intended effect of this

⁵ 12 U.S.C. 1782(a)(6)(D)(iii).

⁶ 12 U.S.C. 1756, 1784, 1789.

proposal is to simplify compliance for credit unions without compromising the integrity of the audit process.

The proposal and the required summary can be found at <https://www.regulations.gov>.

B. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 (“Regulatory Planning and Review”), as amended by Executive Order 14215, a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the Executive Order.⁷ Executive Order 13563 (“Improving Regulation and Regulatory Review”) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.⁸ This proposed rule was drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. OMB has determined that this proposed rule is not a “significant regulatory action” as defined in section 3(f)(1) of Executive Order 12866.

Executive Order 14192 (“Unleashing Prosperity Through Deregulation”) requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.⁹ This proposed rule is expected to be a deregulatory action for purposes of Executive Order 14192.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act¹⁰ generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the agency makes such a certification, it shall publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.¹¹ For purposes of this analysis, the NCUA considers small credit unions to be those having under \$100 million in assets.¹² The Board fully considered the potential economic impacts of the

regulatory amendments on small credit unions.

The proposed changes would reduce burden and confusion by streamlining certain provisions in the NCUA’s audit regulations that apply to all FICUs. The changes would not substantially change FICUs’ audit obligations or the nature of these audits. Rather, the proposed changes would provide clarity and generally reduce the level of detail in the regulations, which may provide relief to FICUs, but are not likely to have a significant economic impact.

Accordingly, the NCUA certifies the proposed rule would not have a significant economic impact on a substantial number of small credit unions.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency may not conduct or sponsor, and not withstanding any other provision of law, a person is not required to respond to, a collection of information, unless it displays a currently valid Office of Management and Budget control number. The PRA applies to rulemakings in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information-collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. The NCUA has determined that the changes described in this notice do not create a new information collection or revise an existing information collection as defined by the PRA.

E. Executive Order 13132 on Federalism

Executive Order 13132 encourages certain regulatory agencies to consider the impact of their actions on state and local interests. The NCUA, an agency as defined in 44 U.S.C. 3502(5), complies with the executive order to adhere to fundamental federalism principles. The NCUA’s audit regulations apply to all FICUs, including federally insured, state-chartered credit unions. The proposed changes would not change or impose any new burdens on FICUs, including state-chartered credit unions. The proposed changes would streamline and clarify certain provisions without changing FICUs’ audit obligations. The rulemaking would therefore not have direct effect on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999.¹³ The proposed rule concerns FICUs’ audit obligations and procedures. Any effect on members’ accounts, and by extension their financial well-being, is likely to be indirect.

List of Subjects in 12 CFR Part 715

Accounting, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board, this 8th day of December 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons stated in the preamble, the NCUA Board proposes to amend 12 CFR part 715 as follows:

PART 715—SUPERVISORY COMMITTEE AUDITS AND VERIFICATIONS

- 1. The authority citation for part 715 continues to read as follows:

Authority: 12 U.S.C. 1761(b), 1761d, 1782(a)(6).

- 2. Revise § 715.2 (h) to read as follows:

§ 715.2 Definitions used in this part.

* * * * *

(h) *Internal control* refers to the process, established by the credit union’s board of directors, officers and employees, designed to provide reasonable assurance of reliable financial reporting and safeguarding of assets against unauthorized acquisition, use, or disposition. Internal control over safeguarding of assets against unauthorized acquisition, use, or disposition refers to prevention or timely detection of transactions involving such unauthorized access, use, or disposition of assets which could result in a loss that is material to the financial statements.

* * * * *

§ 715.8 [Amended]

- 3. In § 715.8(a), remove the words “of the treasurer”.
- 4. Revise § 715.9 (b) to read as follows:

§ 715.9 Assistance from outside, compensated person.

* * * * *

(b) *Engagement letter.* The engagement of a compensated auditor to

⁷ 58 FR 51735 (Oct. 4, 1993).

⁸ 76 FR 3821 (Jan. 21, 2011).

⁹ 90 FR 9065 (Feb. 6, 2025).

¹⁰ 5 U.S.C. 601 *et seq.*

¹¹ 5 U.S.C. 605(b).

¹² 80 FR 57512 (Sept. 24, 2015).

¹³ Public Law 105–277, 112 Stat. 2681 (1998).

perform all or a portion of the scope of a financial statement audit or supervisory committee audit shall be evidenced by an engagement letter. In all cases, the engagement must be contracted directly with the Supervisory Committee.

* * * * *

■ 5. Revise § 715.10 (a) to read as follows:

§ 715.10 Audit report and working paper maintenance and access.

(a) *Audit report.* Upon completion and/or receipt of the written report of a financial statement audit or a supervisory committee audit, the Supervisory Committee must verify that the audit was performed and reported in accordance with the terms of the engagement letter prescribed herein. The Supervisory Committee must submit the report(s) to the board of directors, and provide a summary of the results of the audit to the members of the credit union orally or in writing at the next annual meeting of the credit union. If a member so requests, the Supervisory Committee shall provide the member access to the full audit report.

* * * * *

■ 6. Revise § 715.12(b) to read as follows:

§ 715.12 Statutory audit remedies for Federal credit unions.

* * * * *

(b) *Financial statement audit required.* The NCUA Board may compel a federal credit union to obtain a financial statement audit performed in accordance with GAAS by an independent person who is licensed by the State or jurisdiction in which the credit union is principally located (even if such audit is not required by § 715.5), for any fiscal year in which the credit union has experienced serious and persistent recordkeeping deficiencies as defined in paragraph (c) of this section.

* * * * *

[FR Doc. 2025–22488 Filed 12–10–25; 8:45 am]

BILLING CODE 7535–01–P

**NATIONAL CREDIT UNION
ADMINISTRATION**

12 CFR Part 748

RIN 3133–AF79

**Guidance on Response Programs for
Unauthorized Access to Member
Information and Member Notice**

AGENCY: National Credit Union
Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is proposing to remove Appendix B to part 748, Guidance on Response Programs for Unauthorized Access to Member Information and Member Notice. Appendix B was issued in June 2005. Its purpose was to provide federally insured credit unions (FICUs) with guidance for creating programs to address and respond to instances of unauthorized access to member information. The Board now believes that the placement of Appendix B in the Code of Federal Regulations (CFR) may be confusing because Appendix B itself is guidance to assist FICUs in developing the response programs required pursuant to regulation. The Board instead would publish the content of Appendix B as guidance. This will be a better vehicle for conveying and updating this information and will help to streamline NCUA's regulations.

DATES: Comments must be received on or before February 9, 2026.

ADDRESSES: You may submit written comments by any of the following methods identified by RIN (Please send comments by one method only):

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments for Docket Number NCUA–2025–1305.

- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

- *Hand Delivery/Courier:* Same as mail address.

Mailed and hand-delivered comments must be received by the close of the comment period.

Public Inspection: All public comments are available on the Federal eRulemaking Portal at <https://www.regulations.gov> as submitted, except when impossible for technical reasons. Public comments will not be edited to remove any identifying or contact information. If you are unable to access public comments on the internet, you may contact NCUA for alternative access by calling (703) 518–6540 or emailing OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Gira Bose, Senior Staff Attorney, at (703) 518–6540 or at 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

On May 2, 2005, the Board issued a final rule to revise 12 CFR part 748 to include a requirement that FICUs

respond to incidents of unauthorized access to member information.¹ Appendix B, entitled Guidance on Response Programs for Unauthorized Access to Member Information and Member Notice, was included in the final rule to assist FICUs in developing and maintaining their response programs. It was a further interpretation of the Gramm Leach Bliley Act's requirement that NCUA and other regulators adopt standards for safeguarding customer information that financial institutions could adopt.²

Appendix B notes that each year, millions of Americans throughout the country fall victim to identify theft as a result of the misuse of their personal information obtained by identity thieves from a number of sources, including credit unions.³ It goes on to state that, as a result, credit unions should take preventative measures to safeguard member information against such attempts, and to do so in a way that is appropriate to the size and complexity of the credit union and the nature and scope of its activities. Thus, Appendix B is designed to be risk-based and to give FICUs discretion in addressing incidents of unauthorized access to or use of member information that could result in substantial harm or inconvenience to a member.

B. Legal Authority

The standards in Appendix B fulfill a requirement in the Gramm-Leach-Bliley Act, through which Congress directed NCUA and other federal regulators to establish standards for financial institutions relating to the safeguarding of customer information.⁴ Under the Federal Credit Union Act (FCU Act), NCUA examines all FICUs and is required to ensure that all FICUs operate safely and soundly. In particular, 12 U.S.C. 1786(b) compels the agency to act to correct unsafe or unsound conditions or practices in FICUs. Sections 120 and 209 of the FCU Act are plenary grants of regulatory authority to the Board to examine and require information and reports from credit unions as well as issue the regulations necessary or appropriate to carry out its roles as regulator and share insurer. Section 204 of the FCU Act requires the Board to

¹ 70 FR 22764 (May 2, 2005).

² 15 U.S.C. 6801 *et seq.* (Nov. 12, 1999). Appendix B was issued in consultation with the federal banking agencies (FBAs), comprising the Office of the Comptroller of the Currency, the Federal Reserve Board, the Federal Deposit Insurance Corporation, and the now-defunct Office of Thrift Supervision. The FBAs issued similar guidance on a joint basis. 70 FR 15736 (Mar. 29, 2005).

³ 12 CFR 748 App. B (II)(i).

⁴ 15 U.S.C. 6801 *et seq.* (Nov. 12, 1999).

appoint examiners who shall have the power to thoroughly examine the affairs of (FICUs) and report to the Board. Section 206 of the FCU Act requires the agency to impose corrective measures whenever, in the opinion of the Board, any credit union is engaged in or has engaged in unsafe or unsound practices in conducting its business. Accordingly, the FCU Act grants the Board broad rulemaking authority to protect credit unions, their member owners, and the National Credit Union Share Insurance Fund.

II. Proposed Rule

The Board is now issuing this proposed rule to remove Appendix B from the CFR. The Board believes that the information conveyed in Appendix B can be just as easily communicated by a Letter to Credit Unions, which would have the advantage of being better recognized by FICUs as nonbinding guidance. The Board believes that issuing Appendix B alongside part 748 may give the false impression that it is a legally binding rule rather than an aid to credit unions that can help them meet the regulatory requirements of part 748. The Board seeks comments on all aspects of this proposed rule, including any references to Appendix B in other parts of NCUA's regulations that may need to be revised.

The Board considered retaining Appendix B in its current form. The current practice ensures the agency reviews Appendix B once every three years as part of its one third regulatory review process. Maintaining Appendix B as part of NCUA's regulations also guarantees that any changes, whether technical or substantive, are published in the **Federal Register** typically with an opportunity for public notice and comment (unless an exception under the Administrative Procedure Act applies). Maintaining the current placement would maintain comparability with the FBAs whose guidance is also located in the CFR. However, the Board now believes that streamlining NCUA's regulations and creating a greater separation between binding regulations and nonbinding guidelines outweighs the benefits of the current approach. The Board also believes that the Agency's adoption of separate guidance is appropriate for communicating guidelines such as those in Appendix B. The Board is soliciting feedback on all aspects of this proposed rule, including the option of maintaining the status quo.

III. Regulatory Procedures

A. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (5 U.S.C. 553(b)(4)) requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that shall be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as *regulations.gov*).

In summary, the Board is proposing to remove Appendix B to part 748, Guidance on Response Programs for Unauthorized Access to Member Information and Member Notice. The Board believes that moving Appendix B to a Letter to Credit Unions is a better vehicle for conveying this information and will help to streamline the NCUA's regulations. The intended effect is to simplify the regulatory text and make it easier to navigate, without altering any substantive compliance obligations.

The proposed rule and the required summary are available at <https://www.regulations.gov>.

B. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 ("Regulatory Planning and Review"), as amended by Executive Order 14215, a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the Executive Order. OMB has determined that this proposed rule is not a "significant regulatory action" as defined in section 3(f)(1) of Executive Order 12866.

Executive Order 13563 ("Improving Regulations and Regulatory Review") directs executive agencies to analyze regulations that are "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned." Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. This proposed rule will streamline the NCUA's regulations by removing nonbinding guidelines. This proposed rule is consistent with Executive Order 13563.

Executive Order 14192 ("Unleashing Prosperity Through Deregulation") requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.¹⁸ This proposed rule is expected to be a deregulatory action for purposes of Executive Order 14192.

C. The Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.⁵ If the agency makes such a certification, it shall publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.⁶ For purposes of this analysis, the NCUA considers small credit unions to be those having under \$100 million in assets.⁷ The Board fully considered the potential economic impacts of the regulatory amendments on small credit unions. The proposed rule removes nonbinding guidelines but would retain them in another format without substantive change. Accordingly, the NCUA certifies that the proposed rule would not have a significant economic impact on a substantial number of small credit unions.

D. The Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency may not conduct or sponsor, and not withstanding any other provision of law, a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The PRA applies to rulemakings in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information-collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. The NCUA has determined that the changes in the proposed rule do not create a new information collection or revise an existing information collection as defined by the PRA.

E. Analysis on Executive Order 13132 on Federalism

Executive Order 13132 encourages certain agencies to consider the impact of their actions on state and local interests. The NCUA, an agency as

defined in 44 U.S.C. 3502(5), complies with the executive order to adhere to fundamental federalism principles. This proposed rule is intended to remove nonbinding guidelines from the NCUA's regulations. While it does impact provisions that apply to FISCUs, it does not make a substantive change and is not intended to affect the division of responsibilities between the NCUA and state regulatory authorities.

F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999. The proposed rule removes nonbinding guidelines from the NCUA's regulations, and any effect on family well-being is expected to be indirect.

List of Subjects in 12 CFR Part 748

Administrative practice and procedure, Banks, banking, Credit, Credit unions, Personally identifiable information, Privacy, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board, this 8th day of December 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons stated in the preamble, the NCUA Board proposes to amend 12 CFR part 748 as follows:

PART 748—SECURITY PROGRAM, SUSPICIOUS TRANSACTIONS, CATASTROPHIC ACTS, CYBER INCIDENTS, AND BANK SECRECY ACT COMPLIANCE

■ 1. The authority citation for part 748 continues to read as follows:

Authority: 12 U.S.C. 1766(a), 1766(b)(1), 1766(g), 1789(a)(11); 15 U.S.C. 6801–6809; 31 U.S.C. 5311 and 5318.

■ 2. The table of contents is amended to read as follows:

Sec.
748.0 Security Program.
748.1 Filing of Reports.
748.2 Procedures for monitoring Bank Secrecy Act (BSA) compliance.

■ 3. Remove Appendix B to part 748—Guidance on Response Programs for Unauthorized Access to Member Information and Member Notice.

[FR Doc. 2025–22490 Filed 12–10–25; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 748

RIN 3133–AF76

Guidelines for Safeguarding Member Information

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is proposing to remove Appendix A to part 748, guidelines for safeguarding member information, from the Code of Federal Regulations (CFR). Appendix A was issued to satisfy the NCUA's statutory obligation to establish appropriate standards for federally insured credit unions (FICUs) to protect the security and confidentiality of customer records and information and to protect against unauthorized access to or use of such records. The Board now believes that the placement of Appendix A in the CFR may be confusing because Appendix A is not a regulation but rather a set of guidelines intended to assist FICUs with their statutory compliance obligations. The Board will remove Appendix A from the CFR and publish its contents as a Letter to Credit Unions, which enables more efficient revisions, and streamlines the NCUA's regulations.

DATES: Comments must be received on or before February 9, 2026.

ADDRESSES: Comments may be submitted in one of the following ways. (*Please send comments by one method only*):

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. The docket number for this proposed rule is NCUA–2025–1304. Follow the “Submit a comment” instructions. If you are reading this document on [federalregister.gov](https://www.federalregister.gov), you may use the green “SUBMIT A PUBLIC COMMENT” button beneath this rulemaking's title to submit a comment to the [regulations.gov](https://www.regulations.gov) docket. A plain language summary of the proposed rule is also available on the docket website.

- **Mail:** Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

- **Hand Delivery/Courier:** Same as mailing address.

Mailed and hand-delivered comments must be received by the close of the comment period.

Public inspection: Please follow the search instructions on <https://www.regulations.gov> to view the public comments. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously. If you are unable to access public comments on the internet, you may contact the NCUA for alternative access by calling (703) 518–6540 or emailing OGCMail@ncua.gov.

FOR FURTHER INFORMATION CONTACT: Gira Bose, Senior Staff Attorney, at (703) 518–6540 or at 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

In November 1999, Congress passed the Gramm-Leach Bliley Act (GLBA).¹ Section 501 of GLBA, entitled Protection of Nonpublic Personal Information, required the NCUA, the federal banking agencies (FBAs), and other regulators to establish appropriate standards for financial institutions subject to their respective jurisdictions relating to administrative, technical, and physical safeguards for customer records and information.² These safeguards are intended to: (1) insure [sic]³ the security and confidentiality of customer records and information, (2) protect against any anticipated threats or hazards to the security or integrity of such records, and (3) protect against unauthorized access to or use of such records or information that would result in substantial harm or inconvenience to any customer.⁴

After passage of GLBA, the Board determined that the standards required by GLBA could be most effectively adopted through an amendment to the NCUA's existing regulation governing security programs in FICUs.⁵ This approach is consistent with the FBAs by design: NCUA staff worked with the FBAs to align the agency's guidance with the guidelines approved by the

¹ 15 U.S.C. 6801 *et. seq.* (Nov. 12, 1999).

² *Id.* At this time, “federal banking agencies” refers to the Office of the Comptroller of the Currency, the Federal Reserve Board, and the Federal Deposit Insurance Corporation, although at the time of GLBA's passage the term included the now-defunct Office of Thrift Supervision.

³ The statute uses the word “insure,” but should likely read “ensure.”

⁴ 15 U.S.C. 6801(b).

⁵ 66 FR 8152 (Jan. 30, 2001).

FBA's.⁶ Thus, the NCUA adopted the standards required under GLBA as an appendix to part 748. The resulting Appendix A is intended to provide FICUs with guidance in developing the security program required under § 748.0.

Appendix A has been amended over the years to reflect new requirements and maintain consistency with comparable regulations and guidelines issued by the FBAs. In 2004, the agency revised Appendix A to incorporate amendments to the Fair Credit Reporting Act (FCRA) with respect to the proper disposal of consumer information.⁷ Section 216 of the Fair and Accurate Credit Transactions Act (FACT Act) added a new section to FCRA that was designed to protect a consumer against the risks associated with unauthorized access to information about the consumer contained in a consumer report. *The FACT Act made mandatory the NCUA's practice of maintaining consistency with GLBA through consistency and consultation with the FBAs.* The changes to Appendix A were intended to provide guidance to FCUs for compliance with § 717.83 and were done in consultation with the FBAs.⁸

In 2012 and 2013, the Board again amended part 748 and Appendix A with technical changes mandated by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) and based on the NCUA's rolling, 3-year regulatory review.⁹ The Dodd-Frank Act, among other things, transferred rulemaking authority for many consumer protection regulations from the Federal Reserve Board to the Consumer Financial Protection Bureau (CFPB).¹⁰ As a result, the NCUA was required to update certain cross citations within its regulations and rescind part 716 governing the "Privacy

of Consumer Financial Information" under GLBA.¹¹

B. Legal Authority

The Board is issuing this proposed rule pursuant to its authority under the Federal Credit Union Act (FCU Act).¹² Under the FCU Act, the NCUA is the chartering and supervisory authority for federal credit unions (FCUs) and the federal supervisory authority for federally insured credit unions (FICUs). The FCU Act grants the NCUA a broad mandate to issue regulations governing both FCUs and FICUs. Section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe regulations for the administration of the FCU Act.¹³ Section 209 of the FCU Act is a plenary grant of regulatory authority to the NCUA to issue regulations necessary or appropriate to carry out its role as share insurer for all FICUs.¹⁴ The FCU Act also includes an express grant of authority for the Board to subject federally chartered central, or corporate, credit unions to such rules, regulations, and orders as the Board deems appropriate.¹⁵

II. Proposed Rule

The Board is issuing this proposed rule to remove Appendix A from the CFR. The Board believes that the information conveyed in Appendix A can be provided through Letters to Credit Unions, thereby reinforcing its intended use as nonbinding guidance. The Board believes that issuing Appendix A alongside part 748 may give the false impression that it is a legally binding rule rather than merely an aid to credit unions in satisfying the regulatory requirements of part 748.

The Board seeks comments on all aspects of this proposed rule, including any references to Appendix A in other parts of NCUA's regulations that may need to be revised.

As discussed above, Appendix A was first issued to meet a statutory requirement, and it has been amended several times to reflect new statutory requirements and to remain consistent with guidelines issued by the FBAs. The Board considered retaining Appendix A in its current form for two reasons: first, the current practice ensures the agency reviews Appendix A once every three years as part of its one third regulatory

review process. Second, maintaining Appendix A as part of the NCUA's regulations also guarantees that any changes, whether technical or substantive, are published in the **Federal Register**, typically with an opportunity for public notice and comment (unless an exemption under the Administrative Procedure Act applies).

However, the Board now believes that streamlining the NCUA's regulations and creating a greater separation between binding regulations and nonbinding guidelines outweighs the benefits of the current approach. The Board also believes that the Agency's adoption of Letters to Credit Unions as a communication method is well known to the industry and is appropriate for communicating guidelines such as those in Appendix A. The Board is soliciting feedback on all aspects of this proposed rule, including the option of maintaining the status quo.

III. Regulatory Procedures

A. Providing Accountability Through Transparency Act of 2023

The Providing Accountability Through Transparency Act of 2023 (5 U.S.C. 553(b)(4)) (Act) requires that a notice of proposed rulemaking include the internet address of a summary of not more than 100 words in length of a proposed rule, in plain language, that must be posted on the internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as regulations.gov). In summary, the Board is proposing to remove Appendix A to part 748 from the CFR. The Board now believes that the placement of Appendix A in the CFR may be confusing because Appendix A is not a regulation but rather a set of guidelines intended to assist FICUs with their statutory compliance obligations. The Board believes that moving Appendix A to a Letter to Credit Unions is a better vehicle for conveying this information and will help to streamline NCUA's regulations.

The proposal and the required summary can be found at <https://www.regulations.gov>.

B. Executive Orders 12866, 13563, and 14192

Pursuant to Executive Order 12866 ("Regulatory Planning and Review"), as amended by Executive Order 14215, a determination must be made whether a regulatory action is significant and therefore subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the

⁶ 65 FR 35162 (June 1, 2000).

⁷ The Fair Credit Reporting Act, 15 U.S.C. 1681s(b) and 1681w, as amended by the Fair and Accurate Credit Transactions Act of 2003, 15 U.S.C. 1681s.

⁸ 69 FR 69269 (Nov. 29, 2004). While the FACT Act applied only to FCUs and the changes to the guidelines were done to assist FCUs in complying with § 717.83, as drafted, the changes to the Appendix A guidance apply to all FICUs. As the Board explained in the preamble to the 2004 changes, "the requirements of this final rule only apply to FCUs, while federally insured state-chartered credit unions are subject to the jurisdiction of the FTC on this matter. The NCUA believes, however, that federally insured state charters may find this guidance helpful in adopting meaningful and effective security programs that deal with the disposal of consumer information."

⁹ 77 FR 71085 (Nov. 29, 2012); 78 FR 32541 (May 31, 2013).

¹⁰ 12 U.S.C. 5581(b)(6) (July 21, 2010).

¹¹ 12 CFR part 716. To assist FICUs, the part 716 heading was retained with a cross citation to the CFPB's republished version of the regulation at 12 CFR part 1016.

¹² 12 U.S.C. 1751 *et seq.*

¹³ 12 U.S.C. 1766(a).

¹⁴ 12 U.S.C. 1789.

¹⁵ 12 U.S.C. 1766(a).

Executive Order.¹⁶ Executive Order 13563 (“Improving Regulation and Regulatory Review”) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.¹⁷ This proposed rule was drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. OMB has determined that this proposed rule is not a “significant regulatory action” as defined in section 3(f)(1) of Executive Order 12866. Further, this proposed rule is consistent with Executive Order 13563. This proposed rule will streamline the NCUA’s regulations by removing nonbinding guidelines.

Executive Order 14192 (“Unleashing Prosperity Through Deregulation”) requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.¹⁸ This proposed rule is expected to be a deregulatory action for purposes of Executive Order 14192.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act¹⁹ generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the agency makes such a certification, it must publish the certification at the time of publication of either the proposed rule or the final rule, along with a statement providing the factual basis for such certification.²⁰ For purposes of this analysis, the NCUA considers small credit unions to be those having under \$100 million in assets.²¹ The Board fully considered the potential economic impacts of the regulatory amendments on small credit unions.

The proposed rule removes nonbinding guidelines but would retain them in another format without substantive change. Accordingly, the NCUA certifies the proposed rule would not have a significant economic impact on a substantial number of small credit unions.

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) generally provides that an agency

may not conduct or sponsor, and not withstanding any other provision of law, a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The PRA applies to rulemakings in which an agency creates a new or amends existing information collection requirements. For purposes of the PRA, an information-collection requirement may take the form of a reporting, recordkeeping, or a third-party disclosure requirement. NCUA has determined that the changes in the proposed rule do not create a new information collection or revise an existing information collection as defined by the PRA.

E. Executive Order 13132 on Federalism

Executive Order 13132 encourages certain agencies to consider the impact of their actions on state and local interests. The NCUA, an agency as defined in 44 U.S.C. 3502(5), complies with the executive order to adhere to fundamental federalism principles. This proposed rule is intended to remove nonbinding guidelines from the NCUA’s regulations. While it does impact provisions that apply to FISCUs, it does not make a substantive change. The rulemaking would therefore not have direct effect on the states, the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999.²² The proposed rule removes nonbinding guidelines from the NCUA’s regulations, and any effect on family well-being is expected to be indirect.

List of Subjects in 12 CFR Part 748

Administrative practice and procedure, Banks, Banking, Credit, Credit unions, Personally identifiable information, Privacy, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board, this 8th day of December 2025.

Melane Conyers-Ausbrooks,
Secretary of the Board.

For the reasons stated in the preamble, the Board proposes to revise part 748 as follows:

PART 748—SECURITY PROGRAM, SUSPICIOUS TRANSACTIONS, CATASTROPHIC ACTS, CYBER INCIDENTS, AND BANK SECRECY ACT COMPLIANCE

■ 1. The authority citation for part 748 continues to read as follows:

Authority: 12 U.S.C. 1766(a), 1786(b)(1), 1786(q), 1789(a)(11); 15 U.S.C. 6801–6809; 31 U.S.C. 5311 and 5318.

■ 2. The table of contents is revised to read as follows:

Sec.

748.0 Security Program.

748.1 Filing of Reports.

748.2 Procedures for monitoring Bank Secrecy Act (BSA) compliance.

Appendix A to Part 748—Guidance on Response Programs for Unauthorized Access to Member Information and Member Notice.

■ 3. Remove Appendix A to part 748—Guidelines for Safeguarding Member Information.

[FR Doc. 2025–22489 Filed 12–10–25; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2025–2616; Airspace Docket No. 25–ANM–135]

RIN 2120–AA66

Establishment of Class E Airspace; Providence Seaside Hospital Heliport, Seaside, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface at Providence Seaside Hospital Heliport, Seaside, OR, that would contain the Area Navigation (RNAV) (Global Positioning System [GPS]) 17 approach procedure and the CEKOG ONE (RNAV) departure procedure, which would support the safety and management of instrument flight rules (IFR) operations at the heliport.

DATES: Comments must be received on or before January 26, 2026.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2025–2616 and Airspace Docket No. 25–ANM–135 using any of the following methods:

* *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the

¹⁶ 58 FR 51735 (Oct. 4, 1993).

¹⁷ 76 FR 3821 (Jan. 21, 2011).

¹⁸ 90 FR 9065 (Feb. 6, 2025).

¹⁹ 5 U.S.C. 601 *et seq.*

²⁰ 5 U.S.C. 605(b).

²¹ 80 FR 57512 (Sept. 24, 2015).

²² Public Law 105–277, 112 Stat. 2681 (1998).

online instructions for sending your comments electronically.

* *Mail*: Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier*: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax*: Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11K *Airspace Designations and Reporting Points*, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Bryantjay T. Toves, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3465.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace to support IFR operations at Providence Seaside Hospital Heliport, Seaside, OR.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Incorporation by Reference

Class E5 airspace designations are published in paragraph 6005, of FAA Order JO 7400.11, *Airspace Designations and Reporting Points*, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11K, dated August 20, 2025 and effective September 15, 2025. These amendments would be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11K, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

Background

The FAA published an NPRM in the **Federal Register** for FAA 2025–2616 (90 FR 43580; September 10, 2025) to establish Class E airspace at Providence Seaside Hospital, Seaside, Oregon. The extension proposed was to establish Class E airspace extending upward from 700 feet above the surface at Providence Seaside Hospital Heliport, Seaside, OR, that would contain the RNAV (GPS) 17 approach procedure and the CEKOG ONE (RNAV) departure procedure. Subsequent to the publication of the NPRM, the FAA updated the airspace configuration supporting the CEKOG ONE (RNAV) departure procedure to maintain IFR operations within controlled airspace until reaching 1,200 feet above the surface. The FAA discovered that the containment criteria for the CEKOG ONE (RNAV) departure procedure was incorrect and should be changed to contain departing IFR operations until reaching 1,200 feet above the surface. This SNPRM updates the FAA’s proposal to correct that error.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 that would establish Class E airspace extending upward from 700 feet above the surface at Providence Seaside Hospital Heliport, Seaside, OR. The proposed establishment of Class E airspace is due to the development of IFR procedures, which require controlled airspace for containment.

The amendment to the Class E airspace would encompass an area approximately 3.7 by 10.3 miles to contain IFR operations while conducting the RNAV (GPS) 17 approach procedure or the CEKOG ONE (RNAV) departure procedure. The northern boundary would extend 8 miles to accommodate arriving IFR operations below 1,500 feet above the surface. Additionally, the southern

boundary would extend 2.3 miles to contain departing IFR operations until reaching 1,200 feet above the surface.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1G, *FAA National Environmental Policy Act Implementing Procedures*, prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11K, *Airspace Designations and Reporting Points*, dated August 20, 2025, and effective September 15, 2025, is amended as follows:

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

* * * * *

ANM OR E5 Seaside, OR [New]

Providence Seaside Hospital Heliport OR
(Lat. 45°59′21″ N, long. 123°54′47″ W)

That airspace extending upward from 700 feet above the surface within an area 2.3 miles west and 1.4 miles east of the hospital's 360° bearing extending to 8 miles north of the hospital and within an area 2.3 miles west and 1.4 miles east of the hospital's 180° bearing extending to 2.3 miles south.

* * * * *

Issued in Des Moines, Washington, on December 8, 2025.

B.G. Chew,

*Group Manager, Operations Support Group,
Western Service Center.*

[FR Doc. 2025–22499 Filed 12–10–25; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2023–0515; EPA–R05–OAR–2023–0516; EPA–R05–OAR–2023–0517; FRL–12810–01–R5]

Air Plan Approval; Michigan; Moderate Attainment Plan Elements for the Allegan County, Berrien County, and Muskegon County Areas for the 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Michigan State Implementation Plan (SIP) as meeting the reasonable further progress (RFP) requirements of the Clean Air Act (CAA) for the Allegan County (partial county), Berrien County, and Muskegon County (partial county) Moderate nonattainment areas for the 2015 ozone national ambient air quality standard (NAAQS). EPA is also proposing to approve updated 2017 base year emissions inventories and is initiating the adequacy process and proposing approval of the 2023 motor vehicle emissions budgets (budgets) associated with the Allegan County, Berrien County, and Muskegon County Moderate ozone nonattainment RFP demonstrations. EPA is proposing to approve these portions of the State's SIP submission pursuant to section 110 and part D of the CAA, and EPA's regulations.

DATES: Comments must be received on or before January 12, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2023–0515, EPA–R05–OAR–

2023–0516, or EPA–R05–OAR–2023–0517 at <https://www.regulations.gov>, or via email to arra.sarah@epa.gov. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI, PBI, or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Air and Radiation Division (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–1767, dagostino.kathleen@epa.gov. The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays.

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

I. Background

On December 28, 2015, EPA promulgated a revised 8-hour ozone NAAQS of 0.070 parts per million (ppm).¹ Promulgation of a revised NAAQS triggers a requirement for EPA to designate all areas of the country as nonattainment, attainment, or unclassifiable for the NAAQS. For the ozone NAAQS, this also involves classifying any nonattainment areas at the time of designation.² Ozone nonattainment areas are classified based on the severity of their ozone levels as

¹ 80 FR 65292, October 26, 2015, codified at 40 CFR 50.19.

² CAA sections 107(d)(1) and 181(a)(1).

determined based on the area's "design value," which represents air quality in the area for the most recent 3 years. The classifications for ozone nonattainment areas are Marginal, Moderate, Serious, Severe, and Extreme.³

Areas that EPA designates nonattainment for the ozone NAAQS are subject to the general nonattainment area planning requirements of CAA section 172 and the ozone-specific planning requirements of CAA section 182. Ozone nonattainment areas in the lower classification levels have fewer and/or less stringent mandatory air quality planning and control requirements than those in higher classifications. In EPA's December 6, 2018 (83 FR 62998), rule, "Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements," known as the "SIP Requirements Rule," EPA set forth nonattainment area requirements for the 2015 ozone NAAQS. These requirements are codified at 40 CFR part 51 subpart CC. For Marginal areas, a State is required to submit a baseline emissions inventory, adopt provisions into the SIP requiring emissions statements from stationary sources, and implement a nonattainment new source review program for the relevant ozone NAAQS.⁴ For Moderate areas, a State needs to comply with the Marginal area requirements, plus additional Moderate area requirements, including the requirement to submit a modeled demonstration that the area will attain the NAAQS as expeditiously as practicable but no later than 6 years after designation, the requirement to submit an RFP plan, the requirement to adopt and implement certain emissions controls, such as Reasonably Available Control Technology (RACT) and motor vehicle inspection and maintenance programs, and the requirement for greater emissions offsets for new or modified major stationary sources under the State's nonattainment new source review program.⁵

Effective August 3, 2018, EPA designated the Allegan County (partial county), Berrien County, and Muskegon County (partial county) areas as Marginal nonattainment areas for the 2015 ozone NAAQS.⁶ The Allegan County area includes Casco Township, Cheshire Township, the City of Douglas, the City of Holland, the City of Saugatuck, Clyde Township, Fillmore

Township, Ganges Township, Heath Township, Laketown Township, Lee Township, Manilus Township, Overisel Township, Saugatuck Township, and Valley Township. The Muskegon County area includes Blue Lake Township, the City of Montague, the City of Muskegon, the City of Muskegon Heights, the City of North Muskegon, the City of Roosevelt Park, the City of Whitehall, Dalton Township, (incl. the Village of Lakewood Club), Fruitland Township, Fruitport Township (incl. the Village of Fruitport), Laketon Township, Montague Township, Muskegon Township, Norton Shores Township, White River Township, and Whitehall Township.

On October 7, 2022 (87 FR 60897), pursuant to section 181(b)(2) of the CAA, EPA determined that the Allegan County, Berrien County and Muskegon County areas failed to attain the 2015 ozone NAAQS by the August 3, 2021, Marginal area attainment deadline and thus reclassified the areas from Marginal to Moderate nonattainment. In that action, EPA established January 1, 2023, as the due date for the State to submit all Moderate area nonattainment plan SIP requirements applicable to newly reclassified areas.

II. Evaluation of Michigan's Submittal

The Michigan Department of Environment, Great Lakes, and Energy (EGLE) submitted a SIP revision on October 16, 2023, to address Moderate area requirements for the Allegan County, Berrien County and Muskegon County areas under the 2015 ozone NAAQS. The submittal contained a number of nonattainment plan elements, including an updated 2017 base year emissions inventory for volatile organic compounds (VOC) and oxides of nitrogen (NO_x) and a 15% RFP plan with 2023 VOC and NO_x motor vehicle emissions budgets. The submission also included an attainment demonstration, a reasonably available control measures demonstration, and contingency measures, which are not being addressed in this action.

A. 2017 Base Year Emissions Inventory

1. Background

CAA sections 172(c)(3) and 182(a)(1), 42 U.S.C. 7502(c)(3) and 7511a(a)(1), require States to develop and submit, as SIP revisions, comprehensive, accurate, and complete emissions inventories for all areas designated as nonattainment for the ozone NAAQS. This requirement is codified at 40 CFR 51.1315, and the term "base year inventory" is defined at 51.1300(p). For ozone, the base year inventory is an estimation of actual

emissions of VOC and NO_x from all sources within the boundaries of the nonattainment area.

The regulation at 40 CFR 51.1315(a) requires that the inventory year be selected consistent with the baseline year for the RFP plan as required by 40 CFR 51.1310(b), which states that the baseline emissions inventory shall be the emissions inventory for the most recent calendar year for which a complete triennial inventory is required to be submitted to EPA under the provisions of subpart A of 40 CFR part 51, Air Emissions Reporting Requirements, 40 CFR 51.1 through 50. For areas designated as nonattainment in 2018, the most recent triennial inventory year conducted for the National Emissions Inventory (NEI) pursuant to the Air Emissions Reporting Requirements (AERR) rule is 2017.⁷

Further, 40 CFR 51.1315(c) requires emissions values included in the base year inventory to be actual ozone season day emissions as defined by 40 CFR 51.1300(q), which states: Ozone season day emissions means an average day's emissions for a typical ozone season work weekday. The State shall select, subject to EPA approval, the particular month(s) in the ozone season and the day(s) in the work week to be represented, considering the conditions assumed in the development of RFP plans and/or emissions budgets for transportation conformity.

On December 18, 2020, EGLE submitted a SIP revision addressing the emissions inventory requirement of CAA section 182(a)(1). EPA approved Michigan's 2017 base year emissions inventories for the Allegan County, Berrien County, and Muskegon County areas on January 18, 2023 (88 FR 2834).

2. Michigan's Emission Inventory Submittal

As part of Michigan's Moderate SIP submission, EGLE updated the 2017 base year emissions inventories to incorporate improved emissions estimates where available. In Michigan's original base year emissions inventory submittal, EGLE used the 2016v1 modeling platform to generate emissions data for the point and nonpoint sectors and MOVES2014 to generate emissions data for the onroad and nonroad sectors. EGLE updated the 2017 base year emissions inventories for the Allegan County, Berrien County, and Muskegon County areas using the 2016v2 modeling platform for point and nonpoint sectors and MOVES3⁸ for nonroad and on-road

³ CAA section 181(a)(1).

⁴ CAA section 182(a).

⁵ CAA section 182(b).

⁶ 83 FR 25776, June 4, 2018.

⁷ December 6, 2018, 83 FR 62998, 63005.

⁸ MOVES3 was the most current mobile model available at the time EGLE was developing

sectors. EGLE did not update biogenic emissions estimates.

EGLE converted annual point and nonpoint values to tons/day following the same procedure as was used when preparing the original 2017 base year emissions inventories. EGLE extracted data from the 2016v2 modeling platform to calculate the ratio of July emissions to total annual emissions for each county by sector. These conversion

factors were then divided by 31 days in July to create final daily scaling factors that were applied to the updated annual emissions estimates.⁹ The Michigan Department of Transportation (MDOT) used MOVES3 to generate nonroad and on-road July weekday emissions. Non-point and nonroad emissions for Allegan County and Muskegon County were scaled down based on geographic area. Allegan County is 50 percent of

full county; Muskegon is 58 percent of full county. On-road data for Allegan County and Muskegon County was apportioned using vehicle miles traveled and vehicle hours traveled ratios.

Table 1, below, shows the updated 2017 ozone season day emissions in tons per ozone season day of NO_x and VOC for the Allegan County, Berrien County, and Muskegon County areas.

TABLE 1—2017 BASE YEAR OZONE SEASON EMISSIONS

[Tons/day]

Area	Pollutant	Point	Nonpoint	On-road	Nonroad	Total
Allegan County	NO _x	0.98	0.89	1.86	0.69	4.42
	VOC	0.40	3.18	0.93	0.84	5.35
Berrien County	NO _x	1.54	1.31	5.05	1.63	9.53
	VOC	0.79	5.85	2.66	1.57	10.87
Muskegon County	NO _x	0.31	1.17	2.93	1.00	5.41
	VOC	0.30	3.09	2.26	0.71	6.36

3. Evaluation of Michigan's 2017 Base Year Emission Inventory

EPA has reviewed Michigan's 2017 base year emissions inventory for consistency with sections 172(c)(3) and 182(a)(1) of the CAA, and EPA's emission inventory requirements. The selection of 2017 as the base year comports with the RFP baseline year requirements set forth in the SIP Requirements Rule and codified at 40 CFR 51.1310(b).

EGLE documented the procedures used to estimate the emissions for each of the major source types. The documentation of the emission estimation procedures is adequate to determine that Michigan followed acceptable procedures to estimate the emissions. Accordingly, EPA concludes that Michigan has developed inventories of NO_x and VOC emissions that are comprehensive and complete.

B. 15% RFP Plan

1. Background

The CAA requires that States with areas designated as nonattainment for ozone achieve RFP toward attainment of the ozone NAAQS. CAA section 172(c)(2) contains a general requirement that nonattainment plans must provide for emissions reductions that meet RFP. For areas classified Moderate and above, section 182(b)(1) imposes a more specific RFP requirement that a State was required to meet through a 15% reduction in VOC emissions from the

baseline anthropogenic emissions within 6 years after November 15, 1990.

The SIP Requirements Rule addressed, among other things, RFP requirements as they apply to areas designated nonattainment and classified as Moderate for the 2015 ozone NAAQS.¹⁰ RFP requirements under the 2015 ozone NAAQS are codified at 40 CFR 51.1310. EPA interprets the 15% VOC emission reduction requirement in CAA section 182(b)(1) such that a State that has already met the 15% requirement for VOC for an area under either the 1-hour ozone NAAQS or a prior 8-hour ozone NAAQS would not have to fulfill that requirement through reductions of VOC again. Instead, EPA interprets CAA section 172(c)(2) to require States with such areas to obtain 15% ozone precursor emission reductions from VOC and/or NO_x over the first 6 years after the baseline year for the 2015 ozone NAAQS. Michigan has not met the 15% VOC reduction requirement of CAA section 182(b)(1) for the Allegan County, Berrien County, or Muskegon County areas under previous ozone NAAQS.¹¹ Therefore, the State must rely upon VOC emissions reductions to meet the RFP requirement for the 2008 ozone NAAQS.

The SIP Requirements Rule specifies that the baseline emissions inventory for RFP plans shall be the most recent calendar year prior to designation for which a complete triennial inventory is required to be submitted to EPA under

the provisions of subpart A of 40 CFR part 51, Air Emissions Reporting Requirements, 40 CFR 51.1 through 50. For areas designated as nonattainment in 2018, the most recent triennial inventory year conducted for the NEI pursuant to the AERR rule is 2017. The rule also allows the use of an alternative RFP baseline year that corresponds with the year of the effective date of an area's designation, *i.e.*, 2018 for areas designated nonattainment in 2018.¹²

States may not take credit for VOC or NO_x reductions occurring from sources outside the nonattainment area for purposes of meeting the 15% RFP requirements of CAA sections 172(c)(2), 182(b)(1) and 182(c)(2)(B).¹³

Except as specifically provided in CAA section 182(b)(1)(C) and (D) and CAA section 182(c)(2)(B), all emission reductions from SIP-approved or federally promulgated measures that occur after the baseline emissions inventory year are creditable for purposes of the RFP requirements in this section, provided the reductions meet the requirements for creditability, including the need to be enforceable, permanent, quantifiable, and surplus.¹⁴ Further, the Administrator has determined that the four categories of control measures listed in CAA section 182(b)(1)(D) are no longer required to be calculated for exclusion in RFP analyses because due to the passage of time the effect of these exclusions would be *de minimis*.¹⁵

Moderate SIPs for the Allegan County, Berrien County, and Muskegon County areas.

⁹ EGLE determined that weekend day emissions have a large impact on individual monitor design values and, therefore, included weekend days in the

calculation of typical ozone season day emission values.

¹⁰ 83 FR 62998 at 63004, December 6, 2018.

¹¹ 74 FR 47414, September 15, 2009.

¹² 83 FR 62998 at 63005, December 6, 2018, codified at 40 CFR 51.1310(b).

¹³ 40 CFR 51.1310(a)(6).

¹⁴ 40 CFR 51.1310(a)(5).

¹⁵ 40 CFR 51.1310(a)(7).

2. Michigan's 15% RFP Plan

Emission Inventories

To demonstrate that the Allegan County, Berrien County, and Muskegon County areas have achieved 15% RFP over the 6-year attainment planning period, EGLE is using a 2017 base year inventory and a 2023 RFP inventory. The procedures EGLE used to develop the 2017 base year inventory are discussed in section I.A. of this preamble. When developing the 2023 RFP inventory EGLE estimated onroad and nonroad emissions using EPA's MOVES3 model. For the point and

nonpoint source categories, EGLE used the 2023v3 modeling inventory.

EGLE converted annual point and nonpoint values to tons/day following the same procedure as was used when preparing the 2017 base year emissions inventories. EGLE extracted data from the 2023v2 modeling platform to calculate the ratio of July emissions to total annual emissions for each county by sector. These conversion factors were then divided by 31 days in July to create final daily scaling factors that were applied to the updated annual emissions estimates. The Michigan Department of Transportation (MDOT)

used MOVES3 to generate nonroad and on-road July weekday emissions. Non-point and nonroad emissions for Allegan County and Muskegon County were scaled down based on geographic area. Allegan County is 50 percent of full county; Muskegon is 58 percent of full county. On-road data for Allegan County and Muskegon County was apportioned using vehicle miles traveled and vehicle hours traveled ratios.

2023 ozone season day emissions of NO_x and VOCs for each county by sector are shown in Tables 3 and 4, below.

TABLE 2—2023 OZONE SEASON EMISSIONS
[Tons/day]

Area	Pollutant	Point	Nonpoint	Onroad	Nonroad	Total
Allegan County	NO _x	1.06	0.81	0.96	0.55	3.38
	VOC	0.44	3.32	0.67	0.59	5.02
Berrien County	NO _x	2.07	1.23	2.48	1.33	7.11
	VOC	1.11	5.79	1.8	1.12	9.82
Muskegon County	NO _x	0.52	1.04	1.44	0.79	3.79
	VOC	0.11	3.08	1.58	0.53	5.30

15% RFP Demonstration

EGLE demonstrated that the Allegan County, Berrien County, and Muskegon County Areas have achieved 15% RFP over the 6-year attainment planning period through VOC emission reductions in the onroad and nonroad sectors attributable to EPA's existing Federal regulations, Michigan's VOC RACT rules, Michigan's architectural and industrial maintenance coating rule, and Michigan's consumer products rule.¹⁶

EPA onroad mobile source regulations currently being implemented across the country include: passenger vehicle, SUV, and light duty truck emissions and fuel standards; light-duty truck and medium duty passenger vehicle evaporative standards; heavy-duty highway compression engine standards; heavy-duty spark ignition engine standards; motorcycle emission standards; mobile source air toxics fuel formulation standards, passenger vehicle emission standards, and portable container emission standards.¹⁷ EPA nonroad mobile source regulations

currently being implemented across the country include: aircraft, compression ignition, large spark ignition, locomotive engines, marine compression ignition, marine spark ignition, recreational vehicle, and small spark ignition engine emission standards and evaporative standards.¹⁸

Table 3 shows calculations demonstrating that Michigan's emission reductions meet the 15% RFP requirement for the Allegan County, Berrien County, and Muskegon County areas.

TABLE 3—15% RFP CALCULATIONS
[tpd]

Description	Formula	Area		
		Allegan County	Berrien County	Muskegon County
A. 2017 base year emission inventories		5.35	10.87	6.36
B. Required RFP % reductions—15%		0.15	0.15	0.15
C. RFP emission reductions required between 2017 & 2023	A * B	0.8	1.63	0.95
D. RFP target levels for 2023	A – C	4.55	9.24	5.41
E. 2023 projected emissions inventories		5.02	9.82	5.3
F. Reductions between 2017 and 2023 included in 2023 projected inventories:				
Federal onroad control programs		0.26	0.86	0.68
Federal nonroad control programs		0.25	0.44	0.18
Total		0.51	1.3	0.86
G. Reductions between 2017 and 2023 NOT included in 2023 projected inventories: *				
VOC RACT		0.23	0.6	0.15

¹⁶ EGLE also documented emission reductions from voluntary programs that EPA is not including in RFP calculations.

¹⁷ 40 CFR parts 59, 80, 85, 86, and 600.

¹⁸ 40 CFR parts 54, 60, 87, 89, 90, 1033, 1039, 1042, 1045, 1048, 1051, and 1054.

TABLE 3—15% RFP CALCULATIONS—Continued
[tpd]

Description	Formula	Area		
		Allegan County	Berrien County	Muskegon County
Architectural and industrial maintenance coatings rule		0.21	0.3	0.19
Consumer products rule		0.07	0.1	0.06
Total		0.51	1	0.4
H. Emission reductions allocated to motor vehicle emission budgets		0.03	0.05	0.16
I. Net emission reductions between 2017 and 2023	F + G – H	0.99	2.25	1.1
J. Are creditable emission reductions greater than or equal to 15% of the 2017 base year inventory?	I ≥ C?	Yes	Yes	Yes
K. 2023 RFP inventory: 2023 projected emissions inventories minus reductions not included in 2023 projected inventories plus emission reductions allocated to motor vehicle emission budgets.	E – G + H	4.54	8.87	5.06
L. Has 2023 RFP target been achieved?	K ≤ D?	Yes	Yes	Yes

3. Evaluation of Michigan's 15% RFP Plan

EPA has reviewed Michigan's 15% RFP plan for consistency with sections 172(c)(2) and 182(b)(1) of the CAA, and 40 CFR 51.1310. The selection of 2017 as the base year comports with the RFP baseline year requirements set forth in the SIP Requirements Rule and codified at 40 CFR 51.1310(b). EPA has reviewed the techniques used by Michigan to derive and quality assure the 2017 and 2023 emission estimates. EGLE documented the procedures used to estimate the emissions for each of the major source types. The documentation of the emission estimation procedures is thorough and adequate to determine that EGLE followed acceptable procedures to estimate the emissions. Emission reductions attributable to Federal onroad and nonroad regulations, Michigan's VOC RACT rules, Michigan's architectural and industrial maintenance coating rule, and Michigan's consumer products rule are permanent and enforceable and will result in at least 15% RFP in the Allegan County, Berrien County, and Muskegon County areas over the 6-year attainment planning period beginning with the 2017 base year. Thus, EPA is proposing to approve Michigan's 15% RFP plan for the Allegan County, Berrien County, and Muskegon County areas for the 2015 ozone NAAQS.

C. Motor Vehicle Emission Budgets

1. Background

Under section 176(c) of the CAA, transportation plans, programs, or projects that receive Federal funding or support, such as the construction of new

highways, must “conform” to (*i.e.*, be consistent with) the SIP before they receive Federal funding or approval. Conformity to the SIP means that transportation activities will not cause or contribute to any new air quality violations, increase the frequency or severity of any existing air quality problems, or delay timely attainment or any required interim emissions reductions or any other milestones. Regulations at 40 CFR part 93 subpart A set forth EPA policy, criteria, and procedures for demonstrating and ensuring conformity of transportation activities to a SIP.

Transportation conformity is a requirement for nonattainment and maintenance areas, as defined in 40 CFR 93.101. The budget in a State's SIP serves as a ceiling on emissions from an area's planned transportation system (see definition of “motor vehicle emissions budget” in 40 CFR 93.101 and how the term is used in 40 CFR 93.109 and 93.118).

When reviewing submitted SIPs containing budgets, EPA reviews the budgets for adequacy. Once EPA affirmatively finds the submitted budget is adequate for transportation conformity purposes, that budget must be used by State and Federal agencies in determining whether proposed transportation projects conform to the SIP as required by section 176(c) of the CAA.

EPA's substantive criteria for determining adequacy of a budget are set out in 40 CFR 93.118(e)(4). The process for determining adequacy is found in 40 CFR 93.118(f) and consists of three basic steps: public notification of a SIP submission, a public comment

period, and EPA's adequacy finding. The regulations that allow EPA to begin an adequacy review through a notice of proposed rulemaking in the **Federal Register** are found in 40 CFR 93.118(f)(2). This proposal notifies the public that EPA has received a SIP submission with budgets that EPA will review for adequacy and begins the public comment period. Comments must be submitted to the docket for this proposal by the close of the comment period on this proposal.

2. VOC and NO_x Budgets for the Allegan County, Berrien County, and Muskegon County Areas

The RFP plan includes VOC and NO_x budgets for the Allegan County, Berrien County, and Muskegon County areas for 2023, the milestone year for RFP. EPA invites the public to comment on the adequacy of these budgets as well as on its proposed approval of the budgets and on other actions EPA is proposing in this action.

The Michigan Department of Transportation prepared motor vehicle emissions inventories for 2017 and 2023 for the purpose of setting budgets for the year 2023. These inventories were developed using up-to-date assumptions about vehicles mile traveled (VMT), vehicle age distribution, socioeconomic variables, fuels used, weather inputs, other planning assumptions, and the latest approved motor vehicle emissions model at the time EGLE began to prepare the SIP submission, which was MOVES3. Total onroad emissions in the Allegan County, Berrien County, and Muskegon County areas are shown in Table 4.

TABLE 4—TOTAL ONROAD EMISSIONS IN THE ALLEGAN COUNTY, BERRIEN COUNTY, AND MUSKEGON COUNTY AREAS

Area	Pollutant	2017	2023	Difference
Allegan County	NO _x	1.86	0.96	– 0.9
	VOC	0.93	0.67	– 0.26
Berrien County	NO _x	5.05	2.48	– 2.57
	VOC	2.66	1.8	– 0.86
Muskegon County	NO _x	2.93	1.44	– 1.49
	VOC	2.26	1.58	– 0.68

Table 5 identifies Michigan's 2023 budgets. The budgets, agreed upon as part of the interagency consultation process, include the emission estimates

calculated for 2023 with an additional safety margin allocated to those estimates to accommodate future variations in travel demand models and

VMT forecast. A State can add a safety margin to a budget based on the transportation conformity regulation at 40 CFR 93.124(a).

TABLE 5—2023 BUDGETS FOR THE ALLEGAN COUNTY, BERRIEN COUNTY, AND MUSKEGON COUNTY AREAS
[tpd]

Area	Pollutant	2023 Estimated mobile emissions	Safety margin (% of 2023)	2023 Mobile safety margin allocation	2023 Mobile budget
Allegan County	NO _x	0.96	20	0.19	1.15
	VOC	0.67	5	0.03	0.70
Berrien County	NO _x	2.48	20	0.50	2.98
	VOC	1.8	3	0.05	1.85
Muskegon County	NO _x	1.44	20	0.29	1.73
	VOC	1.58	10	0.16	1.74

3. Evaluation of the VOC and NO_x Budgets for the Allegan County, Berrien County, and Muskegon County Areas

The VOC and NO_x budgets for the Allegan County, Berrien County, and Muskegon County areas were developed as part of an interagency consultation process which includes Federal, State, and local agencies. The budgets were clearly identified and precisely quantified. Michigan has demonstrated that the Allegan County, Berrien County, and Muskegon County areas can meet the 15% RFP requirement with mobile source emissions of 1.15 tpd of NO_x and 0.70 tpd of VOC, 2.98 tpd of NO_x and 1.85 tpd of VOC, and 1.73 tpd of NO_x and 1.74 tpd of VOC, respectively, in 2023 because, as shown in Table 3, despite partial allocation of the RFP plan surplus reductions, emissions will remain under 2023 RFP target levels. EPA is thus proposing to approve the 2023 VOC and NO_x budgets for use in determining transportation conformity in the Allegan County, Berrien County, and Muskegon County areas under the 2015 ozone NAAQS.

III. What action is EPA taking?

EPA is proposing to approve Michigan's updated 2017 base year emissions inventory and 15% RFP demonstration, including the associated motor vehicle emissions budgets, as revisions to Michigan's SIP pursuant to section 110 and part D of the CAA and

EPA's regulations because EGLE's October 16, 2023, submission satisfies the base year inventory and RFP requirements of the CAA for the Allegan County, Berrien County and Muskegon County areas under the 2015 ozone NAAQS. EPA is also initiating the adequacy process for the 2023 motor vehicle emissions budgets for the Allegan County, Berrien County and Muskegon County areas included in this SIP submission.

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;

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

- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

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

- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rulemaking does not have Tribal implications and will not impose substantial direct costs on Tribal

governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

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

Dated: November 24, 2025.

Anne Vogel,

Regional Administrator, Region 5.

[FR Doc. 2025–22607 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2024–0385; FRL–10808–01–R3]

Air Plan Approval; Virginia; Amendment to the State Operating Permit for GP Big Island, LLC

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the Commonwealth of Virginia's (Commonwealth or Virginia) Department of Environmental Quality (VADEQ). This revision pertains to an amendment to an operating permit limiting visibility-impairing air emissions from the GP Big Island, LLC pulp and paper mill facility in Bedford County, Virginia. The EPA is proposing to include this amended operating permit in Virginia's SIP. This proposed action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before January 12, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2024–0385 at www.regulations.gov, or via email to gordon.mike@epa.gov. For comments submitted at Regulations.gov, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be

accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit www.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT:

Philip McGuire, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1600 John F Kennedy Boulevard, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2251. Mr. McGuire can also be reached via electronic mail at mcguire.philip@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 2022, VADEQ submitted to the EPA a revision to the Commonwealth's SIP to align the SIP with the state operating permit for Best Available Retrofit Technology (BART permit) and the Title V permit for GP Big Island pulp and paper mill (GP Big Island Mill), located in Bedford County, Virginia.¹ Currently, the Virginia SIP contains an October 5, 2012 amendment to the BART permit.² The Commonwealth further amended the BART permit on December 12, 2022 and submitted that newly amended BART permit in its December 14, 2022 SIP revision to the EPA for inclusion in the SIP. Specifically, the December 14, 2022 SIP revision, as reflected in the BART permit amended on December 12, 2022, lowers the permitted emission limits for particulate matter (PM₁₀), sulfur dioxide (SO₂), and nitrogen oxides (NO_x) at the

Number 5 Power Boiler and removes conditions related to the use of coal. The amendments to the BART permit are a result of the fuel conversion of the facility's Number 5 Power Boiler from coal to natural gas, wood, wood residuals, and old corrugated container reject.³

II. Summary of SIP Revision and EPA Analysis

The December 14, 2022 proposed SIP revision changes two main aspects of the SIP as reflected in the December 12, 2022 amended BART permit.⁴ The first aspect of the proposed SIP revision submitted to the EPA on December 14, 2022 requests the removal of conditions pertaining to controlling sulfur dioxide emissions when coal is used in the Number 5 Power Boiler. Specifically, the December 12, 2022 amended BART permit no longer contains requirements that were in the October 5, 2012 amended BART permit related to limiting sulfur-content and limiting the firing of coal to a maximum percentage of the annual capacity factor when firing coal at the Number 5 Power Boiler.

Currently, the Number 5 Power Boiler no longer fires coal and the coal feed system for this source has been permanently removed. This shutdown was included in a mutual shutdown agreement between GP Big Island Mill and VADEQ, which was finalized on April 24, 2017.⁵ VADEQ incorporated the removal of the source in the Title V permit for GP Big Island Mill through an April 13, 2021 permit revision. The Number 5 Power Boiler is now permitted to fire natural gas, wood, wood residuals, and old corrugated container reject. GP Big Island Mill requested an amendment to the coal-burning provision of its BART permit through a revision application received by VADEQ on July 26, 2021. VADEQ approved this amendment to the BART permit on December 12, 2022. Now that coal no longer serves as the fuel source

³ This condition specifying natural gas, wood, wood residuals, and old corrugated container reject as the allowable fuels for the Number 5 Power Boiler is only included in the April 13, 2021 Title V permit, which VADEQ did not propose to be included in the SIP. The Title V permit is included in the docket as *Big_Island_TV_Permit_2021_04_13* and is for informational purposes only.

⁴ The proposed inclusion of the BART permit amended December 12, 2022 in the SIP also adds some general conditions related to permit suspension/revocation, recording of and notification for malfunctions, and a condition allowing VADEQ to require the permittee to act to prevent a violation of the ambient air quality standard.

⁵ The GP Big Island Mill-VADEQ mutual shutdown agreement for the GP Big Island Mill coal handling system is available in the docket for this action as *VADEQ_Mutual_Shutdown_Agreement_for_Coal_Handling_PWR09.pdf*.

¹ GP Big Island, LLC was formerly named Georgia-Pacific Big Island and supplemental docket documents may use the names interchangeably.

² On June 12, 2008, VADEQ issued a state operating permit for GP Big Island, LLC for the purpose of complying with the Best Available Retrofit Technology (BART) requirements for control of visibility-impairing pollutants under 40 CFR 51.308(e) of the EPA's Regional Haze Program. The state subsequently amended the BART permit on October 5, 2012 which the EPA approved into the SIP effective June 17, 2014. 79 FR 21855 (April 18, 2014). The current BART permit, which includes the December 12, 2022 amendment submitted for inclusion in Virginia's SIP, is available in the docket for this action as *VADEQ_State_Operating_Permit_2022_12_12*.

for the Number 5 Power Boiler, this action proposes to align the SIP with the December 12, 2022 amended BART permit's removal of conditions regarding SO₂ control during coal use.

The second aspect of the proposed SIP revision requests approval for the lowering of the permitted emissions limits currently in the SIP for PM₁₀, SO₂, and NO_x. The proposed reduced annual limits include lowering PM₁₀ emissions limits from 103.9 tons per year (TPY) to 88.9 TPY, lowering SO₂ emissions limits from 374 TPY to 104.7 TPY, and lowering NO_x emissions limits from 610.1 TPY to 529.9 TPY. The proposed reduced hourly limits include lowering PM₁₀ emissions limits from 23.7 pounds per hour (lbs/hr) to 20.3 lbs/hr, lowering SO₂ emissions limits from 485.1 lbs/hr to 23.9 lbs/hr, and lowering NO_x emissions limits from 139.3 lbs/hr to 121.0 lbs/hr. The current, SIP-approved emission limits for the Number 5 Power Boiler were first established by the BART permit issued by VADEQ on June 12, 2008, for the purpose of complying with the BART requirements for control of visibility-impairing pollutants under 40 CFR 51.308(e) of the EPA's Regional Haze Program. The October 5, 2012 BART permit maintained these limits in the SIP. A Title V permit issued on April 13, 2021, lowered these original emission limits to the limits proposed in this SIP revision, and on July 26, 2021 GP Big Island Mill requested VADEQ amend the BART permit to include these new, lower emission limits to align with the April 13, 2021 Title V permit. VADEQ approved these lower emission limits and issued a new BART permit on December 12, 2022 to replace the pre-existing October 5, 2012 BART permit. This action proposes to align the SIP emission limits with the limits identified in the VADEQ-issued December 12, 2022 amended BART permit by incorporating that BART permit into the SIP. No emissions increases are anticipated as a result of this revision. In fact, this proposed revision to the SIP, if finalized, will lower annual and hourly emissions limits for the GP Big Island Mill compared to what is currently in the SIP.

III. Proposed Action

The EPA is proposing to approve the Virginia SIP revision for GP Big Island Mill, which was submitted on December 14, 2022 by including the December 12, 2022 amended BART permit in the Virginia SIP. Simultaneously—at the request of VADEQ—the EPA is proposing to remove the October 5, 2012 amended BART permit from the

Virginia SIP. This previous SIP revision was approved into the Virginia SIP effective June 17, 2014, and the December 14, 2022 proposed SIP revision updates this prior SIP revision. The EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) “privilege” for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information “required by law,” including documents and information “required by Federal law to maintain program delegation, authorization or approval,” since Virginia must “enforce federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. . . .” The opinion concludes that “[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these

programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.”

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that “[t]o the extent consistent with requirements imposed by Federal law,” any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any federally authorized programs, since “no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.”

Therefore, the EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because the EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, the EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

IV. Incorporation by Reference

In this document, the EPA is proposing to include in an EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the state operating permit, *i.e.*, the BART permit, that VADEQ amended December 12, 2022, as described in section II of this document. The EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

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

List of Subjects in 40 CFR Part 52

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

Amy Van Blarcom-Lackey,

Regional Administrator, Region III.

[FR Doc. 2025–22533 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2025–1048; FRL–13020–01–R5]

Air Plan Disapproval; Ohio; E-Check Attestation Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to disapprove a revision to the Ohio State Implementation Plan (SIP) submitted on July 9, 2025, by the Ohio Environmental Protection Agency (Ohio EPA). The revision, which Ohio EPA submitted pursuant to Ohio Amended Substitute House Bill 54 (“E-Check Ease Act”), includes provisions that would create an alternative to state-run mandatory on-board diagnostic (OBD) inspections with a self-attestation program that allows motorists to self-attest that their vehicles comply with emissions requirements. This approach is inconsistent with statutory and regulatory requirements for Enhanced inspection and maintenance (I/M) programs under the Clean Air Act (CAA) and would interfere with attainment and reasonable further progress toward the 2015 ozone National Ambient Air Quality Standards (NAAQS).

DATES: Comments must be received on or before January 12, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2025–1048 at <https://www.regulations.gov>, or via email to langman.michael@epa.gov. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at <https://www.regulations.gov> any information you consider to be

Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI, PBI, or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Francisco J. Acevedo, Air and Radiation Division (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6061, acevedo.francisco@epa.gov. The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

I. Background

The CAA establishes a framework for controlling emissions of ozone precursors in areas that do not attain the NAAQS. Section 182 of the CAA (42 U.S.C. 7511a) requires that certain ozone nonattainment areas implement vehicle I/M programs to identify and repair high-emitting vehicles operating in the nonattainment area. Nonattainment areas classified as Moderate must adopt at least a “Basic” I/M program (CAA section 182(b)(4)), and areas classified as Serious or above must adopt an “Enhanced” I/M program (CAA section 182(c)(3)). Pursuant to the CAA and EPA's corresponding implementing regulations at 40 CFR 51 subpart S, both Basic and Enhanced I/M programs are subject to certain performance standards and program administration requirements, including mandatory OBD vehicle inspections, corrective action and retesting for vehicles that fail inspection, and enforceable program mechanisms to ensure compliance.

The Cleveland–Akron–Lorain metropolitan area in northeast Ohio is

designated nonattainment for the 2015 ozone NAAQS. The area is classified as a Serious ozone nonattainment area effective January 16, 2025 (89 FR 101901, December 17, 2024). As a result of its classification, Ohio is currently required to implement an Enhanced I/M program meeting all statutory and regulatory requirements for Serious areas.

Ohio implements “E-Check”, its SIP-approved vehicle I/M program, in the Cleveland–Akron–Lorain metropolitan area.¹ E-Check has long been relied upon in Ohio’s SIP to provide emission reductions necessary for both reasonable further progress (RFP) and attainment demonstrations for multiple ozone standards. The program consists of a hybrid network that combines state-contracted centralized inspection facilities with a number of decentralized service centers where approximately 880,000 vehicles annually with a gross vehicle weight rating of up to 10,000 pounds undergo OBD-based testing consistent with EPA’s I/M regulations at 40 CFR part 51, subpart S. EPA fully approved Ohio’s I/M program on April 4, 1995, 60 FR 16989, and approved revisions to the program on January 6, 1997, 62 FR 646.

In March 2025, the Ohio General Assembly enacted the “E-Check Ease Act.” The E-Check Ease Act includes a provision incorporated into Ohio Revised Code (ORC) 3704.14(C)(2) that fundamentally alters the State’s I/M framework. The law creates an alternative compliance pathway under which motorists may obtain an “alternative emissions certificate” by signing a self-attestation form declaring, “to the best of their knowledge,” that their vehicle complies with State and Federal emission requirements. Unlike the current E-Check program, this pathway does not involve the direct inspection of the OBD system to check for the proper functioning of the vehicle’s emissions control systems and to ensure repairs when needed. It also provides no civil or criminal penalties for submitting a false attestation. The only consequence is rejection of the self-attestation form and a requirement to resubmit it or undergo a standard inspection.

The E-Check Ease Act also provides that the addition of the alternative emissions certification to Ohio’s E-Check program is not effective until EPA approves a SIP revision submitted by Ohio EPA incorporating this

modification of Ohio’s I/M program. If EPA approves the modification of Ohio’s I/M program, Ohio EPA would be required to amend their regulations governing the E-Check program contained in Ohio Administrative Code (OAC) 3745–26 to include these provisions and submit the amended regulations to EPA as a revision to Ohio’s OAC 3745–26 SIP-approved regulations.

Accordingly, Ohio EPA developed and submitted a SIP revision on July 9, 2025, requesting EPA approval of the self-attestation option as part of the State’s federally enforceable I/M program. Ohio’s submission included a demonstration under CAA section 110(l), asserting that the revision would not interfere with attainment or reasonable further progress toward the 2015 ozone NAAQS. Ohio’s SIP submission and associated supporting documents are available in the docket for this action, at <https://www.regulations.gov>, Docket ID No. EPA–R05–OAR–2025–1048.

II. EPA’s Evaluation of Ohio’s SIP Revision

EPA has carefully reviewed Ohio’s July 9, 2025, SIP submission requesting approval of an alternative emissions certification process within Ohio’s existing I/M program considering the requirements of the CAA, EPA’s implementing regulations, and longstanding program guidance. Ohio’s July 9, 2025, SIP submission included a copy of the E-Check Ease Act that was signed into law on March 31, 2025. In support of the SIP revision, Ohio also included a demonstration under section 110(l) of the CAA, which prohibits approval of SIP revisions that interfere with attainment or reasonable further progress toward the NAAQS. Ohio’s analysis assumed that 100 percent of eligible motorists could use the self-attestation option within one year of implementation.

In addition, Ohio EPA provided public notice and an opportunity to comment on the SIP revision and associated CAA section 110(l) demonstration. The State received over 650 comments. Most commenters requested elimination of the E-Check program altogether, while others either supported the self-attestation option as a modernization or opposed it as ineffective and detrimental to air quality. Ohio EPA responded to comments and submitted the public notice and response to comments as part of the SIP submittal.

Based on our evaluation, EPA proposes to disapprove the revision because it is inconsistent with

Enhanced I/M statutory requirements, EPA’s I/M regulations at 40 CFR part 51, subpart S, and the anti-backsliding provision of CAA section 110(l).

A. Elimination of Required OBD Inspections

Section 182(c)(3)(C)(vii) of the CAA explicitly requires Enhanced I/M programs to include “inspection of emission control diagnostic systems.” Similarly, CAA section 202(m)(3) requires I/M program SIPs to “provide for inspection of onboard diagnostic systems.” EPA’s I/M regulations at 40 CFR 51.373(g)–(h) further mandate that OBD checks be implemented in all Enhanced I/M areas. The Ohio SIP revision would offer an alternative to OBD inspections with self-attestation by the vehicle owner or lessee, which is not a permissible test method in the CAA or EPA’s I/M regulations. The absence of direct inspection of the motor vehicle removes a critical enforcement mechanism, prevents the identification and effectuation of much-needed vehicle emissions control systems repairs that would benefit air quality, and undermines the performance standard for Enhanced I/M required by the CAA and EPA’s I/M regulations.

B. Lack of Proof of Corrective Action

The CAA requires that vehicles failing inspection must demonstrate proof of corrective action prior to retesting (CAA section 182(a)(2)(B)). Under Ohio’s proposal, a motorist whose self-attestation is rejected may simply amend and resubmit without providing evidence that repairs were made. This creates a mechanism that is inconsistent with statutory intent and undermines the repair and compliance assurance functions that are fundamental elements of I/M programs.

C. Lack of Effective Enforcement Provisions

Effective program administration is a core element of Enhanced I/M. The CAA requires that States employ management and enforcement features necessary to ensure program compliance (CAA section 182(a)(2)(B), 182(c)(3)(B)). EPA regulations require enforceable and meaningful penalties for noncompliance, such as for cases of registration fraud (40 CFR 51.361(a)(10)). However, Ohio’s legislation states that no penalty shall apply to a person who the Ohio EPA director has determined to have falsified a self-attestation form, other than the issuance of a notice directing the person to amend and resubmit the attestation. This minimal consequence fails to deter

¹ Under Ohio’s E-Check program, Ohio EPA is required to ensure emissions testing is performed in Cuyahoga, Geauga, Lake, Lorain, Medina, Portage, and Summit counties.

fraud and does not meet statutory and regulatory requirements for effective enforcement.

D. Interference With Attainment and RFP

CAA section 110(l) prohibits EPA from approving SIP revisions that interfere with attainment of or reasonable further progress towards the NAAQS. As mentioned above, Ohio included a section 110(l) analysis as Attachment B in its July 9, 2025, SIP submittal. This analysis shows that in 2023, 880,832 vehicles were tested, with 55,789 (6.6%) failing their initial inspection. Ohio's analysis did not estimate the impact to ozone precursor and other pollutant emissions as the result of modifications to the I/M program.

The purpose of I/M programs is not only to identify high-emitting vehicles, but also to ensure that effective repairs have been made. A self-attestation program does not provide any compliance assurance for repairs on these high-emitting vehicles. If self-attestation were to replace CAA-mandated test methods, high-emitting vehicles such as the approximately 55,000 vehicles that failed initial inspection in 2023 could continue operating unrepaired.

Another significant benefit of an OBD I/M test program is the reduction of emissions as the result of pre-inspection repairs. Since the OBD system allows motorists to see that repairs are necessary via a lit Check Engine light and that their vehicle would fail an OBD test inspection, many motorists will opt to have their vehicles repaired prior to the required periodic inspection to avoid the inconvenience of a failed test and a return trip for a retest. Thus, vehicles that fail an initial I/M test represent a portion of the vehicles that have their emissions reduced as the result of an OBD I/M program that ensures repairs for compliance. However, there is no incentive in a self-attestation program for motorists to get pre-inspection repairs, so a self-attestation program would not be expected to get the emission reduction benefits from pre-inspection repairs.

If Ohio's proposed modification to its E-Check program were to be approved, tens of thousands of vehicles with malfunctioning emission controls could remain in service, increasing ozone precursor emissions and jeopardizing attainment of the 2015 ozone NAAQS in the Cleveland-Akron-Lorain area. This strongly suggests interference with both attainment and reasonable further progress.

E. Lack of Statutory Authority for Self-Certification

While the CAA allows States flexibility in program design (e.g., frequency of testing, centralized vs. decentralized networks, exemptions for certain newer model years), the CAA and EPA's corresponding implementing I/M regulations require actual inspection methods to identify high-emitting vehicles. EPA has previously approved flexibilities such as remote OBD testing, clean screening using on-road sensing, and kiosks (66 FR 18156, April 5, 2001; 72 FR 14235, March 27, 2007). However, no provision of the CAA authorizes wholesale replacement of inspections with self-attestation. As mentioned above in section II.A., the CAA is explicit that the "inspection of onboard diagnostic systems" is a required element of I/M programs.² Thus, Ohio's proposed self-attestation approach is not permissible.

EPA notes that, while the CAA and EPA's I/M regulations require actual inspection of emission control systems, States retain significant flexibility in how these requirements are implemented. For example, Ohio and other States have successfully incorporated options such as:

- Vehicle model year exemptions (e.g., exempting very new vehicles, which are less likely to have emission control failures, or very old vehicles not equipped with OBD).
- Modified inspection frequencies (annual versus biennial testing).
- Different inspection network types (centralized test-only facilities versus decentralized networks of service stations).
- Remote OBD testing through telematics, which allows certain vehicles to transmit OBD information electronically without visiting a station.
- Self-service kiosks or mobile testing units, which can make testing more convenient and less intrusive for motorists.
- "Clean screening" programs using on-road remote sensing devices, which allow low-emitting vehicles to be exempted from scheduled testing based on demonstrated real-world performance.

Where these flexibilities have been incorporated, States have generally found that public perception of I/M programs is more positive, as these approaches are seen as modernized, less burdensome, and less intrusive for motorists while still ensuring compliance with statutory requirements.

² CAA section 202(m)(3).

Importantly, all of these options retain an objective inspection mechanism consistent with Clean Air Act requirements and EPA's implementing regulations. In contrast, Ohio's proposed self-attestation provision would eliminate the core requirement for inspection of OBD systems and therefore cannot be considered a permissible flexibility.

III. What action is EPA taking?

Because the E-Check Ease Act eliminates mandatory OBD testing, fails to require proof of corrective action for failing vehicles, and lacks enforceable penalties for falsification, EPA determines the SIP revision is inconsistent with CAA requirements for Enhanced I/M programs (sections 182(c)(3) and 202(m)(3)), EPA's I/M regulations at 40 CFR part 51, subpart S, and the anti-backsliding provisions of section 110(l). Therefore, EPA is proposing to disapprove Ohio's July 9, 2025, SIP revision. If finalized, Ohio must continue implementing its existing Enhanced I/M program or submit a new SIP revision that complies with CAA and regulatory requirements.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is not expected to be an Executive Order 14192 regulatory action because this action is not significant under Executive Order 12866;

C. Paperwork Reduction Act (PRA)

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This action will not impose any requirements on small entities. This action is disapproving SIP provisions that are inconsistent with CAA requirements for Enhanced I/M programs (sections 182(c)(3) and 202(m)(3)), EPA's I/M regulations at 40 CFR part 51, subpart S, and the anti-backsliding provisions of section 110(l).

E. Unfunded Mandates Reform Act (UMRA)

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

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

This rule does not have Tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on Tribal governments. Thus, Executive Order 13175 does not apply to this rule.

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

This action is not subject to Executive Order 13045 because it is not 3(f)(1) significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children because it disapproves revisions to a State program that are inconsistent with statutory and regulatory requirements for vehicle inspection and maintenance programs under the CAA and would interfere with attainment and reasonable further progress toward the 2015 ozone NAAQS.

I. 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.

J. National Technology Transfer Advancement Act

This rulemaking does not involve technical standards.

List of Subjects in 40 CFR Part 52

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

Dated: November 20, 2025.

Cheryl Newton,

Acting Regional Administrator, Region 5.

[FR Doc. 2025–22594 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2025–1938; FRL–13058–01–R9]

Air Plan Approval; California; San Joaquin Valley Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the San Joaquin Valley Air Pollution Control District (SJVAPCD or “District”) portion of the California State Implementation Plan (SIP) concerning two rules submitted to address section 185 of the Clean Air Act (CAA or the “Act”) with respect to the 2008 and 2015 ozone national ambient air quality standards (NAAQS or “standards”). We are taking comments on this proposal and plan to follow with a final action.

DATES: Comments must be received on or before January 12, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2025–1938 at <https://www.regulations.gov>. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.regulations.gov). The EPA may publish any comment received to its public

docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Tom Kelly, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105, telephone number: (415) 972–3856, email address: kelly.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

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

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I. The State’s Submittal

A. What rules did the State submit?

Table 1 lists the rules addressed by this proposal with the dates that they were adopted by the local air agency and submitted to the EPA by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
SJVAPCD	3172	Federally Mandated Ozone Nonattainment Fee—2008 8-Hour Standard.	12/21/23	03/13/24

TABLE 1—SUBMITTED RULES—Continued

Local agency	Rule No.	Rule title	Adopted	Submitted
SJVAPCD	3173	Federally Mandated Ozone Nonattainment Fee—2015 8-Hour Standard.	12/21/23	03/13/24

On September 13, 2024, the submittal for SJVAPCD Rules 3172 and 3173 was deemed by operation of law to be complete. We have reviewed the submittal to ensure it meets the completeness criteria in 40 CFR part 51, appendix V.

B. Are there other versions of these rules?

There are no previous versions of SJVAPCD Rule 3172 or 3173 in the SIP. These rules address the CAA section 185 fee requirement for the 2008 and 2015 ozone NAAQS. SJVAPCD has previously issued a rule addressing the 1-hour ozone NAAQS, Rule 3170 which the EPA has approved into the SIP,¹ and the 1997 8-hour ozone NAAQS, Rule 3171 which the EPA has proposed to approve into the SIP.²

C. What is the purpose of the submitted rules?

Under sections 182(d)(3), (e), (f) and 185 of the Act, states with ozone nonattainment areas classified as Severe or Extreme are required to submit a SIP revision that requires major stationary sources of volatile organic compounds (VOC) or oxides of nitrogen (NO_x) emissions in the area to pay a fee if the area fails to attain the standard by the attainment date. The required SIP revision must provide for annual payment of the fees, computed in accordance with CAA section 185(b). SJVAPCD Rule 3172 is intended to satisfy the requirements for the 2008 ozone NAAQS and Rule 3173 is intended to satisfy the requirements for the 2015 ozone NAAQS.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rules?

Rules in the SIP must be enforceable (see CAA section 110(a)(2)) and must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)). The EPA is also evaluating the rule for consistency with the statutory requirements of CAA section 185.

Guidance and policy documents that we used to evaluate enforceability, revision/relaxation, and rule stringency requirements include the following:

1. "State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990," 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
2. "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations," EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).
3. "Guidance Document for Correcting Common VOC & Other Rule Deficiencies," EPA Region 9, August 21, 2001 (the Little Bluebook).

B. Do the rules meet the evaluation criteria?

This rule meets CAA requirements and is consistent with relevant guidance regarding enforceability and SIP revisions. The rules are also consistent with the requirements of section 185. As required by section 185, these rules apply to all major sources of VOC or NO_x, and calculate the fees to be paid as specified in section 185(b). The rules will become applicable if and when the EPA finalizes a finding that the San Joaquin Valley Air Basin has failed to attain either the 2008 ozone NAAQS (for Rule 3172) or the 2015 ozone NAAQS (for Rule 3173) by the applicable attainment date for that NAAQS. The EPA's technical support document for this rulemaking has more information on our evaluation.

C. Proposed Action and Public Comment

As authorized in section 110(k)(3) of the Act, the EPA proposes to approve the submitted rules because they fulfill all relevant requirements. We will accept comments from the public on this proposal until January 12, 2026. If we take final action to approve the submitted rules, our final action will incorporate SJVAPCD Rules 3172 and 3173 into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference SJVAPCD Rule 3172, Federally Mandated Ozone Nonattainment Fee—2008 8-Hour Standards and Rule 3173, Federally Mandated Ozone

Nonattainment Fee—2015 8-Hour Standards, both adopted on December 21, 2023, and described in more detail in section I.A. The EPA has made, and will continue to make, these materials available through <https://www.regulations.gov> and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it proposes to approve a state program;

¹ 77 FR 50021 (August 20, 2012).

² 90 FR 44155 (September 12, 2025).

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and

- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

List of Subjects in 40 CFR Part 52

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

Dated: November 24, 2025.

Michael Martucci,

Acting Regional Administrator, Region IX.

[FR Doc. 2025–22530 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2025–1741; FRL–13115–01–R1]

Air Plan Approval; New Hampshire; Single Source VOC RACT Order for Hutchinson Sealing Systems

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of New Hampshire. This revision proposes to approve a revised reasonable available control technology (RACT) order for Hutchinson Sealing Systems, Inc., located in Newfields, New Hampshire. This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before January 12, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2025–1741 at <https://www.regulations.gov>, or via email to Meredith Gutierrez at:

gutierrez.meredith@epa.gov. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the “For Further Information Contact” section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. Publicly available docket materials are available at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that, if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection.

FOR FURTHER INFORMATION CONTACT: Meredith Gutierrez, Energy and Resilience Branch (ERB), Air and Radiation Division (ARD) (Mail Code 5–MD), U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts, 02109–3912; (617) 918–1193; gutierrez.meredith@epa.gov.

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

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- I. Background and Purpose
- II. Proposed Action
- III. Incorporation by Reference
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I. Background and Purpose

Hutchinson Sealing Systems, Inc. (HSS) produces sealing systems, body seals, and soft rubber glass-run channels used in automobiles and various other applications. HSS owns and operates a facility located at 171 Exeter Road in

Newfields, New Hampshire. The sealing strips are produced by several complex processes involving metal roll foaming, rubber and plastic extruding, flocking (or the application of a low-friction coating), and curing, followed by certain secondary operations including but not limited to trimming, notching, saw cutting, stretch bending, molding, and assembly.

The New Hampshire Department of Environmental Services (NH DES) submitted Reasonably Available Control Technology (RACT) Order ARD–11–001 to the EPA as a State Implementation Plan (SIP) revision on March 23, 2012. RACT Order ARD–11–001 required HSS to comply with a volatile organic compound (VOC) content limit of 6.3 lb. VOC/gallon of coating as applied (excluding water and exempt VOC compounds) for motor vehicle weatherstrip adhesive coatings, as specified in Env-A 1220.02, *Compliance Standards for Miscellaneous Industrial Adhesives*.¹ Order ARD–11–001 contained an allowance for alternate compliance to be met by using add-on controls, bubbling, discrete emissions reductions (DERs), emissions reduction credits (ERCs), or any combination of the previous methods to comply with the limit. In addition, Order ARD–11–001 indicated that the company will install and operate a catalytic oxidizer to control VOC emissions from emissions unit Thermoplastics Extrusion Line #9 (TPV Line #9) at the facility. On August 28, 2012, HSS submitted a permit application to NH DES to allow for the modification of Thermoplastics Extrusion Line #6 (TPV Line #6) and the installation of a catalytic oxidizer control device to control HAP emissions. The adhesives used in TPV Line #6 are subject to the VOC content limits in the RACT order.

On November 5, 2012, the EPA approved New Hampshire’s March 23, 2012 submittal for a single source order requiring RACT at HSS into the New Hampshire SIP.² Subsequently, on December 21, 2012, NH DES issued permit TP–0115 to HSS requiring the use of a catalytic oxidizer to control emissions from TPV Line #6. Although RACT Order ARD–11–001 allows the facility to use an add-on control device as a compliance option for the emission limit, the requirement to use a catalytic oxidizer to control emissions from TPV Line #6 was only included in NH DES’s December 21, 2012 permit and was not

¹ These standards are approved in the NH SIP as part of Env-A 1200, *Volatile Organic Compounds (VOCs) Reasonably Available Control Technology (RACT)* (see 77 FR 66388, November 5, 2012; and 87 FR 26999, May 6, 2022).

² See 77 FR 66388.

part of EPA's 2012 approval of RACT Order ARD-11-001 into the SIP.

On April 24, 2023, HSS submitted a request to NH DES for a modification to its State Permit to Operate (SP-0141) to, among other items, remove TPV Line #9 and its associated control device from the permit, since that process no longer emits VOCs. On September 29, 2023, HSS submitted a permit application to NH DES for the renewal of SP-0141, which included a request to remove the required use of the catalytic oxidizer associated with TPV Line #6 since the motor vehicle weatherstrip adhesives used in the process meet the VOC content limit without the need for additional control. The revised RACT Order ARD-11-001, issued on January 24, 2025, by NH DES, maintains the existing RACT requirement for HSS to comply with the VOC limit of 6.3 lb. VOC/gallon for motor vehicle weatherstrip coatings. The Order specifies that HSS shall continue to research and test water-based and/or high solids coatings as new products become available. The Order also outlines the processes through which HSS shall be allowed to use DERs, ERCs, and/or bubbling for the purpose of complying with VOC RACT.³ Furthermore, the Order removes the alternate compliance option to use an add-on control device as an alternative to meet the VOC limit. In addition, the Order removes the allowance for HSS to generate discrete emission reduction credits due to the removal of the catalytic oxidizer. On April 17, 2025, NH DES submitted a revision to its SIP consisting of the revised RACT Order ARD-11-001, which is intended to limit emissions of VOCs from the facility.

According to Economic Incentive Program Rules (59 FR 16690), the ability of RACT sources to meet RACT requirements through RACT or non-RACT trading shall result in "an exceptional environmental benefit," which can be demonstrated through "a trading ratio of 1.1 to 1, at a minimum." This is further clarified in Env-A 3100, *Discrete Emissions Reductions Trading Program*, which states that users of DERs "shall permanently retire ten percent of all DERs dedicated to that particular use, such that the amount of DERs required to demonstrate compliance shall equal the source's calculated need divided by 0.9."

HSS was issued an ERC certificate (98VHSS01C) on August 1, 2002, that allows them to generate 22 tons of VOC

credits per year from the permanent shutdown of the Body Stock Preparation Process and the Metal Parts Painting Operation (also referred to as the "King-Way Line"). These 22 tons per year are the difference between the baseline before the shutdown of those two processes and the facility-wide emissions after the shutdown. HSS is allowed to use these credits each year, but unused credits do not roll over to succeeding years. Additionally, these credits cannot be sold, transferred, or traded. The use of these credits, ERCs generated by other facilities, or DERs for the purpose of complying with VOC RACT shall comply with recordkeeping and reporting requirements outlined in Env-A 3000, *Emissions Reduction Credits Trading Program*, and Env-A 3100, *Discrete Emissions Reductions Trading Program*. HSS is also required to true up the balance of credits required for the previous year (from June 1 to May 31) annually by September 1 and report the balance to NH DES. Additional reporting requirements listed in the Order are detailed in SIP-approved Env-A 900, Owner or Operator Recordkeeping and Reporting Obligations.

Neither Env-A 3000, *Emissions Reduction Credits Trading Program*, nor Env-A 3100, *Discrete Emissions Reductions Trading Program*, are in the New Hampshire SIP. Consequently, in order to comply with VOC RACT, approval to generate and use ERCs and DERs must be approved on a facility-by-facility basis. EPA approved into the New Hampshire SIP RACT Order ARD-11-001 in 2012, which contained a VOC content limit of 6.3 lb. VOC/gallon for motor vehicle weatherstrip adhesive coatings at HSS, and an allowance for alternate compliance to be met by using add-on controls, bubbling, DERs, ERCs, or any combination of the previous methods to comply with the limit. HSS is no longer able to meet the facility-wide emission rate of 15% uncontrolled emissions required for DERs generation, as specified in Env-A 3100, due to the removal of the catalytic oxidizer control device on TPV Line #6. Thus, the revised RACT Order ARD-11-001 removes self-generation of DERs and the use of add-on controls as methods of compliance.

The revised RACT Order for HSS maintains the same 6.3 lb. VOC/gallon emissions limit, which is consistent with Env-A 1220, which EPA previously approved as RACT in 2022. EPA also approved New Hampshire's VOC RACT certification for the 2008 and 2015 ozone standards on September 6, 2023 (88 FR 60893). EPA is proposing to approve the revisions to RACT Order

ARD-11-001 into the New Hampshire SIP, which do not change the previously approved 6.3 lb. VOC/gallon emissions limit for motor vehicle weatherstrip adhesive coatings at HSS.

IV. Proposed Action

EPA is proposing to approve the revised RACT Order ARD-11-001 into the New Hampshire SIP. The Order was issued by the New Hampshire DES to Hutchinson Sealing Systems of Newfields on January 24, 2025, and submitted to EPA as a SIP revision on April 17, 2025. Clean Air Act (CAA) section 110(I) provides that EPA may approve a SIP revision that removes or modifies control measures in the SIP only if such removal or modification would not interfere with attainment and maintenance of the NAAQS, reasonable further progress, or any other applicable requirement of the CAA. EPA is proposing to determine that the revisions to the RACT order issued to HSS are consistent with CAA section 110(I) because the removal of the add-on control device as an alternate compliance option will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA. EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

V. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference RACT Order ARD-11-001 dated January 24, 2025, issued by the New Hampshire DES to Hutchinson Sealing Systems, Inc. of Newfields. The EPA has made, and will continue to make, these documents generally available through <https://www.regulations.gov> and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the

³ Hutchinson only needs to use credits when non-compliant coatings are employed, which is on an infrequent basis and is being phased out over time, though no anticipated deadline has been given for the removal of these coatings from their processes.

provisions of the Clean Air 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 that they meet the criteria of the Clean Air Act. Accordingly, this proposed 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 proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
 - Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
 - Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
 - Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
 - Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4);
 - Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
 - Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
 - Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
 - Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.
- In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead,

Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: December 3, 2025.

Mark Sanborn,

Regional Administrator, EPA Region 1.

[FR Doc. 2025-22610 Filed 12-10-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2025-0266; FRL-12991-01-OCSPJ]

RIN 2070-ZA16

Pesticide Tolerances; Implementing Registration Review Decisions for Certain Pesticides; Atrazine, et al.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is proposing to implement several tolerance actions under the Federal Food, Drug, and Cosmetic Act (FFDCA) that the Agency determined were necessary or appropriate during the registration review conducted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). During registration review, EPA reviews all aspects of a pesticide case, including existing tolerances, to ensure that the pesticide continues to meet the standard for registration under FIFRA. The pesticide tolerances and active ingredients addressed in this rulemaking are identified and discussed in detail in Unit III. of this document.

DATES: Comments must be received on or before February 9, 2026.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2025-0266, through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Alex McKee, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 566-1939; email address: mckee.alex@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

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

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

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What action is the Agency taking?

EPA is proposing several tolerance actions that the Agency previously determined were necessary or appropriate during registration review of the pesticide active ingredients identified in Unit III. The tolerance actions for each pesticide active ingredient are described in Unit III. and may include but are not limited to the following types of actions:

- Revising tolerance expressions;
- Modifying commodity definitions;
- Updating crop groupings;
- Removing expired tolerances;
- Revoking tolerances that are no longer needed; and
- Harmonizing tolerances with the Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs).

Although it may not have been identified in the registration review of a particular pesticide, this proposed rule reflects the Agency's 2019 adoption of the Organization of Economic Cooperation and Development (OECD) Rounding Class Practice. More information on the OECD Rounding Class Practice can be found at https://www.oecd.org/en/publications/mrl-calculator-users-guide-and-white-paper_9789264221567-en.html. Where applicable, these adjustments are proposed for specific pesticides as indicated in Unit III.

C. What is EPA's authority for taking this action?

Section 408(e) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), authorizes EPA to establish, modify, or revoke tolerances or exemptions from the requirement of a tolerance on its own initiative.

Under FIFRA section 3(g), 7 U.S.C. 136a(g), EPA is required to periodically review all registered pesticides and determine if those pesticides continue to meet the standard for registration under FIFRA. As part of the registration review of a pesticide, EPA also evaluates the existing tolerances and any tolerance changes identified as necessary or appropriate during registration review of a pesticide are summarized in the registration review decision documents for each pesticide active ingredient or registration review case (e.g., in the Proposed Interim Decision (PID), Proposed Final Decision (PFD), Interim Decision (ID) and Final Decision (FD)). These documents can be found in the public docket opened for each pesticide undergoing registration review. Additional information about pesticide registration review is available at <https://www.epa.gov/pesticide-reevaluation>.

Prior to issuing the final regulation, FFDCA section 408(e)(2) requires EPA to issue a notice of proposed rulemaking for a 60-day public comment period, unless the Administrator for good cause finds that it would be in the public interest to have a shorter period and states the reasons in the proposed rulemaking.

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

1. *Submitting CBI.* Do not submit CBI to EPA through email or <https://www.regulations.gov>. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

E. What can I do if I want the Agency to maintain a tolerance that the Agency proposes to revoke?

This proposed rule provides a 60-day public comment period that allows any person to state an interest in retaining

a tolerance proposed for revocation. If EPA receives such a comment within the 60-day period, EPA will not proceed to revoke the tolerance immediately. However, EPA will take steps to ensure the submission of any needed supporting data and will issue an order in the **Federal Register** under FFDCA section 408(f), if needed. If the data are not submitted as required in the order, EPA will take appropriate action under FFDCA.

After considering comments that are received in response to this proposed rule, EPA will issue a final rule. At the time of the final rule, you may file an objection or request a hearing on the action taken in the final rule. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. After the filing deadline specified in the final rule, issues resolved in the final rule cannot be raised again in any subsequent proceedings.

II. Background

A. What is a tolerance?

A "tolerance" represents the maximum level for residues of a pesticide chemical legally allowed in or on food, which includes raw agricultural commodities and processed foods and feed for animals. Under the FFDCA, residues of a pesticide chemical that are not covered by a tolerance or exemption from the requirement of a tolerance are considered unsafe. See 21 U.S.C. 346a(a)(1). Foods containing unsafe residues are deemed adulterated and may not be distributed in interstate commerce. See 21 U.S.C. 331(a) and 342(a)(2)(B). Consequently, for a food-use pesticide (i.e., a pesticide use that is likely to result in residues in or on food) to be sold and distributed in the United States, the pesticide must not only have appropriate tolerances or exemptions under the FFDCA, but also must be registered under FIFRA. Food-use pesticides not registered in the United States must have tolerances or exemptions in order for commodities treated with those pesticides to be imported into the United States. For additional information about tolerances, go to <https://www.epa.gov/pesticide-tolerances/about-pesticide-tolerances>.

B. Why does EPA consider international residue limits?

When establishing a tolerance for residues of a pesticide, EPA must determine whether Codex has established a MRL for that pesticide. See 21 U.S.C. 346a(b)(4). Additionally, as

part the registration review of a pesticide (see Unit II.C.), EPA determines whether Codex or other international MRLs exist for commodities and chemicals for which U.S. tolerances have been established. Where appropriate, EPA's intention is to harmonize U.S. tolerances with those international MRLs to facilitate trade. EPA's effort to harmonize with international MRLs is summarized in the tolerance reassessment section of the individual Human Health Draft Risk Assessments that support the pesticide registration review.

C. What is registration review?

Under FIFRA section 3(g), 7 U.S.C. 136a(g), EPA is required to periodically review all registered pesticides and determine if those pesticides continue to meet the standard for registration under FIFRA. See also 40 CFR 155.40(a). The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides can continue to be used without causing unreasonable adverse effects on human health and the environment. As part of the registration review of a pesticide, EPA also evaluates whether existing tolerances are safe, whether any changes to existing tolerances are necessary or appropriate, and whether any new tolerances are necessary to cover residues from registered pesticides. In addition, any tolerance changes identified as necessary or appropriate during registration review of a pesticide are summarized in the registration review decision documents for each pesticide active ingredient or registration review case (e.g., in the Proposed Interim Decision (PID), Proposed Final Decision (PFD), Interim Decision (ID) and Final Decision (FD)). These documents can be found in the public docket that has been opened for each pesticide, which is available online at <https://www.regulations.gov>, using the docket ID number listed in Unit III. for each pesticide active ingredient included in this proposed action. Additional information about pesticide registration review is available at <https://www.epa.gov/pesticide-reevaluation>.

D. EPA's Safety Assessments

FFDCA section 408(b) authorizes EPA to establish a tolerance, if the Agency determines that a tolerance is safe; FFDCA section 408(c) authorizes EPA to establish an exemption from the requirement of a tolerance if the Agency determines that the exemption is safe. See 21 U.S.C. 346a(b) and (c). If EPA

determines that a tolerance or exemption is not safe, EPA must modify or revoke that tolerance or exemption. The FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” 21 U.S.C.

346a(b)(2)(A)(ii), (c)(2)(A)(ii). This includes exposure through drinking water and in residential settings but does not include occupational exposure. FFDCA section 408(b)(2)(C) requires EPA to give special consideration to the exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue[s.]” 21 U.S.C. 346a(b)(2)(C). In addition, FFDCA section 408(b)(2)(D) contains several factors EPA must consider when making determinations about establishing, modifying, or revoking tolerances. 21 U.S.C. 346a(b)(2)(D). FFDCA section 408(c)(2)(B) requires that EPA, when making determinations about exemptions, to take into account, among other things, the considerations set forth in FFDCA section 408(b)(2)(C) and (D). 21 U.S.C. 346a(c)(2)(B).

Furthermore, when establishing tolerances or exemptions from the requirement of a tolerance, FFDCA sections 408(b)(3) and (c)(3) require that there be a practical method for detecting and measuring pesticide chemical residue levels in or on food, unless in the case of exemptions, EPA determines that such method is not needed and states the reasons therefore in the rulemaking. 21 U.S.C. 346a(b) and (c).

Consistent with its obligations under FIFRA section 3(g), 7 U.S.C. 136a(g), and FFDCA section 408, 21 U.S.C. 346a, EPA has reviewed the available scientific data and other relevant information on toxicity and exposure of the individual chemicals represented in this rulemaking. As part of registration review, the Agency has published risk assessments detailing the risks from aggregate exposure, including to infants and children, for each of the pesticides represented herein. The chemical-specific toxicity and exposure analyses, which support the safety determinations contained in Unit III., can be found in the human health risk assessment documents and related registration review decision documents, which are available in the public docket that has been opened for each pesticide, as noted in Unit III.

After considering all available information, EPA has determined it is appropriate based on the underlying safety assessments to take the tolerance actions being proposed in this rulemaking and that adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expressions.

III. Proposed Tolerance Actions

EPA is proposing to take the specific tolerance actions identified in this unit. All tolerance values proposed in the regulatory text of this rule, modified or otherwise, are being proposed to reflect current OECD rounding practices.

A. 40 CFR 180.220; Atrazine; Case 0062 (Docket ID No. EPA-HQ-OPP-2013-0266)

EPA is proposing to amend the current tolerances by:

- Revising the tolerance expression in paragraph (a) for atrazine to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression would clarify that (1) as provided in FFDCA section 408(a)(3), the tolerances cover metabolites and degradates of atrazine not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression would not substantively change the tolerances or, in any way, modify the permissible level of residues permitted by the tolerances.

- Modifying the tolerance level in paragraph (a) for “Corn, sweet, forage” from 15 ppm to 1.5 ppm, which is supported by the updated pre-harvest interval. The Agency previously reviewed crop field trial data conducted on sweet corn, reflecting maximum use rates of post-emergent applications of atrazine and a 45-day pre-harvest interval for forage. These data indicate that a tolerance level of 1.5 ppm is adequate to cover potential residues of atrazine in/on corn, sweet, forage following post-emergent application at maximum registered use rates and a 45-day pre-harvest interval for forage. Because the proposed action would lower the existing tolerance, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

- Updating the existing crop group tolerance in paragraph (d) for indirect or inadvertent residues of atrazine from

“Vegetable, leafy, except brassica, group 4” to the updated crop groups “Leaf petiole vegetable subgroup 22B” and “Leafy greens subgroup 4–16A” at the same level, 0.25 ppm. The Agency is also proposing to establish tolerances for the following individual commodities, which would otherwise lose coverage under the updated crop groupings: “Arugula”, “Celtuce”, “Fennel, Florence, fresh leaves and stalk”, “Cress, garden”, and “Cress, upland” at 0.25 ppm.

40 CFR 180.40(j) states that “At appropriate times, EPA will amend tolerances for crop groups that have been superseded by revised crop groups to conform the pre-existing crop group to the revised crop group.” EPA has indicated in updates to its crop group rulemakings that registration review is one of those appropriate times. See, e.g., Tolerance Crop Grouping Program V (85 FR 70985) (November 6, 2020).

- Establishing new tolerances in paragraph (d) for indirect or inadvertent residues of atrazine in or on “Vegetable, foliage of legume, group 7” at 0.5 ppm. Rotational crop studies support the establishment of this tolerance.

- Modifying tolerances to reflect current OECD rounding practices.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the atrazine tolerances would be safe, i.e., there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to atrazine residues. Adequate enforcement methodology is available.

This proposed rule only proposes atrazine tolerance actions which EPA previously identified as necessary or appropriate during registration review. It does not serve as a response to the petition that EPA received in February 2025 from the Center for Biological Diversity, *A Petition to Make America Healthy Again by Eliminating Extraordinarily Toxic Pesticides From Food* (available at https://www.epa.gov/system/files/documents/2025-07/maha_petition.pdf), which asks, in part, that EPA revoke all tolerances for residues of atrazine. That petition is currently under review by the Agency.

B. 40 CFR 180.226; Diquat; Case 0288 (Docket ID No. EPA-HQ-OPP-2009-0846)

EPA is proposing to amend the current tolerances by:

- Revising the commodity definitions in paragraph (a)(2) from “Vegetable, brassica, leafy, group 5” to “Vegetable, Brassica, leafy, group 5” and

“Vegetable, leafy, except brassica, group 4” to “Vegetable, leafy, except *Brassica*, group 4.” These revisions of commodity definitions would help facilitate efficient commodity searches and would not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Updating existing crop group tolerances in paragraph (a)(2) from “Berry group 13” to “Berry and small fruit, group 13–07”, “Cotton, undelinted seed” to “Oilseeds, group 20”, “Fruit, citrus, group 10” to “Fruit, citrus, group 10–10”, “Fruit, pome, group 11” to “Fruit, pome, group 11–10”, “Fruit, stone, group 12” to “Fruit, stone, group 12–12”, and “Nut, tree, group 14” to “Nut, tree, group 14–12”. The Agency also proposes to remove tolerances for the individual commodities “Cranberry”, “Grape”, and “Strawberry”, which would be covered under the updated crop group “Berry and small fruit, group 13–07” at the same level, 0.05 ppm.

40 CFR 180.40(j) states that “At appropriate times, EPA will amend tolerances for crop groups that have been superseded by revised crop groups to conform the pre-existing crop group to the revised crop group.” EPA has indicated in updates to its crop group rulemakings that registration review is one of those appropriate times. *See, e.g.*, Tolerance Crop Grouping Program V (85 FR 70985) (November 6, 2020).

- Revoking the tolerance from paragraph (a)(3) for “Soybean, hulls” at 0.6 ppm, because domestic use of diquat on soybeans was cancelled. Because the proposed action would revoke the existing tolerance, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

- Establishing a new tolerance in paragraph (a)(1) for “Clover, seed” at 2 ppm. This was recommended in the 2002 Tolerance Reassessment Eligibility Document (TRED) based on the registered use on clover grown for seed.

- Establishing new tolerances in paragraph (a)(2) for “Animal feed, nongrass, group 18, forage”, “Animal feed, nongrass, group 18, hay”, and “Herb and spice, group 19” at 0.2 ppm, and for “Vegetable, bulb, group 3” and “Vegetable, leaves of root and tuber, group 2” at 0.02 ppm. Translation of available commodity data support the establishment of these tolerances.

- Moving the tolerances for “Banana”, and “Coffee, bean, green” from paragraph (a)(3) to paragraph (a)(1), moving the tolerances for “Potato, granules/flakes” and “Potato, chips” from paragraph (a)(4) to paragraph

(a)(1), and moving and establishing an expiration date for the tolerance for “Soybean, hulls” from paragraph (a)(3) to paragraph (a)(1).

- Modifying tolerances to reflect current OECD rounding practices.

Where appropriate, it is the Agency’s intention is to harmonize U.S. tolerances with international MRLs to facilitate trade. EPA has identified opportunities to harmonize with Codex MRLs for diquat and is proposing to harmonize tolerances for bananas and coffee from 0.05 ppm to 0.02 ppm as there are no U.S. registrations for these crop uses. Tolerances for residues in/on banana and coffee were established at the limit of quantitation, which was 0.05 ppm at the time of the petitions for the tolerances in/on banana and coffee in 1995. The Agency determined that the 0.02 ppm level reflects the limit of quantitation of the current enforcement method. Because the proposed action would lower the existing tolerances, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the diquat tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to diquat residues. Adequate enforcement methodology is available.

C. 40 CFR 180.318; MCPB; Case 2365 (Docket ID No. EPA-HQ-OPP-2014-0181)

EPA is proposing to amend the current tolerances by:

- Revising the tolerance expression in paragraph (a) for MCPB to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression would clarify that (1) as provided in FFDCA section 408(a)(3), the tolerances cover metabolites and degradates of MCPB not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression would not substantively change the tolerances or, in any way, modify the permissible level of residues permitted by the tolerances.

- Revising the commodity definition and modifying the tolerance levels in paragraph (a) from “Pea” at 0.1 ppm to

“Pea, dry, seed” at 0.03 ppm, “Pea, edible, podded” at 0.02 ppm, and “Pea, succulent, shelled” at 0.02 ppm, which is supported by field trial data. As part of registration review, the Agency reviewed crop field trials conducted on pea, which reflect registered use patterns of MCPB. These data indicate that a tolerance level of 0.03 ppm is adequate to cover potential residues of MCPB in/on pea, dry, seed following application at maximum registered use rates. Additionally, the tolerance level of 0.02 ppm for residues in/on “Pea, edible podded” and “Pea, succulent, shelled” is based on the limit of quantification, as no residues were detected in these commodities in the reviewed field trial data. Because the proposed action would lower the existing tolerance, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

- Revising the commodity definitions in paragraph (a) from “Peppermint, tops” to “Peppermint, fresh leaves” and “Spearment, tops” to “Spearment, fresh leaves”. These revisions of commodity definitions would help facilitate efficient commodity searches and would not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Revising the title to “MCPB” in 40 CFR 180.318 to more accurately reflect the chemical covered by the tolerances in that section.

- Modifying tolerances to reflect current OECD rounding practices.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the MCPB tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to MCPB residues. Adequate enforcement methodology is available.

D. 40 CFR 180.328; Napropamide; Case 2450 (Docket ID No. EPA-HQ-OPP-2016-0019)

EPA is proposing to amend the current tolerances by:

- Revising the tolerance expression in paragraph (a) for napropamide to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression would clarify that (1) as provided in FFDCA section 408(a)(3), the tolerances cover metabolites and degradates of napropamide not specifically

mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression would not substantively change the tolerances or, in any way, modify the permissible level of residues permitted by the tolerances.

- Revising the commodity definitions in paragraph (a) from “Spearment, tops” to “Spearment, fresh leaves” and “Peppermint, tops” to “Peppermint, fresh leaves”. These revisions of the commodity definitions would help facilitate efficient commodity searches and would not substantively change the tolerances or, in any way, modify the permissible level of residues in or on the commodities listed in the regulation.

- Updating existing crop group tolerances in paragraph (a) from “Vegetable, fruiting, Group 8” and “Nut, tree, Group 14” to the updated crop groups “Vegetable, fruiting, Group 8–10” and “Nut, tree, Group 14–12” at the same level, 0.1 ppm. The Agency also proposes to remove the tolerance for the individual commodity “Almond, hulls”, which would be covered under the updated crop grouping “Nut, tree, Group 14–12” at the same level, 0.1 ppm.

- Updating existing crop group tolerances in paragraph (a) from “Vegetable, Brassica, leafy, group 5” to “Brassica, leafy greens, subgroup 4–16B”, “Vegetable, brassica, head and stem, group 5–16”, and “Stalk and stem vegetable subgroup 22A” at the same level, 0.1 ppm. The Agency also proposes to remove the tolerance for the individual commodity “Asparagus”, which would be covered under the updated crop groupings at the same level, 0.1 ppm.

- Updating existing crop group tolerances in paragraph (a) from “Berry group 13” to “Berry, low growing, subgroup 13–07G”, “Bushberry subgroup 13–07B”, “Caneberry Subgroup 13–07A”, and “Fruit, small, vine climbing, subgroup 13–07D” at the same level, 0.1 ppm. The Agency also proposes to remove the tolerances for the individual commodities “Cranberry”, “Grape”, “Kiwifruit”, and “Strawberry”, which would be covered under the updated crop groupings at the same level, 0.1 ppm.

40 CFR 180.40(j) states that “At appropriate times, EPA will amend tolerances for crop groups that have been superseded by revised crop groups to conform the pre-existing crop group to the revised crop group.” EPA has indicated in updates to its crop group rulemakings that registration review is

one of those appropriate times. *See, e.g.*, Tolerance Crop Grouping Program V (85 FR 70985) (November 6, 2020).

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the napropamide tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to napropamide residues. Adequate enforcement methodology is available.

E. 40 CFR 180.339; MCPA; Case 0017 (Docket ID No. EPA-HQ-OPP-2014-0180)

EPA is proposing to amend the current tolerances by:

- Modifying the tolerance levels in paragraph (a) for “Pea, field, hay” from 0.1 ppm to 1.5 ppm and “Pea, field, vines” from 0.1 to 0.6 ppm, based on updated field trial data and OECD calculations.

- Revising the commodity definition in paragraph (a) from “Pea, succulent” to “Pea, succulent shelled”. The revision of commodity definition would help facilitate efficient commodity searches and would not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Revising the commodity definition in paragraph (a) from “Pea, dry” to “Pea, dry, seed” and modifying the tolerance level from 0.1 ppm to 0.01 ppm, based on updated field trial data and OECD calculations. As part of registration review, the Agency reviewed crop field trials conducted on dry pea, which reflect registered use patterns of MCPA. These data indicate that a tolerance level of 0.01 ppm is adequate to cover potential residues of MCPA in/on pea, dry, seed following application at maximum registered use rates. The revision of the commodity definition and permissible tolerance level would help facilitate efficient commodity searches as well as harmonize the tolerance level with Codex. Because the proposed action would lower the existing tolerance, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

- Establishing new crop group tolerances in paragraph (a) for “Grass, forage, fodder, and hay, group 17, forage” at 500 ppm, and “Grass, forage, fodder, and hay, group 17, hay” at 200 ppm, based on updated OECD calculations. The Agency also proposes to remove the tolerances for the

individual commodities “Grass, forage” at 300 ppm and “Grass, hay” at 20 ppm, which would be covered under the updated crop grouping. The establishment of the new crop group tolerance for “Grass, forage, fodder, and hay, group 17, forage” at 500 ppm would help facilitate efficient commodity searches as well as harmonize permissible levels with Codex.

40 CFR 180.40(j) states that “At appropriate times, EPA will amend tolerances for crop groups that have been superseded by revised crop groups to conform the pre-existing crop group to the revised crop group.” EPA has indicated in updates to its crop group rulemakings that registration review is one of those appropriate times. *See, e.g.*, Tolerance Crop Grouping Program V (85 FR 70985) (November 6, 2020).

- Revoking the tolerances in paragraph (a) for “Hog, fat”, “Hog, meat”, and “Hog, meat byproducts”. An updated dietary burden calculation showed no reasonable expectation of finite residues in hog commodities (see 40 CFR 180.6(a)(3)). Because the proposed action would revoke the existing tolerances, EPA is proposing to add an expiration date for the existing tolerances of June 9, 2026.

- Modifying tolerances by removing trailing zeros to reflect current OECD rounding practices.

Where appropriate, it is the Agency’s intention to harmonize U.S. tolerances with international MRLs to facilitate trade. EPA has identified opportunities to harmonize with Codex MRLs for MCPA and is proposing to modify the following tolerance values in paragraph (a) to do so: “Oat, straw” from 25 ppm to 50 ppm, “Rye, forage” from 20 ppm to 50 ppm, “Rye, straw” from 25 ppm to 50 ppm, “Wheat, forage” from 20 ppm to 50 ppm, and “Wheat, straw” from 25 ppm to 50 ppm.

In addition to harmonizing with Codex, EPA is proposing to modify the following tolerance values based on updated OECD calculations: “Barley, grain” from 1 ppm to 0.2 ppm, “Oat, grain” from 1 ppm to 0.2 ppm, “Oat, hay” from 115 ppm to 50 ppm, “Rye, grain” from 1 ppm to 0.2 ppm, “Wheat, grain” from 1.0 ppm to 0.2 ppm, and “Wheat, hay” from 115 ppm to 50 ppm. As part of registration review, the Agency reviewed crop field trials conducted at an exaggerated application rate on wheat, which reflect registered uses of MCPA. These data indicate that tolerance levels of 0.2 ppm and 50 ppm are adequate to cover potential residues of MCPA in/on wheat, grain and wheat, hay, respectively, following application at maximum registered use rates. These

tolerance levels have been translated to other small cereal grains, including barley, oat, and rye. Because the proposed action would lower the existing tolerances, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

In addition to harmonizing with Codex, EPA is proposing to modify the following tolerance values based on an updated dietary burden calculations: “Cattle, fat” from 0.1 ppm to 0.2 ppm, “Cattle, meat byproducts” from 0.1 ppm to 3 ppm, “Goat, fat” from 0.1 ppm to 0.2 ppm, “Goat, meat byproducts” from 0.1 ppm to 3 ppm, “Horse, fat” from 0.1 ppm to 0.2 ppm, “Horse, meat byproducts” from 0.1 ppm to 3 ppm, “Milk” from 0.1 ppm to 0.04 ppm, “Sheep, fat” from 0.1 ppm to 0.2 ppm, and “Sheep, meat byproducts” from 0.1 ppm to 3 ppm. Because the proposed action would lower the existing tolerance for “Milk”, EPA is proposing to establish an expiration date for the existing tolerance of EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**. The updated tolerance level is based on livestock feeding studies and updated dietary burden calculations, which incorporates residues from updated crop field trial data reviewed under registration review.

In addition to harmonizing with Codex, EPA is proposing to modify the tolerance value for “Flax, seed” from 0.1 ppm to 0.01 ppm, based on updated residue data. As part of registration review, the Agency reviewed crop field trials conducted on flax, which reflect registered use patterns of MCPA. These data indicate that a tolerance level of 0.01 ppm is adequate to cover potential residues of MCPA in/on flax, seed following application at maximum registered use rates. Because the proposed action would lower the existing tolerance, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the MCPA tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to MCPA residues. Adequate enforcement methodology is available.

F. 40 CFR 180.409; Pirimiphos-Methyl; Case 2535 (Docket ID No. EPA-HQ-OPP-2009-0056)

EPA is proposing to amend the current tolerances by:

- Revising the tolerance expression in paragraph (a) for pirimiphos-methyl to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression would clarify that (1) as provided in FFDCA section 408(a)(3), the tolerances cover metabolites and degradates of pirimiphos-methyl not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression would not substantively change the tolerances or, in any way, modify the permissible level of residues permitted by the tolerances.

- Modifying tolerances to reflect current OECD rounding practices.

Where appropriate, it is the Agency's intention is to harmonize U.S. tolerances with international MRLs to facilitate trade. EPA has identified opportunities to harmonize with Codex MRLs for pirimiphos-methyl and is proposing to modify tolerance levels for the following commodities to do so: “Cattle, fat” from 0.02 ppm to 0.01 ppm, “Cattle, meat byproducts” from 0.02 ppm to 0.01 ppm, “Corn, field, grain” from 8 ppm to 7 ppm, “Corn, pop, grain” from 8 ppm to 7 ppm, “Goat, fat” from 0.02 ppm to 0.01 ppm, “Goat, meat byproducts” from 0.02 ppm to 0.01 ppm, “Hog, fat” from 0.02 ppm to 0.01 ppm, “Hog, meat byproducts” from 0.02 ppm to 0.01 ppm, “Horse, fat” from 0.02 ppm to 0.01 ppm, “Horse, meat byproducts” from 0.02 ppm to 0.01 ppm, “Poultry, fat” from 0.02 ppm to 0.01 ppm, “Sheep, fat” from 0.02 ppm to 0.01 ppm, “Sheep, meat byproducts” from 0.02 ppm to 0.01 ppm, and “Sorghum, grain, grain” from 8 ppm to 7 ppm. The Agency is proposing the revisions to “Corn, field, grain”, “Corn, pop, grain”, and “Sorghum, grain, grain” based on the maximum application rate of pirimiphos-methyl on corn and sorghum grain and pesticide monitoring data showing little, if any, residues in or on corn and sorghum grain. For the livestock tolerances, the Agency concluded that the decreased tolerance level is sufficient to cover anticipated residues in or on “Cattle, fat”, “Cattle, meat byproducts”, “Goat, fat”, “Goat, meat byproducts”, “Hog, fat”, “Hog, meat

byproducts”, “Horse, fat”, “Horse, meat byproducts”, “Poultry, fat”, “Sheep, fat”, and “Sheep, meat byproducts” based on the calculated dietary burden and available residue chemistry data. Because the proposed action would lower the existing tolerances, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the pirimiphos-methyl tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to pirimiphos-methyl residues. Adequate enforcement methodology is available.

G. 40 CFR 180.411; Fluazifop-P-Butyl; Case 2285 (Docket ID No. EPA-HQ-OPP-2014-0779)

EPA is proposing to amend the current tolerances by:

- Revising the tolerance expressions in paragraphs (a) and (c) for fluazifop-P-butyl to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression would clarify that (1) as provided in FFDCA section 408(a)(3), the tolerances cover metabolites and degradates of fluazifop-P-butyl not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression would not substantively change the tolerances or, in any way, modify the permissible level of residues permitted by the tolerances.

- Removing the tolerances from paragraph (a) for “Fruit, citrus, group 10” at 0.03 ppm and “Fruit, stone” at 0.05 ppm. These tolerances were time-limited to allow a reasonable interval for producers to adapt to the requirement when the current crop group tolerances were established and expired on June 26, 2023.

- Removing the tolerance from paragraph (a) for “Citrus, juice” at 0.06 ppm. Based on a new citrus processing study, EPA determined that any residues in this commodity would be covered by the “Fruit, citrus, group 10–10” tolerance of 0.01 ppm. Because the proposed action would lower the tolerance level for this commodity, EPA is proposing to add an expiration date for the existing tolerance of 180 days

after publication of the final rule in the **Federal Register**.

- Modifying tolerance levels in paragraph (a) for “Citrus, dried pulp” from 0.40 to 0.06 ppm, “Citrus, oil” from 30.0 to 0.05 ppm, and “Soybean, seed” from 2.5 to 4 ppm. While the existing tolerances for these citrus commodities were based on theoretical concentration factors, EPA is proposing to modify the tolerances based on a new citrus processing study. Likewise, EPA is proposing to modify the tolerance for “Soybean, seed” based on new data on soybean residues. Because the proposed action would lower the existing tolerances for the citrus commodities, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

- Revising the commodity definitions and modifying the tolerance levels in paragraph (a) from “Beans, dry, seed” at 50 ppm to “Bean, dry, seed” at 40 ppm, and from “Pecans” at 0.05 ppm to “Pecan” at 0.01 ppm. For “Bean, dry, seed”, the Agency determined that the U.S. tolerance was determined using the North American Free Trade Agreement (NAFTA) calculator, while the Codex MRL was determined using the Organisation for Economic Co-operation and Development (OECD) calculator. As the Agency currently relies on the OECD calculator and the Codex MRL was determined using the same dataset as the U.S. tolerance, the tolerance should be lowered to harmonize with Codex. For “Pecan”, the Agency determined that the 0.01 ppm level reflects the limit of quantitation of the current enforcement method. This level is appropriate as there are no detects in the field trial data, residue translocation into tree/vine fruit is not expected based on the registered use pattern, and suitably sensitive analytical enforcement methods are available, so the tolerances should be lowered to harmonize with Codex. The revisions of the commodity definitions and permissible tolerance levels would help facilitate efficient commodity searches as well as harmonize the tolerance levels with Codex. Because the proposed action would lower the existing tolerances, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

- Modifying tolerances to reflect current OECD rounding practices.

Where appropriate, it is the Agency’s intention to harmonize U.S. tolerances with international MRLs to facilitate trade. EPA has identified opportunities to harmonize with Codex MRLs for fluazifop-P-butyl and is proposing to

modify the following tolerance values in paragraphs (a) and (c) to do so: “Beet, sugar, roots” from 0.25 ppm to 0.5 ppm, “Cattle, fat” from 0.05 ppm to 0.09 ppm, “Cattle, meat” from 0.05 ppm to 0.09 ppm, “Cattle, meat byproducts” from 0.05 ppm to 0.2 ppm, “Coffee, bean” from 0.1 ppm to 0.01 ppm, “Cotton, undelinted seed” from 1 ppm to 0.7 ppm, “Egg” from 0.05 ppm to 0.03 ppm, “Goat, fat” from 0.05 ppm to 0.09 ppm, “Goat, meat” from 0.05 ppm to 0.09 ppm, “Goat, meat byproducts” from 0.05 ppm to 0.2 ppm, “Hog, fat” from 0.05 ppm to 0.09 ppm, “Hog, meat” from 0.05 ppm to 0.09 ppm, “Hog, meat byproducts” from 0.05 ppm to 0.2 ppm, “Horse, fat” from 0.05 ppm to 0.09 ppm, “Horse, meat” from 0.05 ppm to 0.09 ppm, “Horse, meat byproducts” from 0.05 ppm to 0.2 ppm, “Milk” from 0.05 ppm to 0.2 ppm, “Poultry, fat” from 0.05 ppm to 0.03 ppm, “Poultry, meat” from 0.05 ppm to 0.03 ppm, “Poultry, meat byproducts” from 0.05 ppm to 0.2 ppm, “Sheep, fat” from 0.05 ppm to 0.09 ppm, “Sheep, meat” from 0.05 ppm to 0.09 ppm, and “Sheep, meat byproducts” from 0.05 ppm to 0.2 ppm. For “Coffee, bean”, the Agency determined that the 0.01 ppm level reflects the limit of quantitation of the current enforcement method. This level is appropriate as there are no detects in the field trial data, residue translocation into tree/vine fruit is not expected based on the registered use pattern, and suitably sensitive analytical enforcement methods are available, so the tolerances should be lowered to harmonize with Codex. For “Cotton, undelinted seed”, the same dataset was used to establish the U.S. tolerance (1.0 ppm) and the Codex MRL (0.7 ppm). The difference in levels appears to result from a difference in the residue value determined from the trial with the highest residue and should be lowered to the same level as the Codex MRL so it is more representative. For “Egg”, “Poultry, fat”, and “Poultry meat”, the U.S. tolerances are currently higher due to differences in the livestock method limit of quantitation (LOQ) when the levels were determined and should be lowered as they now share the same LOQ as the Codex MRLs. Because the proposed action would lower the existing tolerances for “Coffee, bean”, “Cotton, undelinted seed”, “Egg”, “Poultry, fat”, and “Poultry, meat”, EPA is proposing to add an expiration date for the existing tolerance of 180 days after publication of the final rule in the **Federal Register**.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that

the proposed amendments to the fluazifop tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to fluazifop residues. Adequate enforcement methodology is available.

H. 40 CFR 180.458; Clethodim; Case 7226 (Docket ID No. EPA-HQ-OPP-2008-0658).

EPA is proposing to amend the current tolerances by:

- Updating existing individual and crop group tolerances in paragraph (a) from “Flax, seed” at 0.6 ppm and “Rapeseed subgroup 20A, except flax seed” at 0.50 ppm to the crop group “Rapeseed subgroup 20A” at 0.6 ppm. Upon establishment of the new crop group, and to prevent redundancy, the Agency proposes to remove tolerances that will be unnecessary once they are superseded by the tolerances established for the new crop group, including the tolerances for “Flax, seed” and “Rapeseed subgroup 20A, except flax seed” that will now be covered under the updated crop grouping “Rapeseed subgroup 20A.”

- Removing the tolerance from paragraph (a) for “Kohlrabi” at 3 ppm. This tolerance was time-limited to allow a reasonable interval for producers to adapt to the requirement when the current crop group tolerances were established and expired on October 12, 2018.

- Modifying tolerances to reflect current OECD rounding practices.

Where appropriate, it is the Agency’s intention to harmonize U.S. tolerances with those international MRLs to facilitate trade. EPA has identified opportunities to harmonize with Codex MRLs for clethodim and is proposing to increase the tolerance for “Peanut” from 3.0 ppm to 5 ppm.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the clethodim tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to clethodim residues. Adequate enforcement methodology is available.

I. 40 CFR 180.572; Bifenazate; Case 7609 (Docket ID No. EPA-HQ-OPP-2012-0633)

EPA is proposing to amend the current tolerance by:

- Revising the tolerance expressions in paragraphs (a)(1), (a)(2), and (c) for bifenazate to describe more clearly the

scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression would clarify that (1) as provided in FFDCA section 408(a)(3), the tolerances cover metabolites and degradates of bifenazate not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression would not substantively change the tolerances or, in any way, modify the permissible level of residues permitted by the tolerances.

- Revising the commodity definitions in paragraph (a) from “Bean, dry seed” to “Bean, dry, seed”, “Berry, low-growing subgroup 13–07G” to “Berry, low-growing, subgroup 13–07G”, “Black sapote” to “Sapote, black”, “Fruit, small, vine climbing subgroup 13–07F, except fuzzy kiwifruit” to “Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F”, “Herb, subgroup 19A, except chervil and chive” to “Herb subgroup 19A, except chervil and chive”, “Peppermint, tops” to “Peppermint, fresh leaves”, “Soybean, succulent shelled” to “Soybean, vegetable, succulent shelled”, and “Spearment, tops” to “Spearment, fresh leaves.” These revisions of commodity definitions would help facilitate efficient commodity searches and would not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Removing the tolerances from paragraph (a) for the individual commodities “Grape” at 0.75 ppm and “Okra” at 2 ppm. These commodities are covered by the existing crop group tolerances “Fruit, small, vine climbing subgroup 13–07F, except fuzzy kiwifruit,” at 1.0 ppm and “Vegetable, fruiting, group 8–10” at 4.0 ppm, respectively, and they would continue to be covered under the revisions proposed in this rule.

- Modifying tolerances to reflect current OECD rounding practices.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the bifenazate tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to bifenazate residues. Adequate enforcement methodology is available.

J. 40 CFR 180.620; Etofenprox; Case 7407 (Docket ID No. EPA–HQ–OPP–2007–0804)

EPA is proposing to amend the current tolerance by:

- Revising the tolerance expression in newly designated paragraph (a)(1) for etofenprox to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression would clarify that (1) as provided in FFDCA section 408(a)(3), the tolerances cover metabolites and degradates of etofenprox not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression would not substantively change the tolerances or, in any way, modify the permissible level of residues permitted by the tolerances.

- Establishing a tolerance of 5 ppm under a newly designated paragraph (a)(2) for residues of etofenprox in or on all food/feed items resulting from use of etofenprox as a wide-area mosquito adulticide.

- Modifying tolerances to reflect current OECD rounding practices.

Where appropriate, it is the Agency’s intention is to harmonize U.S. tolerances with those international MRLs to facilitate trade. EPA has identified opportunities to harmonize with Codex MRLs for etofenprox and is proposing to harmonize the U.S. tolerances for “Cattle, meat”, “Goat, meat”, “Horse, meat”, and “Sheep, meat”, all from 0.40 ppm to 0.5 ppm and “Hog, meat” from 0.20 ppm to 0.5 ppm.

As discussed in Unit II.D., based on the supporting registration review documents, EPA has determined that the proposed amendments to the etofenprox tolerances would be safe, *i.e.*, there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to etofenprox residues. Adequate enforcement methodology is available.

IV. Proposed Effective and Expiration Date(s)

EPA is proposing that these tolerance actions would be effective on the date of publication of the final rule in the **Federal Register**. For actions in the final rule that lower or revoke existing tolerances, EPA is proposing to add an expiration date for the existing tolerance of 180 days (approximately six months) after the date of publication of the final

rule in the **Federal Register**, to allow a reasonable interval for producers in exporting members of the World Trade Organization’s (WTO’s) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it proposes to establish or modify a pesticide tolerance or a tolerance exemption under FFDCA section 408. This exemption also applies to tolerance revocations for which extraordinary circumstances do not exist. As such, this exemption applies to the tolerance revocations in this proposed rule because the Agency knows of no extraordinary circumstances that warrant reconsideration of this exemption for those proposed tolerance revocations.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because this tolerance action under FFDCA section 408 is exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, EPA concludes that the impact of concern for this action is any significant adverse economic impact on small entities and that the Agency is certifying that this action will not have a significant economic impact on a substantial number of small entities because the action has no net burden on small entities subject to this rulemaking. This determination takes into account an EPA analysis for tolerance establishments and modifications that published in the **Federal Register** of May 4, 1981 (46 FR 24950) (FRL–1809–5) and for tolerance revocations on

December 17, 1997 (62 FR 66020) (FRL–5753–1). Additionally, in a 2001 memorandum, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. *See* Memorandum from Denise Keehner, Division Director, Biological and Economic Analysis Division, Office of Pesticide Programs, entitled “RFA/SBREFA Certification for Import Tolerance Revocation” and dated May 25, 2001, which is available in docket ID No. EPA–HQ–OPP–2005–0322 at <https://www.regulations.gov>.

Any comments about the Agency’s determination for this rulemaking should be submitted to EPA along with comments on the proposed rule and will be addressed in the final rule.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local or Tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (See Unit V.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, EPA’s 2021 *Policy on Children’s Health* applies to this action. This rule proposes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .” (FFDCA 408(b)(2)(C)). The Agency’s consideration is documented in the pesticide-specific registration review documents, located in each chemical docket at <https://www.regulations.gov>.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant

regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

List of Subjects in 40 CFR Part 180

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

Dated: December 3, 2025.

Edward Messina,
Director, Office of Pesticide Programs.

For the reasons set forth in the preamble, EPA is proposing to amend 40 CFR chapter I as follows:

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

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

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

■ 2. Amend § 180.220 by revising and replacing § 180.220 to read as follows:

§ 180.220 Atrazine; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide atrazine, including its metabolites and degradates, in or on the commodities in Table 1 to Paragraph (a). Compliance with the tolerance levels specified in Table 1 to Paragraph (a) is to be determined by measuring only the sum of atrazine, 6-chloro-*N*-ethyl-*N'*-(1-methylethyl)-1,3,5-triazine-2,4-diamine, its metabolites 2-amino-4-chloro-6-isopropylamino-*s*-triazine, 2-amino-4-chloro-6-ethylamino-*s*-triazine, and 2,4-diamino-6-chloro-*s*-triazine, calculated as the stoichiometric equivalent of atrazine, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Corn, field, forage	1.5
Corn, field, grain	0.2
Corn, field, stover	0.5
Corn, pop, forage	1.5
Corn, pop, grain	0.2
Corn, pop, stover	0.5
Corn, sweet, forage ¹	15
Corn, sweet, forage	1.5
Corn, sweet, kernel plus cob with husks removed	0.2
Corn, sweet, stover	2

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Grass, forage	4
Grass, hay	4
Guava	0.05
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Nut, macadamia	0.2
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02
Sorghum, forage, forage	0.25
Sorghum, grain, forage	0.25
Sorghum, grain, grain	0.2
Sorghum, grain, stover	0.5
Sugarcane, cane	0.2
Wheat, forage	1.5
Wheat, grain	0.1
Wheat, hay	5
Wheat, straw	0.5

¹ This tolerance expires on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

(b) *Section 18 emergency exemptions.*
[Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect and inadvertent residues.*
Tolerances are established for indirect or inadvertent residues of the herbicide atrazine, including its metabolites and

degradates, in or on the commodities in Table 2 to Paragraph (d). Compliance with the tolerance levels specified in Table 2 to Paragraph (d) is to be determined by measuring only the sum of atrazine, 6-chloro-*N*-ethyl-*N'*-(1-methylethyl)-1,3,5-triazine-2,4-diamine,

its metabolites, 6-chloro-2-*N*-(1-methylethyl)-1,3,5-triazine-2,4-diamine, 6-chloro-2-*N*-ethyl-1,3,5-triazine-2,4-diamine, and 6-chloro-1,3,5-triazine-2,4-diamine, calculated as the stoichiometric equivalent of atrazine, in or on the commodity.

TABLE 2 TO PARAGRAPH (d)

Commodity	Parts per million
Arugula	0.25
Celtuce	0.25
Fennel, Florence, fresh leaves and stalk	0.25
Garden cress	0.25
Leaf petiole vegetable subgroup 22B	0.25
Leafy greens subgroup 4–16A	0.25
Upland cress	0.25
Vegetable, foliage of legume, group 7	0.5

■ 3. Amend § 180.226 by:

■ a. Adding the heading “Table 1 to Paragraph (a)(1)” to the table in paragraph (a)(1);

■ b. Revising and republishing the table in paragraph (a)(1);

■ c. Revising and republishing paragraph (a)(2)(i); and

■ d. Removing paragraphs (a)(3) and (a)(4) in their entirety.

The revisions and additions read as follows:

§ 180.226 Diquat; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Alfalfa, seed	3
Banana ^{1 2}	0.05
Banana ¹	0.02
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Canola, meal	6
Canola, seed	2
Clover, seed	2

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
Coffee, bean, green ^{1 2}	0.05
Coffee, bean, green ¹	0.02
Egg	0.05
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.02
Pea and bean, dry and shelled, except soybean, subgroup 6C ¹	0.9
Potato	0.1
Potato, chips	0.5
Potato, granules/flakes	0.5
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Soybean, hulls ²	0.6

¹ There are no U.S. registrations for this commodity.

² This tolerance expires on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

(2)
(i) Tolerances are established for residues of the herbicide diquat, including its metabolites and degradates, derived from application of the dibromide salt to ponds, lakes, reservoirs, marshes, drainage ditches,

canals, streams, and rivers which are slow-moving or quiescent in programs of the Corp of Engineers or other Federal or State public agencies and to ponds, lakes and drainage ditches only where there is little or no outflow of water and which are totally under the control of

the user, in or on the commodities in Table 2 to Paragraph (a)(2). Compliance with the tolerance levels specified below is to be determined by measuring only diquat (6,7-dihydrodipyrido[1,2-*a*:2',1'-*c*]pyrazinediium).

TABLE 2 TO PARAGRAPH (a)(2)(i)

Commodity	Parts per million
Animal feed, nongrass, group 18, forage	0.2
Animal feed, nongrass, group 18, hay	0.2
Avocado	0.2
Berry and small fruit, group 13–07	0.05
Fish	2
Fruit, citrus, group 10–10	0.05
Fruit, pome, group 11–10	0.02
Fruit, stone, group 12–12	0.02
Grain, cereal, forage, fodder and straw, group 16	0.02
Grain, cereal, group 15	0.02
Grass, forage, fodder and hay, group 17	0.2
Herb and spice, group 19	0.2
Hop, dried cones	0.2
Nut, tree, group 14–12	0.02
Oilseeds, group 20	0.2
Shellfish	20
Sugarcane, cane	0.2
Vegetable, <i>Brassica</i> , leafy, group 5	0.05
Vegetable, bulb, group 3	0.02
Vegetable, cucurbit, group 9	0.02
Vegetable, foliage of legume, group 7	0.2
Vegetable, fruiting, group 8–10	0.05
Vegetable, leafy, except <i>Brassica</i> , group 4	0.05
Vegetable, leaves of root and tuber, group 2	0.02
Vegetable, legume, group 6	0.05
Vegetable, root and tuber, group 1, except potato	0.02

(ii) * * *

* * * * *

■ 4. Amend § 180.318 by:

■ a. Revising the section heading to read “MCPB; tolerance for residues.”; and

■ b. Revising and republishing paragraph (a).

The revisions read as follows:

§ 180.318 MCPB; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide MCPB, including its metabolites and degradates, in or on the commodities in Table 1 to Paragraph (a). Compliance with the tolerance levels specified in Table 1 to Paragraph (a) is to be

determined by measuring only the sum of MCPB, 4-(4-chloro-2-methylphenoxy)butanoic acid and MCPA, (4-chloro-2-methylphenoxy)acetic acid, calculated as the stoichiometric equivalent of MCPB, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Pea ¹	0.1
Pea, dry, seed	0.03
Pea, edible, podded	0.02
Pea, succulent, shelled	0.02
Peppermint, fresh leaves	0.2
Spearmint, fresh leaves	0.2

¹ This tolerance expires on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

* * * * *

■ 5. Amend § 180.328 by revising and republishing paragraph (a) to read as follows:

§ 180.328 Napropamide; tolerances for residues.

(a) *General.* Tolerances are established for residues of napropamide, including its metabolites and degradates, in or on the commodities in Table 1 to Paragraph (a). Compliance

with the tolerance levels specified in Table 1 to Paragraph (a) is to be determined by measuring only napropamide (*N,N*-diethyl-2-(1-naphthalenyloxy)propionamide) in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond, hulls	0.1
Asparagus	0.1
Basil	0.1
Berry, low growing, subgroup 13–07G	0.1
Brassica, leafy greens, subgroup 4–16B	0.1
Bushberry subgroup 13–07B	0.1
Caneberry subgroup 13–07A	0.1
Coffee, green bean	0.1
Cranberry	0.1
Fruit, small, vine climbing, subgroup 13–07D	0.1
Grape	0.1
Kiwifruit	0.1
Marjoram	0.1
Nut, tree, group 14–12	0.1
Peppermint, fresh leaves	0.1
Persimmon	0.1
Rhubarb	0.1
Rosemary	0.1
Savory, summer	0.1
Savory, winter	0.1
Spearmint, fresh leaves	0.1
Stalk and stem vegetable subgroup 22A	0.1
Strawberry	0.1
Sweet potato, roots	0.1
Vegetable, <i>brassica</i> , head and stem, group 5–16	0.1
Vegetable, <i>brassica</i> , leafy, group 5	0.1
Vegetable, fruiting, group 8–10	0.1

* * * * *

■ 6. Amend § 180.339 by revising and republishing the section to read as follows:

§ 180.339 MCPA; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide MCPA, including its metabolites and degradates, in or on the commodities in Table 1 to Paragraph (a). Compliance

with the tolerance levels specified in Table 1 to Paragraph (a) is to be determined by measuring only MCPA, 2-(4-chloro-2-methylphenoxy)acetic acid, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Alfalfa, forage	0.5
Alfalfa, hay	2
Barley, grain ¹	1
Barley, grain	0.2
Barley, hay	50
Barley, straw	50
Cattle, fat	0.2
Cattle, meat	0.1
Cattle, meat byproducts	3
Clover, forage	0.05
Clover, hay	0.05
Flax, seed ¹	0.1
Flax, seed	0.01
Goat, fat	0.2
Goat, meat	0.1
Goat, meat byproducts	3
Grain, aspirated fractions	3
Grass, forage, fodder and hay, group 17, forage	500
Grass, forage, fodder and hay, group 17, hay	200
Hog, fat ¹	0.1
Hog, meat ¹	0.1
Hog, meat byproducts ¹	0.1
Horse, fat	0.2
Horse, meat	0.1
Horse, meat byproducts	3
Lespedeza, forage	0.5
Lespedeza, hay	2
Milk ¹	0.1
Milk	0.04
Oat, forage	50
Oat, grain ¹	1
Oat, grain	0.2
Oat, hay ¹	115
Oat, hay	50
Oat, straw	50
Pea, dry ¹	0.1
Pea, dry, seed	0.01
Pea, field, hay	1.5
Pea, field, vines	0.6
Pea, succulent shelled	0.1
Rye, forage	50
Rye, grain ¹	1
Rye, grain	0.2
Rye, straw	50
Sheep, fat	0.2
Sheep, meat	0.1
Sheep, meat byproducts	3
Tea, dried	0.3
Trefoil, forage	0.5
Trefoil, hay	2
Vetch, forage	0.5
Vetch, hay	2
Wheat, forage	50
Wheat, grain ¹	1
Wheat, grain	0.2
Wheat, hay ¹	115
Wheat, hay	50
Wheat, straw	50
Wheatgrass, intermediate, forage	50
Wheatgrass, intermediate, grain	0.2
Wheatgrass, intermediate, hay	50
Wheatgrass, intermediate, straw	50

¹ This tolerance expires on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

(b) *Section 18 emergency exemptions.*
[Reserved].

(c) *Tolerances with regional registrations.* [Reserved].

(d) *Indirect or inadvertent residues.*
[Reserved].

* * * * *

■ 7. Amend § 180.409 by revising and republishing paragraph (a) to read as follows:

§ 180.409 Pirimiphos-methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide pirimiphos-methyl, including its metabolites and

degradates, in or on the commodities in Table 1 to Paragraph (a). Compliance with the tolerance levels specified in Table 1 to Paragraph (a) is to be determined by measuring only

pirimiphos-methyl (*O*-[2-(diethylamino)-6-methyl-4-pyrimidinyl]*O,O*-dimethyl phosphorothioate) in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Cattle, fat ¹	0.02
Cattle, fat	0.01
Cattle, meat byproducts ¹	0.02
Cattle, meat byproducts	0.01
Corn, field, grain ¹	8
Corn, field, grain	7
Corn, pop, grain ¹	8
Corn, pop, grain	7
Goat, fat ¹	0.02
Goat, fat	0.01
Goat, meat byproducts ¹	0.02
Goat, meat byproducts	0.01
Grain, aspirated fractions	20
Hog, fat ¹	0.02
Hog, fat	0.01
Hog, meat byproducts ¹	0.02
Hog, meat byproducts	0.01
Horse, fat ¹	0.02
Horse, fat	0.01
Horse, meat byproducts ¹	0.02
Horse, meat byproducts	0.01
Poultry, fat ¹	0.02
Poultry, fat	0.01
Sheep, fat ¹	0.02
Sheep, fat	0.01
Sheep, meat byproducts ¹	0.02
Sheep, meat byproducts	0.01
Sorghum, grain, grain ¹	8
Sorghum, grain, grain	7

¹ This tolerance expires on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

* * * * *

■ 8. Amend § 180.411 by:

- a. Revising and republishing paragraph (a);
- b. Revising the title of paragraph (b);
- c. Revising the introductory text in paragraph (c);
- d. Revising the entry “Coffee, bean” in the table in paragraph (c); and
- e. Adding an additional entry for “Coffee, bean” in the table in paragraph (c).

The revisions and addition read as follows:

§ 180.411 Fluazifop-P-butyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide fluazifop-P-butyl, butyl (2*R*)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, including its metabolites and degradates, in or on the commodities in

Table 1 to Paragraph (a). Compliance with the tolerance levels specified in Table 1 to Paragraph (a) is to be determined by measuring only those fluazifop-P-butyl residues convertible to fluazifop, butyl 2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Banana	0.01
Bean, dry, seed	40
Beans, dry, seed ¹	50
Beet, sugar, dried pulp	1
Beet, sugar, molasses	3.5
Beet, sugar, roots	0.5
Berry, low growing, subgroup 13–07G	3
Brassica, leafy greens, subgroup 4–16B	15
Bushberry subgroup 13–07B	0.3
Caneberry subgroup 13–07A	0.08
Carrot, roots	2
Cattle, fat	0.09
Cattle, meat	0.09
Cattle, meat byproducts	0.2

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Chives, dried leaves	40
Chives, fresh leaves	4
Citrus, dried pulp ¹	0.40
Citrus, dried pulp	0.06
Citrus, juice ¹	0.06
Citrus, oil ¹	30.0
Citrus, oil	0.05
Cotton, gin byproducts	1.5
Cotton, refined oil	1.3
Cotton, undelinted seed ¹	1
Cotton, undelinted seed	0.7
Egg ¹	0.05
Egg	0.03
Endive	6
Fruit, citrus, group 10–10	0.01
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.03
Fruit, stone, group 12–12	0.01
Goat, fat	0.09
Goat, meat	0.09
Goat, meat byproducts	0.2
Hog, fat	0.09
Hog, meat	0.09
Hog, meat byproducts	0.2
Horse, fat	0.09
Horse, meat	0.09
Horse, meat byproducts	0.2
Leaf petiole vegetable subgroup 22B	3
Lettuce, head	3
Lettuce, leaf	5
Milk	0.2
Nut, macadamia	0.1
Onion, bulb, subgroup 3–07A	0.5
Onion, green, subgroup 3–07B	1.5
Papaya	0.01
Peanut	1.5
Peanut, meal	2.2
Pecan	0.01
Pecans ¹	0.05
Poultry, fat	0.03
Poultry, meat	0.03
Poultry, meat byproducts	0.2
Potato ²	1
Potato, chips ²	2
Potato, granules/flakes ²	4
Sheep, fat	0.09
Sheep, meat	0.09
Sheep, meat byproducts	0.2
Soybean, seed	4
Vegetable, <i>Brassica</i> , head and stem, group 5–16	30
Vegetable, tuberous and corm, except potato, subgroup 1D	1.5

¹ This tolerance expires on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

² There are no U.S. registrations.

(b) *Section 18 emergency exemptions.*
[Reserved].

(c) *Tolerances with regional registrations.* Tolerances are established for residues of the herbicide fluzifop-P-butyl, butyl (2R)-2-[4-[[5-(trifluoromethyl)-2-

pyridinyl]oxy]phenoxy]propanoate, including its metabolites and degradates, in or on the commodities listed in Table 2 to Paragraph (c). Compliance with the tolerance levels specified in Table 2 to Paragraph (c) is to be determined by measuring only

those fluzifop-P-butyl residues convertible to fluzifop-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluzifop, in or on the commodity.

TABLE 2 TO PARAGRAPH (c)

Commodity	Parts per million
* * * * *	
Coffee, bean ¹	0.1
Coffee, bean	0.01

TABLE 2 TO PARAGRAPH (c)—Continued

Commodity	Parts per million
* * * * *	*

¹ This tolerance expires on [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

* * * * *

■ 9. Amend § 180.458 by:

■ a. Adding the heading “Table 1 to Paragraph (a)” to the table in paragraph (a); and

■ b. Revising and republishing the table in paragraph (a).

The revisions and additions read as follows:

§ 180.458 Clethodim; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Alfalfa, forage	6
Alfalfa, hay	10
Almond, hulls	0.2
Artichoke, globe	1.2
Berry, low growing, subgroup 13–07G, except cranberry	3
Beet, sugar, molasses	1
Beet, sugar, roots	0.2
Beet, sugar, tops	1
Brassica, leafy, greens, subgroup 4–16B	3
Bushberry subgroup 13–07B	0.2
Caneberry subgroup 13–07A	0.3
Canola, meal	1
Cattle, fat	0.2
Cattle, meat	0.2
Cattle, meat byproducts	0.2
Clover, forage	10
Clover, hay	20
Corn, field, forage	0.2
Corn, field, grain	0.2
Corn, field, stover	0.2
Cotton, meal	2
Cottonseed subgroup 20C	1
Cranberry	0.5
Egg	0.2
Flax, meal	1
Fruit, pome, group 11–10	0.2
Fruit, stone, group 12–12	0.2
Goat, fat	0.2
Goat, meat	0.2
Goat, meat byproducts	0.2
Herb subgroup 19A	12
Hog, fat	0.2
Hog, meat	0.2
Hog, meat byproducts	0.2
Hop, dried cones	0.5
Horse, fat	0.2
Horse, meat	0.2
Horse, meat byproducts	0.2
Leaf petiole vegetable subgroup 22B	0.6
Leafy greens subgroup 4–16A	2
Melon subgroup 9A	2
Milk	0.05
Nut, tree, group 14–12	0.2
Okra	1.5
Onion, bulb, subgroup 3–07A	0.5
Onion, green, subgroup 3–07B	2
Peanut	5
Peanut, hay	3
Peanut, meal	5
Peppermint, tops	5
Potato, granules/flakes	2
Poultry, fat	0.2
Poultry, meat	0.2
Poultry, meat byproducts	0.2
Radish, tops	0.7
Rapeseed subgroup 20A	0.6

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Safflower, meal	10
Sheep, fat	0.2
Sheep, meat	0.2
Sheep, meat byproducts	0.2
Soybean	10
Spearmint, tops	5
Squash/cucumber subgroup 9B	0.5
Stalk and stem vegetable subgroup 22A	1.7
Stevia, dried leaves	12
Sunflower, meal	10
Sunflower subgroup 20B	5
Vegetable, <i>brassica</i> , head and stem, group 5–16	3
Vegetable, fruiting, group 8–10, except okra	1
Vegetable, legume, group 6, except soybean	3.5
Vegetable, root, except sugar beet, subgroup 1B	1
Vegetable, tuberous and corm, subgroup 1C	1

* * * * *

■ 10. Amend § 180.572 by:

■ a. Revising and republishing paragraph (a)(1);

■ b. Revising the introductory text in paragraph (a)(2);

■ c. Adding the table heading “Table 2 to Paragraph (a)(2)” to the table in paragraph (a)(2);

■ d. Revising the introductory text in paragraph (c); and

■ e. Add the table heading “Table 3 to Paragraph (c)” to the table in paragraph (c).

The revisions and additions read as follows:

§ 180.572 Bifenazate; tolerances for residues.(a) *General.*

(1) Tolerances are established for residues of the insecticide bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate),

including its metabolites and degradates, in or on the commodities listed in Table 1 to Paragraph (a)(1). Compliance with the tolerance levels specified in Table 1 to Paragraph (a)(1) is to be determined by measuring only the sum of bifenazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, (calculated as the stoichiometric equivalent of bifenazate) in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Acerola	0.9
Almond, hulls	15
Apple, wet pomace	1.2
Atemoya	1.6
Avocado	7
Bean, dry, seed	0.6
Berry, low-growing, subgroup 13–07G	1.5
Biriba	1.6
Caneberry subgroup 13–07A	5
Canistel	7
Cattle, fat	0.1
Cherimoya	1.6
Cotton, gin byproducts	35
Cotton, undelinted seed	0.75
Custard apple	1.6
Feijoa	0.9
Fruit, pome, group 11–10	0.7
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	1
Fruit, stone, group 12, except plum	2.5
Goat, fat	0.1
Grape, raisin	1.2
Guava	0.9
Herb subgroup 19A, except chervil and chive	300
Hog, fat	0.1
Hop, dried cones	15
Horse, fat	0.1
llama	1.6
Jaboticaba	0.9
Longan	5
Lychee	5
Mango	7
Nut, tree, group 14	0.2
Papaya	7
Passionfruit	0.9

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
Pea and bean, succulent shelled, subgroup 6B	0.7
Peppermint, fresh leaves	25
Pistachio	0.2
Plum	0.2
Pulasan	5
Rambutan	5
Sapodilla	7
Sapote, black	7
Sapote, mamey	7
Sheep, fat	0.1
Soursop	1.6
Soybean, vegetable, succulent shelled	0.7
Spanish lime	5
Spearmint, fresh leaves	25
Star apple	7
Starfruit	0.9
Strawberry	1.5
Sugar apple	1.6
Vegetable, cucurbit, group 9	0.75
Vegetable, fruiting, group 8–10	4
Vegetable, legume, edible-podded, subgroup 6A	6
Vegetable, tuberous and corm, subgroup 1C	0.1
Wax jambu	0.9

(2) Tolerances are established for residues of the insecticide bifentazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl) hydrazinecarboxylate), including its metabolites and degradates, in or on the commodities

listed in Table 2 to Paragraph (a)(2). Compliance with the tolerance levels specified in Table 2 to Paragraph (a)(2) is to be determined by measuring only the sum of bifentazate and its metabolites diazinecarboxylic acid, 2-(4-

methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester; 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (calculated as the stoichiometric equivalent of bifentazate) in or on the commodity.

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
* * * * *	*

(b) * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(l), are established for residues of the insecticide bifentazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-

yl)hydrazinecarboxylate), including its metabolites and degradates, in or on the commodities in Table 3 to Paragraph (c). Compliance with the tolerance levels specified in Table 3 to Paragraph (c) is to be determined by measuring only the

sum of bifentazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, (calculated as the stoichiometric equivalent of bifentazate) in or on the commodity.

TABLE 3 TO PARAGRAPH (c)

Commodity	Parts per million
* * * * *	*

* * * * *

■ 11. Amend § 180.620 by revising and republishing paragraph (a) to read as follows:

§ 180.620 Etofenprox; tolerances for residues.

(a) *General.*

(1) Tolerances are established for residues of the insecticide etofenprox, including its metabolites and degradates, in or on the commodities in Table 1 to Paragraph (a)(1). Compliance with the tolerance levels specified in Table 1 to Paragraph (a)(1) is to be

determined by measuring only etofenprox, 1-[[2-(4-ethoxyphenyl)-2-methylpropoxy]methyl]-3-phenoxybenzene in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Cattle, fat	10
Cattle, meat	0.5
Cattle, meat byproducts	10
Egg	0.4
Fungi, edible, group 21	3
Goat, fat	10
Goat, meat	0.5
Goat, meat byproducts	10
Hog, fat	4
Hog, meat	0.5
Hog, meat byproducts	4
Horse, fat	10
Horse, meat	0.5
Horse, meat byproducts	10
Milk	0.6
Poultry, fat	1
Poultry, meat	0.01
Poultry, meat byproducts	1
Rice, grain	0.01
Sheep, fat	10
Sheep, meat	0.5
Sheep, meat byproducts	10

(2) A tolerance of 5 parts per million is established for residues of the insecticide etofenprox, including its metabolites and degradates, in or on all food/feed items (other than those covered by a higher tolerance as a result of use on growing crop(s)) when etofenprox is used as a wide-area mosquito adulticide. Compliance with the tolerance levels specified in this paragraph (a)(2) is to be determined by measuring only etofenprox, 1-[[2-(4-ethoxyphenyl)-2-methylpropoxy]methyl]-3-phenoxybenzene in or on the food/feed item.

* * * * *

[FR Doc. 2025-22519 Filed 12-10-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 248

[EPA-R06-RCRA-2025-3129; FRL-13097-01-R6]

No-Migration Variance From Land Disposal Restrictions for Clean Harbors Lone Mountain, Oklahoma

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposal to grant.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to grant, with conditions, no-migration variances for nine categories/groups of wastes, containing up to a combined 100 temporary disposal units (“put piles”) at any one time, from the Resource Conservation and Recovery Act (RCRA)

Land Disposal Restrictions (LDR) standards at Clean Harbors’ Lone Mountain (Clean Harbors) commercial treatment, storage and disposal facility (TSDF) in Waynoka, Oklahoma. These variances will allow Clean Harbors to temporarily store treated hazardous wastes that are awaiting LDR compliance verification in put piles within its Subtitle C (hazardous waste) landfill. The petitioner demonstrated, to a reasonable degree of certainty, that there will be no migration of hazardous constituents from the put piles for as long as the wastes remain hazardous. Additionally, once LDR compliance is verified, the put piles will be disposed within the onsite RCRA hazardous waste landfill area and will be subject to the conditions set out in the Compliance Monitoring Plan section of this document.

DATES: Comments must be received on or before January 12, 2026.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-R06-RCRA-2025-3129, by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov> (our preferred method). Follow the online instructions for submitting comments.
- *Email:* Mustafa.golam@epa.gov. Include Docket ID No. EPA-R06-RCRA-2025-3129 in the subject line of the message.
- *Courier/Hand Delivery:* Golam Mustafa, Land, Chemicals and Redevelopment Division, EPA Region 6, 1201 Elm Street, Dallas, Texas 75270, Mail Code: R6LCR-RP, telephone number: (214) 665-6576. Courier or hand deliveries are only accepted

during the Regional Office’s normal hours of operation. The public is advised to call in advance to verify the business hours. Special arrangements should be made of deliveries of boxed information.

- *Instructions:* All submissions must include the Docket ID No. EPA-R06-RCRA-2025-3129 for this proposed approval. Comments received may be posted without change to <https://www.regulations.gov>, including any personal information provided. For detailed instructions on sending comments and additional information, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Golam Mustafa, Land, Chemicals and Redevelopment Division, EPA Region 6, 1201 Elm Street, Dallas, Texas 75270, Mail Code: R6LCR-RP, telephone number: (214) 665-6576; and email: Mustafa.golam@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Docket

EPA has established a docket for this action under Docket ID No. EPA-R06-RCRA-2025-3129. All documents in the docket are listed in the <https://www.regulations.gov> index.

B. Written Comments

Submit your comments, identified by Docket ID No. EPA-R06-RCRA-2025-3129, at <https://www.regulations.gov> (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments

cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

C. Submitting CBI

Do not submit information that you consider to be CBI electronically through <https://www.regulations.gov> or email. Send or deliver information identified as CBI to only the following address: RCRA Document Control Officer, La Gayla Johnson, Office of Regional Counsel, EPA Region 6, 1201 Elm Street, Dallas, Texas 75270, Mail Code: R06-ORC-DRCGLCB-FIAB; telephone number: (214) 665-7517; and email: Johnson.lagayla@epa.gov.

Attn: Docket ID No. EPA-R06-RCRA-2025-3129.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM to clearly indicate that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) Part 2.

II. General Information

A. Does this document apply to me?

This action applies only to Clean Harbors' Lone Mountain facility (Clean

Harbors) located in Waynoka, Oklahoma.

B. What action is the Agency taking?

On November 29, 2023, Clean Harbors submitted a no-migration variance (NMV) petition, in accordance with 40 CFR 268.6, seeking an exemption from the Land Disposal Restrictions (LDR) prohibition on land placement of hazardous waste that does not meet the prescribed LDR standards of 40 CFR 268.40 for temporary piles of treated waste, referred to as put piles, placed within the boundary of a RCRA-permitted hazardous waste landfill. Because the petition demonstrated to a reasonable degree of certainty that, for as long as the wastes remain hazardous, there will be no migration of hazardous constituents from the put piles, EPA proposes to grant, with conditions, Clean Harbors' variance from the LDR prohibition for up to a combined 100 put piles at any one time for the nine categories/groups of wastes identified in the Waste Characterization section of this proposal. If granted, the term of this NMV shall be no longer than the term of the RCRA Subtitle C permit for the permitted landfill.

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

Sections 3004(d) through (g) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6294(d)–(g), prohibit the land disposal of hazardous wastes unless such wastes meet the LDR treatment standards ("treatment standards") established by EPA ("Agency").

However, RCRA 3004(d)(1),¹ and its implementing regulations found at 40 CFR 268.6, provide an option for land disposal of hazardous waste that does not meet the applicable treatment standards where EPA has approved an NMV petition. Specifically, 40 CFR 268.6(a) describes the components that a demonstration of no migration must address; 268.6(b) specifies certain criteria that must be satisfied for that demonstration, and 268.6(c) describes the monitoring program that will be used to verify that the conditions of the NMV are being met.

¹ RCRA 3004(d)(1)(c) states: ". . . For the purposes of this paragraph, a method of land disposal may not be determined to be protective of human health and the environment for a hazardous waste referred to in paragraph (2) . . . unless, upon application by an interested person, it has been demonstrated to the Administrator, to a reasonable degree of certainty, that there will be no migration of hazardous constituents from the disposal unit or injection zone for as long as the wastes remain hazardous."

III. Background

A. No-Migration Variances and Guidance

An NMV is a formal decision that can be rendered by the EPA in response to a petition filed with the Agency to allow land disposal within a particular disposal unit of specific prohibited waste when it has been demonstrated, "to a reasonable degree of certainty, that there will be no migration of hazardous constituents from the disposal unit . . . for as long as the wastes remain hazardous."² It must be demonstrated, to a reasonable degree of certainty, that hazardous constituents will not exceed Agency-approved human health-based levels (or environmentally protective levels, if they are appropriate) beyond the boundary of the disposal unit.³ In most cases, the disposal unit boundary is defined as the outermost limit of engineered components.⁴

Approval of an NMV petition is delegated to the EPA Regional Administrator for the EPA Region in which the waste management unit is located. States are not authorized to implement the NMV authority; however, the EPA consulted with Oklahoma prior to proposing to grant this NMV. The final decision will be published in the **Federal Register**. If granted, the term of an NMV may be no longer than the term of the existing RCRA Subtitle C permit for the landfill. Any petitions to renew an NMV must undergo notice and comment procedures. An NMV that has been issued can be revoked for cause, including any migration of hazardous constituents.

The regulatory requirements for an NMV under the RCRA LDRs were codified in 40 CFR 268.6 in 1986,⁵ and EPA issued guidance on these requirements in 1992. The 1992 guidance is applicable to landfills, surface impoundments, and waste piles. While the 1992 guidance acknowledged temporary placement of waste under an approved NMV, it did not address the issue of temporary placement of treated wastes in put piles while awaiting LDR compliance verification (or retreatment) within the boundary of a RCRA-permitted Subtitle C (hazardous waste) landfill. After a put pile is confirmed to meet the LDR standards, it is moved to the "working face"⁶ of the landfill for

² See 51 FR at 40578, November 7, 1986.

³ 57 FR 35941, August 11, 1992.

⁴ *Id.*

⁵ 51 FR 40572, November 7, 1986.

⁶ The working face of a landfill is the area within a specific cell where waste is currently being placed and compacted. It is the designated section where

final disposal; however, if there is an exceedance of an LDR standard, the put pile is returned to the treatment process for further treatment.

Hazardous waste in a put pile either must meet the LDR standards or have an approved NMV. To provide guidance specific to this circumstance, the EPA issued “*Information for Petitioners Seeking a No-Migration Variance Under the RCRA Land Disposal Restrictions for Temporary Placement of Treated Hazardous Waste Within a Permitted Subtitle C Landfill*” (88 FR 10894, February 22, 2023). This information (i.e., the “2023 Guidance”) is posted online at <https://rcrapublic.epa.gov/files/14952.pdf>.

The 2023 Guidance acknowledges the need for unique considerations when a no migration demonstration for put piles occurs within a Subtitle C landfill prior to permanent disposal in the landfill. “EPA expects that petitioners will be able to take advantage of existing facility information (e.g., existing monitoring, inspections, engineered barriers, waste analyses), where appropriate, as part of any demonstration For example, the use of temporary barriers, such as plastic covers above and below the piles; visual monitoring, prompt responses to possible releases, and good housekeeping practices that ensure the treated waste remains in the pile during the temporary storage period would be elements to consider. Attributes of the permitted landfill cell (e.g., design, existing controls, monitoring) in which the pile or piles are located should also be considered to the extent that they support the demonstration criteria being applied to the piles themselves.”

40 CFR 268.6(e) acknowledges the potential for post-approval changes in conditions at the no migration unit(s) and/or the environment around the no migration unit(s). For the purpose of these put pile variances, all changes that significantly depart from the conditions described in the variances and affect the potential for migration of hazardous constituents from the put piles must be reported to the Region 6 Administrator as follows:

1. If Clean Harbors plans to make changes to the unit(s)’ design, construction, or operation, such a change must be proposed, in writing, and include a demonstration to the Region 6 Administrator at least 30 days prior to making the change. The Region 6 Administrator will determine whether the proposed change invalidates the terms of the approved variance and will

determine the appropriate response. A proposed change must first be approved by the Region 6 Administrator before taking any action.

2. If Clean Harbors discovers a site condition in the petition that does not occur as modeled or predicted, this change must be reported, in writing, to the Region 6 Administrator within 10 days of discovery. The Region 6 Administrator will determine whether the reported change from the terms of the approved variance requires further action.

B. Clean Harbors’ Petition for No Migration Variances

On November 29, 2023, Clean Harbors’ Lone Mountain facility in Waynoka, Oklahoma, submitted an NMV petition to the EPA seeking an exemption from the LDR prohibition on placing hazardous waste on the ground, if that waste does not meet the prescribed LDR standards of 40 CFR 268.40, by demonstrating that for as long as the waste remains hazardous, there will be no migration of hazardous constituents from the disposal units. Clean Harbors’ no migration demonstration applies to nine categories/groups of wastes stored in up to a combined 100 put piles at any one time located within the facility’s Subtitle C Landfill cell, known as “Cell 15.” If Clean Harbors anticipates needing to exceed 100 put piles at any one time, it must request approval from EPA Region 6 prior to creating new put piles. Clean Harbors also requested that this variance proactively apply to future put piles of identical waste characteristics that would be staged in a future proposed and permitted Subtitle C landfill cell, known as “Cell 16.”

While this Notice of Proposal to Grant applies only to those put piles placed within existing Landfill Cell 15, upon permit approval of Cell 16, Clean Harbors may submit to the Agency, an addendum to this petition to expand this NMV and all of its conditions and requirements, for the put piles located within the new landfill cell if:

1. Clean Harbors is in compliance with the approved NMV,
2. The new landfill cell uses the same disposal unit engineered controls (e.g., landfill cell interior berms for run-on and run-off control) as approved in this variance,
3. The duration of temporary placement remains at six (6) months or less and complies with the conditions established herein,
4. The waste categories remain the same, and

5. The monitoring program (e.g., groundwater monitoring) is expanded to include the new landfill cell.

In response to EPA requests following the original November 2023 submission, Clean Harbors provided supplemental information for the Agency’s evaluation of Clean Harbors’ no-migration demonstration. The original petition and associated responses to Agency information requests (together referred to as “the petition”) can be found in the docket (EPA–R06–RCRA–2025–3129).

Clean Harbors’ petition includes the following components: (a) facility description, (b) site characterization/unit description, (c) identification and characterization of the affected wastes, (d) disposal unit engineered controls, (e) duration of temporary staging, (f) uncertainty analysis, (g) monitoring program, and (h) documented compliance with other laws. These are discussed below.

IV. Basis for the EPA’s Proposed Determination

A. Components of the Petition

1. Facility Description

Clean Harbors’ Lone Mountain facility (EPA ID Number: OKD065438376) is located 14 miles southeast of the town of Waynoka. The mean annual precipitation in the region is approximately 28 inches and 11 inches for rain and snow, respectively. The permitted facility, which covers an area of approximately 560 acres, is expected to be in operation for more than ten years from the date of this notice. A RCRA Part B Permit (hazardous waste permit) was issued by the Oklahoma Department of Environmental Quality (ODEQ). The currently approved RCRA permit was signed on April 2, 2011, for a 10-year term, and then administratively continued.

Clean Harbors’ hazardous waste permit authorizes the facility to manage liquid, solid, or semisolid hazardous waste and non-hazardous industrial waste. The facility has 15 hazardous waste landfill cells. Waste treatment services provided at the facility include solidification, stabilization, and macro/microencapsulation of hazardous waste. Solid, liquid, and sludge wastes are accepted in containerized or bulk loads (e.g., roll-off containers); however, the wastes that would be covered under this NMV are generally received as bulk loads.

2. Site Characterization/Unit Description

All put piles are temporarily stored in Landfill Cell 15 until LDR compliance has been confirmed. LDR-compliant

waste is unloaded, and daily cover is applied at the end of each working day.

piles are then moved to the working face of Landfill Cell 15 after verification of successful treatment. Put piles that fail to meet LDR standards are retreated and subsequently returned as a put pile to landfill Cell 15. This variance, if approved, will apply to put piles of the nine waste categories/groups and not to Landfill Cell 15. As stated in the 2023 guidance, where multiple piles contain the same or similar wastes, the petition can address these units as a group where such piles are effectively being managed as a single unit. As such, the Agency proposes that this NMV apply to the put piles containing the nine categories/groups described in the Waste Characterization section below; however, each put pile within each category/group will be assigned its own unit boundary.

Each put pile measuring approximately 35-cubic yards is placed on a polyethylene barrier sheet (20-millimeter (mil) minimum thickness) within landfill Cell 15. Because wastes are treated and presumed to meet LDR standards prior to placement in Landfill Cell 15, and storage in the petitioned units is temporary, the Agency herein proposes to establish unit boundaries (*i.e.*, points of compliance for no-migration purposes) for each of the put piles to account for existing landfill controls and appropriate deviations from the waste pile liner design standards of 40 CFR 264.251.

The Agency proposes that each put pile boundary extend vertically one inch below the 20-mil thick polyethylene liner and laterally one foot short of the outermost surface edges of the 20-mil thick polyethylene liner. Air dispersion compliance will be demonstrated at the outer thickness of the Posi-Shell® liner, described in the *Covers* section, below.

3. Waste Characterization

In accordance with 40 CFR 268.6(a)(1), Clean Harbors indicated that the following nine categories/groups of hazardous wastes and their underlying hazardous constituents (UHCs) found at 40 CFR 268.48 could be temporarily placed in the put piles in Landfill Cell 15 after treatment to meet LDR standards: (1) general metals (D001, D002, D004 through D011, K046, F006, F019, F039 and U051); (2) cyanide/sulfide with metals (D001 through D011, F006 through F012, F019, K052 and P106); (3) cyanide/sulfide (D001 through D011, F006 through F012, F019, P106 and U135); (4) high-chromium wastes (D001 through D011, F006 and F019); (5) high arsenic wastes (D004, D005, D006, D008, D009, D010, P011 and P012); (6) oxidizers with metals

(D001, D002, D003, D005, D007, D008, D011 and K088); (7) acids with metals (D001, D002, D004 through D011, K061, K062, F006, U204 and U134); (8) bases with metals (D002 through D011, D028, K061, F006 through F008, F019, F035, P106, U144, U151, U188 and U210); and (9) waste certified by generators to meet all or some LDR treatment standards (referenced as CBPR by Clean Harbors; codes vary and include K052, F020 and U210).

Appropriate and adequate sampling and analysis of both incoming hazardous wastes and treated hazardous wastes are essential to precise waste characterization for accurate creation of treatment protocols or “recipes,” and ultimately, confirmation of treatment effectiveness/LDR compliance. These are discussed in Clean Harbors’ Waste Analysis Plan (WAP), approved by ODEQ in February 2010, and included in the docket for this notice and available, at the time of this notice, on the ODEQ website at <https://oklahoma.gov/deq/divisions/land-protection/waste-management/waste-management-facilities/clean-harbors-lone.html>.

The following generalized summary of waste characterization (also referred to as a fingerprint analysis), waste treatment, and verification of effective treatment/LDR compliance is extracted from the Clean Harbors’ WAP for incoming bulk loads of hazardous waste. Incoming bulk wastes undergo a fingerprint analysis that includes eight basic screening procedures (physical appearance, pH, specific gravity, reactive cyanides, reactive sulfides, water reactivity, ignitability, and halogen organic compound content) to provide a general waste characterization for appropriate treatment, storage, or disposal. Additional analyses are performed, as appropriate, to ensure adequate waste characterization. After characterization, bulk hazardous wastes are treated in stabilization tanks to reduce the hazardousness of the wastes, make them safer to dispose, and/or reduce the volume of the wastes. Waste treatment processes include stabilization, blending, and the LDR technology standards for chemical oxidation (CHOXD), neutralization (NEUTR), chromium or chemical reduction (CHRED), and deactivation (DEACT). If stabilization is performed, any combination of the following reagents may be used to prevent leaching: cement kiln dust, water, calcium polysulfide, lime, caustic, fly ash, portland cement, clay, ferrous sulfate, sodium hypochlorite, oxidizer soak, and acid.

Post-treatment, samples are collected directly from the stabilization tank and a paint filter test is performed to ensure that all free liquids have chemically reacted, and the mixture is suitable for disposal in the landfill. Treated batches are subsequently sampled and analyzed for LDR compliance pursuant to the WAP. The treated wastes are then moved to a put pile within a temporary staging area in Landfill Cell 15 while curing and awaiting LDR compliance confirmatory sampling. Section 4.2.2 of the WAP defines how sampling of the waste piles for LDR compliance must be performed.

4. Uncertainty Analysis

40 CFR 268.6(b)(5) requires the petitioner to include an analysis to identify and quantify any aspects of the demonstration that contribute significantly to uncertainty. The analysis must include an evaluation of the consequences of predictable future events, including, but not limited to, earthquakes, floods, severe storm events, droughts, or other natural phenomena. The Agency accepts Clean Harbors’ uncertainty analysis as presented in the petition located in the docket.

5. No-Migration Demonstration

The bases for EPA’s proposed conclusion that Clean Harbors demonstrated to a reasonable degree of certainty that no hazardous constituents will migrate from the put piles for as long as the wastes remain hazardous are discussed in this section. Although wastes are treated with the intent of meeting the RCRA LDR standards prior to being placed in put piles, the conditions established in this NMV are a safeguard to ensure that if a put pile does not meet LDR standards and must be retreated, hazardous constituents will not migrate beyond the boundary of the put pile. This NMV is conditioned upon the temporary nature of the put piles within Landfill Cell 15 and is intended for situations where the put piles are used as part of an overall strategy to confirm consistent and compliant treatment that meets the applicable LDR treatment standards.

Where reasonable, the Agency took into consideration existing landfill design and operating requirements (40 CFR 264.301) that include run-on and run-off controls to prevent the migration of hazardous constituents beyond the designated unit boundary. Additional information including monitoring data and discussions regarding the temporary nature of these put piles (*i.e.*, duration of storage), testing for verification of treatment effectiveness, retreatment

protocols and engineered controls, as referenced in this section, is available in the petition or supplemental information in the RCRA regulatory docket for this document.

i. Treatment Effectiveness

As required by 40 CFR 268.6(a)(2), Clean Harbors characterizes the subject wastes, post-treatment, to determine if LDR standards were met. Specifics on sampling protocols can be found in the WAP. Analytical data were provided in non-sequential order in tables A-2 (inorganic constituents) and A-3 (organic constituents) for January 2022 through October 2023 for each category of hazardous waste identified in the petition in the docket for today's notice. Analyses were performed for compliance with the 40 CFR 268.48 Universal Treatment Standards (UTS) for all UHCs, including antimony (Sb), arsenic (As), barium (Ba), beryllium (Be), cadmium (Cd), chromium (Cr), lead (Pb), nickel (Ni), selenium (Se), silver (Ag), thallium (Tl), vanadium (V), zinc (Zn), mercury (Hg), sulfides (S), and cyanides (CN).

Clean Harbors provided analytical data indicating that approximately 98–99% of all wastes treated met the LDR standards following the first treatment procedure, without the need for additional treatment. They reported that in 2022, of the 770 put piles treated and analyzed, 762 met post-treatment LDR standards, resulting in a net “pass rate” of 98.9%. In 2023, 519 put piles were treated and analyzed and 509 met post-treatment LDR standards (98.1%).

The sampling methodology used by Clean Harbors to verify compliance with LDR standards for the wastes post-treatment was deemed adequate by ODEQ through the issuance of the existing RCRA Part B permit, including the WAP. Clean Harbors' sampling strategy for confirmation of LDR compliance is discussed in Appendix A of Clean Harbors' September 10, 2024, Response to Request for Additional Information included in the docket. Clean Harbors reported in the petition that the current “pass rate” for temporarily staged put piles exceeds 98%, demonstrating that these put piles do not routinely receive treated wastes that do not meet applicable LDR standards, thereby supporting the “temporary” nature of storage for each waste category. The Agency herein relies on ODEQ's approval of the LDR confirmatory sampling methodology in the WAP and Clean Harbors' presentation of historical analytical data to conclude that Clean Harbors has provided sufficient waste characterization information in its

petition to support the conclusion of treatment effectiveness.

ii. Duration of Temporary Storage

When the LDR standard for a put pile is confirmed to “pass,” it is moved to the working face of Landfill Cell 15 for final disposal generally within 45 days⁷ of initial placement of the put pile in the temporary storage area. LDR verification sampling must conform to the WAP, and a generalized procedure for this verification process is discussed in Appendix A of Clean Harbors' September 10, 2024, Response to Request for Additional Information included in the docket.

The end result of a multi-stage process for sampling and retreating is that a few put piles may remain temporarily staged even after an LDR “fail” if the analytical data indicate additional curing time is appropriate. Clean Harbors requested up to twelve (12) months duration for temporary staging of a put pile to account for the retreatment and curing process; however, in Clean Harbors' August 4, 2025 Response to EPA's May 2025 Review Comments on the Response to Request for Additional Information located in the docket, the state agreed that exceedances of six (6) months of temporary staging have not occurred and are unlikely and as such agreed that six (6) months are a sufficient duration for temporary staging of put piles. The Agency concludes that Clean Harbors has provided sufficient analytical data to justify a six (6)-month duration for storage of a put pile from the time the pile is first staged until final disposal in the working face of the Landfill Cell 15. If an issue arises where greater than 180 days temporary staging of a put pile is necessary, ODEQ may issue such an extension, if warranted.

iii. Disposal Unit Engineered Controls

This section describes existing and proposed put pile liners, put pile covers, and run-off/run-on controls. Man-made barriers or engineered systems (e.g., liner systems) alone generally will not meet the “no migration” standard. In the case of put piles, however, the containment of hazardous waste within engineered barriers is considered in making the “no migration” demonstration for waste awaiting the results of verification sampling after treatment, provided that wastes are to be removed after a reasonably short storage period that is conservatively projected to be well

⁷ May take up to 90 days in cases when specialized compliance tests are required or laboratory backup delays LDR compliance confirmation data.

before the failure of the engineered barrier system.⁸ Because Clean Harbors' temporary storage for each put pile must not exceed six (6) months, and the lifespan of the engineered barriers described below extends into multiple decades with appropriate operational controls to prevent rips or tears, excluding the Posi-Shell® system, which has an observed lifespan of up to 2 (two) years, the Agency concurs that Clean Harbors' use of the barriers described below will prevent migration of hazardous constituents via infiltration, lateral migration (e.g., erosion, surface water interaction or movement of infiltration), and air dispersion/particulate loss.

The put piles will be encapsulated (liner below and Posi-Shell® atop) by the unit-specific engineered barriers discussed below to prevent migration of hazardous constituents beyond the put pile boundary. These unit-specific barriers are distinct from the existing landfill controls for Landfill Cell 15, such as run-on and run-off controls, that were considered in the overall prevention of migration of hazardous constituents.

Liners

A liner of at least 20-mil thickness polyethylene geomembrane must be used as a barrier to vertical and lateral migration for the put piles. The liner beneath the pile will provide a barrier for vertical migration. The Agency agrees that a minimum of 20-mil thickness barrier is sufficient for this temporary application that will last six (6) months or less. Because the layout of the put piles is accommodated within the standard width of a prefabricated geomembrane roll, the liner must be one solid piece without the need for welding of seams. The lack of seams lends to additional assurance that hazardous constituents will not migrate through a broken seam. The Agency concludes that a liner of at least 20-mil thickness, in conjunction with the inspection program described in the Compliance Monitoring Program section, is appropriate for use in this temporary disposal scenario; however, there must always be at least 12 inches of the liner visible on all sides of the put pile to prevent potential horizontal migration of the waste from the edge of the liner.

Covers

Clean Harbors will use a Posi-Shell® cover to act as a rain and wind barrier for put piles, to ensure no migration of

⁸ No Migration Variances to the Hazardous Waste Land Disposal Prohibitions: A Guidance Manual for Petitioners, at 4, EPA Office of Solid Waste, July 1992, EPA-530-R92-023.

hazardous constituents from the put piles occurs via lateral migration or air pathways. Posi-Shell® is a spray-applied mortar applied as a coating to the surface of the put piles, with a minimum cover thickness of 3/8-inch. Because Posi-Shell® is a mortar, curing is necessary to allow it to harden. Curing typically occurs within 12–24 hours in dry weather, forming a relatively impermeable thin layer of durable, hardened mortar. However, if moderate to heavy rainfall occurs unexpectedly or is imminent, sustained freezing temperatures are expected for more than one day, or the temperature falls below 30 °F, the Posi-Shell® will not harden sufficiently. During these times of inclement weather, Clean Harbors must temporarily cover the put piles with polyethylene sheeting of at least 20-mil thickness, anchored with sandbags around its edges, until the adverse weather conditions abate, and the Posi-Shell® coating can be applied. Within twenty-four (24) hours of weather conditions amenable to Posi-Shell® application, Clean Harbors must apply the coating.

To ensure Posi-Shell® is appropriate for put pile covering, the Agency reviewed several case studies provided by Clean Harbors where Posi-Shell® was demonstrated to prevent erosion, air dispersion, infiltration of rainwater, and overall migration of wastes. Table 2 in the petition located in the docket summarizes these case studies.

The Agency concludes that Posi-Shell®, or a minimum 20-mil polyethylene sheeting cover under the limited inclement weather circumstances described above, will serve as an appropriate barrier to protect the put pile from wind dispersion, erosion, and rainwater infiltration.

Run-On/Run-Off Controls

Before placing the put piles in the temporary storage area of Landfill Cell 15, Clean Harbors must grade the temporary storage area where put piles will be located. The grading must be relatively flat but with a slight positive grade to preclude ponding of water on the polyethylene liners. Clean Harbors must construct and/or maintain a diversion berm of sufficient height/width to direct run-on away from the put pile upgradient of the staging area. As Landfill Cell 15 is filled, if the waste grade changes adjacent to the put pile temporary storage area, additional diversion berms must be added, if necessary to divert stormwater run-on and run-off to isolate the staging area on the working face of Landfill Cell 15. To control run-off, in addition to the Posi-shell® coating, Clean Harbors will

include, at a minimum, ditches around the inside perimeter of Landfill Cell 15 embankments and will remove ponded stormwater that accumulates on top of the put piles. In combination with General Surrounding Area Engineered Controls described below, these controls must be constructed and operated to contain at least the water volume of a 24-hour, 25-year storm event or greater if required by the permit.

iv. General Surrounding Area Engineered Controls

All put piles are temporarily stored in a designated area of Landfill Cell 15 until LDR compliance has been confirmed. The put piles are then moved to the working face of Landfill Cell 15. Landfill Cell 15's existing liner system bolsters prevention of vertical or horizontal migration of hazardous constituents. The liner system consists of: (1) a bottom 60-mil textured high density polyethylene (HDPE) liner atop a 3-foot-thick compacted clay layer with a hydraulic conductivity of less than 1.7×10^{-7} cm/sec; (2) a double-sided geocomposite leak detection system drainage layer; (3) a top composite liner consisting of geosynthetic clay between two 60-mil textured HDPE liners; (4) a double-sided geocomposite leak collection system; and (5) a 2-foot thick cover layer.

v. Groundwater Monitoring

Clean Harbors has a groundwater monitoring well network at the facility that currently includes five (5) upgradient monitoring wells and 39 downgradient monitoring wells. In particular, Landfill Cell 15 has five (5) downgradient monitoring wells in its proximity. The wells are monitored semi-annually under the Groundwater Detection Monitoring program as required by the facility's RCRA Part B permit for the analytes set forth therein. The Groundwater Detection Monitoring program is an attachment to the Part B permit and is located in the docket. Clean Harbors Lone Mountain has two relevant RCRA permits—an Operations Permit for current hazardous waste treatment and disposal activities and a Post-Closure Permit for landfill cell(s) undergoing closure. In the last 10-year monitoring period, no hazardous waste constituents have been reported above their respective health-based levels in groundwater wells that monitor the operating portions of the landfill where the put piles will be staged. The Permit Renewal Application is currently undergoing technical review and pending completion of ongoing Class 3 Tier III Permit Modifications for

container management expansion and proposed Landfill Cell 16.

vi. Sufficient Information

40 CFR 268.6(a)(5) requires that sufficient information exists to assure the Administrator that the owner/operator of an NMV unit will comply with other applicable Federal, State, and local laws. Clean Harbors is in compliance with their state-issued permits, and the Agency concludes that sufficient assurances exist through the RCRA, air, and water permits that govern Clean Harbors' treatment, storage, and disposal operations.

vii. Compliance Monitoring Plan

40 CFR 268.6(a)(4) requires a petition to include a monitoring plan to verify continued compliance with the conditions of the NMV. The monitoring plan must be designed to detect migration "at the earliest practicable time." As stated in the 2023 Guidance, the plan must include frequent visual monitoring and prompt responses to possible releases, and generally good housekeeping practices that ensure the treated waste remains in the pile during the temporary storage period. The monitoring plan must also include a discussion of the sampling and analysis of the treated waste that determines when the put pile will be moved to the working face of the landfill for final disposal.

Clean Harbors must maintain at the facility a put pile monitoring plan that includes, at a minimum, components 1–16 below, many of which were included by Clean Harbors in the petition and the Agency adopts as proposed.

Deficiencies identified during inspection must be remedied/repared to ensure no migration of hazardous constituents occurs. Deficiencies may include but are not limited to cracking, breakdown, or insufficient application of the Posi-Shell cover; gaps, tears, or holes in plastic sheeting utilized for the management of the unit; presence of stormwater run-on flow and/or ponded water; visibly exposed waste; and poor overall pile condition. Deficiencies must be remedied within one (1) week of discovery, and remedies must be recorded in the facility's operating record.

Deficiencies described by this section must be remedied regardless of whether Clean Harbors determines that a migration of hazardous constituents has occurred or may have occurred if LDR compliance verification of the waste in the unit is not yet available. If Clean Harbors determines that there has been a migration of hazardous constituents from any of the put piles or is unable

to remedy any deficiency within one (1) week of discovery, Clean Harbors must immediately suspend receipt of waste at the affected put pile and notify the Region 6 Administrator, in writing, within ten (10) days of the determination that a release has occurred or that a deficiency was unable to be remedied within one (1) week.

Monitoring Plan Conditions

1. Review and track LDR standard “pass rates” for put piles to ensure that the put piles are only being “temporarily stored,” as described in the February 2023 guidance. If the failure rate of the initial verification test for treated put piles exceeds 5% in a calendar month, Clean Harbors must conduct a root cause analysis and adjust the treatment protocol for the affected category of waste.

2. Inspection of the temporary staging area for put piles must be performed before installation of the 20-mil polyethylene liner. The underlying area must be free of large, sharp, or rigid objects that may damage the liner.

3. Observing that the liner is not displaced or damaged during placement of the put piles on the liner to confirm the integrity of the liner beneath a put pile. A damaged liner must be replaced with a new liner.

4. Daily inspection of covered put piles to verify integrity of the liner, cover, and overall pile condition. Inspectors must, at a minimum, check for: (1) signs of stormwater run-on flow that has or is migrating towards a put pile or other signs of the potential for put pile erosion, undermining, or washout of the waste encapsulation barriers; (2) damage from strong winds, heavy rain, or other extreme weather events (*e.g.*, in particular, causing holes, uplift, or other breaches in the Posi-Shell® cover) within 24 hours of such an event; (3) visible exposed waste; (4) releases of waste (washout/undermining, displacement/movement of pile, such as shifting or slumping, windblown waste particles, etc.); (5) other indications of potential for migration or actual observed migration of hazardous constituents from the pile (*e.g.*, liquid seeps on the put pile slopes or emanating from its base); and (6) cracks in the Posi-Shell®.

5. Appropriate Posi-Shell® application. Adhering to inclement weather application prohibitions as recommended by the manufacturer. If a put pile is unable to be immediately covered with a Posi-Shell® (*e.g.*, due to moderate to heavy rainfall), the put pile must be temporarily covered with polyethylene liner that is at least 20-mil thick and anchored with sandbags

around its edges until the adverse weather conditions abate and the Posi-Shell® coating can then be applied. Posi-Shell® should not be applied when sustained freezing temperatures are expected for more than one day or during temperatures below 30 °F.

6. Verify that 100% coverage of Posi-Shell® is achieved over the entire put pile (no bare or thin spots).

7. Confirm that the minimum 3/8-in thickness of Posi-Shell® is achieved.

8. Confirm that the Posi-Shell® cover is sufficiently set (hardened) before a moderate to heavy rainfall event.

9. Promptly re-apply Posi-Shell® cover if any deficiencies are identified during application, including but not limited to lack of coverage, thickness, or hardening.

10. Check for loss of 100% coverage of Posi-Shell® or other signs of cover degradation (imminent potential for loss of barrier effectiveness or thickness).

Landfill Cell 15-Specific Remediation Requirements

11. Remove ponded water on the landfill surface that could affect the put piles.

12. Modify, as needed, run-on controls to continue to divert surface water around the put pile staging area.

13. Maintain or alter, as appropriate, landfill grading to prevent put pile run-on.

14. Isolate the nine waste categories/groups of put piles from each other to prevent potential commingling.

15. Maintain landfill equipment.

16. Submit a duplicate copy of the RCRA annual report required by 40 CFR 268.6(c)(3). This will include all LDR verification sampling, resampling, and retreatment to EPA Region 6 at: Golam Mustafa, Land, Chemicals and Redevelopment Division, EPA Region 6, 1201 Elm Street, Dallas, Texas 75270, Mail Code: R6LCR-RP.

V. Conclusion

The Agency proposes that Clean Harbors has successfully demonstrated, to a reasonable degree of certainty, that there will be no migration of hazardous constituents beyond the unit boundary for treated hazardous wastes temporarily stored in put piles within their permitted Subtitle C hazardous waste Landfill Cell 15 while awaiting LDR compliance verification.

Therefore, EPA proposes to grant, with the conditions stated herein, no-migration variances for the nine categories/groups of wastes designated herein, containing up to 100 put piles at any one time at Clean Harbors' Lone Mountain facility.

Dated: December 2, 2025.

Walter Mason,

Regional Administrator, Region 6.

[FR Doc. 2025–22553 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 251205–0178]

RIN 0648–BN39

Pribilof Islands Administration; Dogs Prohibited

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to revise regulations that prohibit dogs on the Pribilof Islands by creating an exception for NMFS to authorize certified and trained rodent detection dogs to respond to and prevent the establishment of invasive rodents on the Pribilof Islands. Invasive rodents could have significant consequences for the wildlife species that live and breed on the Pribilof Islands and the health and food security of community members. This action supports Tribal, local, and Federal agency efforts and is intended to promote the goals and objectives of the Fur Seal Act (FSA), the Marine Mammal Protection Act (MMPA), and other applicable laws.

DATES: Submit comments on or before January 12, 2026.

ADDRESSES: A plain language summary of this proposed rule is available at <https://www.regulations.gov/docket/NOAA-NMFS-2025-0405>. You may submit comments on this document, identified by NOAA–NMFS–2025–0405, by either of the following methods:

- **Electronic Submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov and type NOAA–NMFS–2025–0405 in the Search box. Click the “Comment” icon, complete the required fields, and enter or attach your comments.

- **Mail:** Submit written comments to the Assistant Regional Administrator, Protected Resources Division, Alaska Region NMFS, P.O. Box 21668, Juneau, AK 99802–1668.

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 the draft Regulatory Impact Review prepared for this proposed rule may be obtained from www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Michael Williams, NMFS Alaska Region, 907-271-5117, michael.williams@noaa.gov.

SUPPLEMENTARY INFORMATION:

Authority for Action

The FSA (16 U.S.C. 1161–1169b) requires the Secretary of Commerce (Secretary) to administer Federal lands of the Pribilof Islands and ensure that activities on such Federal lands are consistent with the purposes of conserving, managing, and protecting northern fur seals, *Callorhinus ursinus*, and other wildlife. The Secretary is authorized to promulgate regulations necessary for the administration of the Pribilof Islands (16 U.S.C. 1169), which NMFS, acting pursuant to delegated authority, has promulgated at 50 CFR part 216, subpart G-Pribilof Islands Administration. NMFS manages northern fur seals consistent with both the FSA and MMPA.

Background

The current text of 50 CFR 216.82, "Dogs prohibited," states: "*In order to prevent molestation of fur seal herds, the landing of any dogs at Pribilof Islands is prohibited.*" NMFS has interpreted the molestation of the fur seal herds to include physical disturbance and disease transmission by a dog or its feces.

An invasive rat was reported on St. Paul Island (of the Pribilof Islands) in June 2024. The introduction of an invasive rat (or invasive rodent) could have significant ecological consequences for the indigenous species that live and breed on the islands, including northern fur seals, which have been designated as depleted under the MMPA (53 FR 17888, May 18, 1988).

As such, the Aleut Community of St. Paul Island (ACSPI) and the U.S. Fish and Wildlife Service (USFWS)

requested that NMFS consider allowing a rat detection dog to land on St. Paul Island for the purpose of confirming the presence of and locating any rats. NMFS has historically supported Tribal, local, and Federal agency efforts to prevent the introduction of invasive rodents on the Pribilof Islands. Invasive rodents include brown rats or Norway rats, black rats or roof rats, mice, and other less common species. Mice do not pose the same wildlife risk as rats, but have been observed killing seabird chicks, and also have a human health and zoonotic disease risk. Black rats generally avoid water, but have been observed on one of the Aleutian Islands.

NMFS has an MMPA section 119 (16 U.S.C. 1388) cooperative agreement (also referred to herein as a co-management agreement) with the ACSPI to share responsibility for the conservation of northern fur seals (and other marine mammal species) and the management of subsistence use (the agreement can be found at <https://www.fisheries.noaa.gov/alaska/marine-mammal-protection/co-management-marine-mammals-alaska#tribal-government-of-st-paul>). The co-management agreement between NMFS and ACSPI includes shared responsibility for management decisions regarding northern fur seal conservation and subsistence use through a co-management council, which is comprised of equal membership between NMFS and ACSPI. The co-management council process includes regular meetings.

The City of St. George, City of Saint Paul (16.10), ACSPI Tribal Code (7.05), and the State of Alaska (5 AAC 92.141) have promulgated regulations preventing rodents. The communities primarily carry the significant burden of preventing rodent invasions on St. Paul and St. George, including implementing increased biosecurity measures when the threat of invasive rodents occurs.

ACSPI has assumed the burden of rodent prevention on St. Paul Island since the late 1990s, after initiation of the program by the USFWS in 1993. Today, the prevention efforts include 75 specialized rodenticide and snap trap stations positioned around the harbor, fish processing plant, warehouses, and docks where rodents might escape from an arriving vessel. From 1995 through 1996, nine rats were found on St. Paul Island and all were dead. In 2018, the first live rat was detected in the fish processing plant and, after 10 months of active trapping and multiple detections, the rat was confirmed dead immediately outside the plant. No subsequent sightings occurred over the next 12 months, and no rats were sighted on St.

Paul Island until the June 2024 sighting. St. George Island has never had a rat detection, suggesting that its rat prevention stations established around the harbor and landfill have been effective. St. George did respond to an invasive mouse event within the last decade, and St. Paul has had intermittent mouse detections over the past decade. Dutch Harbor, which has rats, is the closest port to the Pribilof Islands and is often the origin for local and regional cargo vessels and barges. Fishing vessels come to St. Paul and St. George for fuel, resupply, and emergencies, many of which originate from Dutch Harbor. The risk of rodent introductions to the Pribilof Islands is also growing primarily due to increased vessel traffic in the sub-arctic and Arctic for tourism. Vessels are the primary source of introductions of rats to islands worldwide (Drake and Hunt 2008).

Request From Multi-Agency Invasive Rat Task Force

In June 2024, the ACSPI and USFWS Alaska Maritime National Wildlife Refuge (USFWS AMNWR) contacted NMFS regarding the report of an invasive rat on St. Paul Island. NMFS staff participated in regular task force meetings between ACSPI, USFWS AMNWR, and U.S. Department of Agriculture to discuss the invasive rat situation. Multiple methods of detection have been implemented around the initial observation site on St. Paul Island, including motion sensing trail cameras, chew blocks, bait stations, and snap traps. No additional detections have been observed, but given the abundance of wild food for rats during the summer and fall, the task force expects that these methods may not yield additional detections of the rat if it is on island. After other methods of detection were unsuccessful and after numerous meetings, the task force determined that a dog specially trained in rat detection was the most likely method to detect any rats on St. Paul Island.

The Proposed Rule, Need for This Action, and Expected Effects

This rule would provide an exception to the current regulatory prohibition by allowing the Regional Administrator to authorize the use of rodent detection dogs to respond to any incidents that could otherwise lead to the establishment of a rodent population on any of the Pribilof Islands. NMFS believes the ecological benefits of successfully detecting and eradicating any invasive rodents on the Pribilof Islands outweigh the manageable risks of molestation of the fur seal herd and

disease transmission from dogs or their feces. The potential environmental consequences of dogs on the Pribilof Islands include the exposure of indigenous wildlife to canine diseases transmitted through feces or urine and molestation of indigenous wildlife by an uncontrolled dog. After careful review, NMFS has preliminarily determined (pending consideration of public comments) that the landing of certified and trained rodent detection dogs, subject to certain conditions that would be imposed by NMFS, would not create any significant environmental risk to fur seals or other wildlife populations on the Pribilof Islands. These conditions would include: (1) the only dogs that could be authorized on the Pribilof Islands would be rodent detection dogs certified to have been trained for that purpose; (2) the certified rodent detection dog(s) will undergo any quarantine period required by the State of Alaska; (3) any such dog must have current immunizations and health certifications required by the State of Alaska; (4) any such dog must be under constant control (*i.e.*, voice, electronic, or leash) by a professional dog handler; and (5) the handler will be responsible for feces management, including collecting all feces, securing all feces from exposure to indigenous wildlife, and disposing of all feces by incineration on the island from which it is collected.

There are certified and trained rodent detection dogs available through the U.S. Department of Agriculture and several private organizations.

The purpose of the current regulation at 50 CFR 216.82 is to prevent molestation of fur seals; NMFS has interpreted “molestation” as including physical disturbance and disease transmission by the dog or its feces. The current regulation allows no exceptions to the prohibition on the landing of dogs on the Pribilof Islands. NMFS is proposing to revise 50 CFR 216.82 to create a limited exception to allow landowners to request the Regional Administrator to authorize the landing of certified and trained rodent detection dogs for up to 180 days for the sole purpose of detecting and eradicating invasive rodents. The regulation would continue to prohibit the landing of dogs on the Pribilof Islands for any other purpose, including as household pets.

There are several potential rodent detection methods, including trail cameras, chew blocks, and baited snap traps. These methods, for example, have been deployed and monitored on St. Paul Island since the first sighting was reported in June 2024 in an attempt to confirm the initial rat sighting. No

additional sightings have been made using these methods. These methods will continue to be used by ACSPI and USFWS to detect or capture the rat; however, they are known to be less effective than a trained rodent detection dog.

Since a rodent detection dog is much more effective than other methods, NMFS believes the ecological benefits of detecting and eradicating any invasive rodents through this rule outweigh the manageable risks of molestation of the fur seal herd and disease transmission from dogs or their feces. The dog(s) would be under constant control, so there is very little risk of molestation of the fur seal herd, or other wildlife, as contemplated in the original rulemaking (34 FR 13371, August 19, 1969). In addition, to minimize disease transmission, any dogs must have proof of current immunizations and health certifications required by the State of Alaska, and the handler would be responsible for collecting and disposing of all feces. Finally, the exception is limited to a total of 180 days per incident and is triggered when a dog or dogs are necessary for rodent detection on an island because of an incident that may potentially lead to the establishment of a rodent population on any of the Pribilof Islands. The 180-day limit applies based on the incident triggering the need for a rodent detection dog on that specific island. If two islands have rodent incidents, the dogs deployed to each island will be subject to separate 180-day limits. The 180-day period starts on the date of the dog’s arrival on the island and is calculated by the total number of days the dog is present on that island. If for any reason the dog needs to depart prior to the 180-day limit, only those days that a dog was present on that island count toward the limit, and certified and trained rodent detection dog(s) would be allowed to return to the island for the remainder of the 180-day period if necessary for rodent detection. Each 180-day period will apply to the island and circumstances for which it was authorized. If new circumstances emerge after a 180-day period expires, the Regional Administrator would consider whether to authorize a new 180-day period based on the evidence available, including evidence of the presence of any rodents.

This rulemaking is meant to address the need of preventing the establishment of an invasive rodent population and improving the ability to detect invasive rodents on the Pribilof Islands. A single pregnant female rat is capable of breeding with her own male offspring with no negative genetic

consequences, resulting in the creation of a viable new population (Costa et al., 2016). Rodents may predate on subsistence resources, such as seabirds, their eggs, and chicks (Angel et al., 2009). Cliff and burrow nesting seabirds on the islands use habitats that limit exposure to arctic fox predation, but those same habitats are particularly vulnerable to rats as cliffs and burrows do not limit their access to nests. In addition, rodents are common carriers of many diseases transmissible to humans, fur seals, and other wildlife, including Leptospirosis (Richardson et al., 2017).

While alternative methods have been deployed to try to locate the rat or signs of its presence without importing a rat detection dog to St. Paul Island, those methods to date have not located the rat. ACSPI and USFWS will continue to deploy and monitor for the presence and signs of a rat in 2025 while NMFS pursues this rulemaking to create a regulatory exception that would apply to all of the Pribilof Islands. While this rulemaking was initiated by the local observation on St. Paul Island in 2024, the risk of invasive rodents being introduced to any of the Pribilof Islands has grown in the past decade due largely to an increase in vessel and cruise ship traffic. As such, this rule would allow a landowner to respond to an incident involving an invasive rodent by requesting NMFS’s authorization for an exception to land a rodent detection dog. The exception would remain in effect for up to 180 days from the date of the dog’s first landing on the island with the rodent incident, allowing for the logistical challenges involved in arranging for landing an invasive rodent detection dog on the Pribilof Islands, and having adequate time to detect rodents if present on the Pribilof Islands.

This rulemaking is not likely to have adverse economic impacts on small businesses or the economies of St. Paul or St. George Islands. NMFS intends for this action to apply to the Pribilof Islands, not just St. Paul and St. George, because the risk of shipwrecks introducing rodents is also possible on the uninhabited islands. Not taking this action and allowing the invasive rat to persist or allowing an invasive rodent to otherwise become established on St. Paul could result in negative environmental impacts, which could in turn impact the wildlife-viewing tourist economy managed by the Tanadgusix (TDX) Corporation, the local Alaska Native Claims Settlement Act village corporation for St. Paul. There is no similar tourism economy on St. George Island, only the incidental revenue from

hotel occupancy operated by the Tanaq Corporation, the local Alaska Native Claims Settlement Act village corporation for St. George. The communities of St. Paul and St. George also rely on marine and terrestrial species breeding on the Pribilof Islands for subsistence purposes and food security that could be affected by an invasive rodent introduction. The TDX Corporation and Tanaq Corporation may be affected as the dog may need to search on their lands. The landowner who requests authorization to land a dog or dogs on island would be responsible for obtaining permission from other landowners before any search occurs on their properties.

Scope of Proposed and Potential Regulatory Changes and Request for Comment

In this proposed rule, NMFS would revise the regulations at 50 CFR 216.82 to allow an exception, lasting up to 180 total days a dog (or dogs) is on island, to the regulatory prohibition against landing dogs on the Pribilof Islands in order to land certified and trained rodent detection dogs on the Pribilof Islands to support Tribal, local, and Federal agency efforts to detect, locate, and eradicate any invasive rodents on the Pribilof Islands. This exception would allow certified and trained rodent detection dogs on the Pribilof Islands. This regulatory change would respond to the June 2024 report of an invasive rat on St. Paul Island but also allows flexibility for NMFS to authorize landowners to land certified and trained rodent detection dogs on any of the Pribilof Islands to respond to any future incidents, such as a shipwreck or observations of invasive rodents on the Pribilof Islands.

Rather than proposing a one-time exemption for this current incident on St. Paul Island, NMFS proposes to create an exception to the regulatory prohibition of dogs to last up to 180 days in order to land certified and trained rodent detection dogs on any of the Pribilof Islands as needed to respond to and prevent the introduction of invasive rodents. This would allow a timely response to any incident that may potentially lead to the establishment of a rodent population on any of the Pribilof Islands. The exception would allow for a landowner to request the NMFS Alaska Regional Administrator to authorize the landing of certified and trained rodent detection dogs on any of the Pribilof Islands for 180 days to search for, detect, and eradicate rodents. The implementation of the exception will balance the need to reduce exposure of seasonal wildlife,

the availability of human and wild food sources, refuge from the weather, and the urgency of the incident being considered in terms of the likelihood of rodents establishing a population on the Pribilof Islands.

The landowners would be responsible for providing the evidence of the rodent sighting, certification the dog(s) have been trained for rodent detection, immunization and health certification records for the dog(s) to be used to detect rodents, the expected duration and location of the search, any permissions needed for searches on lands owned by others, number of dogs expected to be used, and the feces management plan to NMFS. NMFS will review the information provided and the Regional Administrator may authorize the exception in writing to the landowner within 10 working days of receipt of the completed information package so that, if the request is approved, the certified and trained dog(s) could be secured and transported to the island in a timely manner for rodent detection. When authorizing the use of rodent detection dog(s), the Regional Administrator may impose conditions on their use on the specified Pribilof Island to address and mitigate the potential risks of molestation of the fur seal herd and disease transmission from dogs or their feces. Such conditions could include requirements for the control and handling of the dogs and dog feces by a professional dog handler while the dogs are on the Pribilof Island, compliance with any required quarantine period, and direction for the Pribilof Island landowner to communicate to NMFS when the dog(s) arrive and depart the Island, where the searches occurred, when the searches were completed, and whether any invasive rodents were detected. This action does not create any other exceptions to the existing prohibition on landing dogs on the Pribilof Islands, including household pets.

Classification

The Assistant Administrator for Fisheries, NOAA, has determined that this proposed rule is consistent with the FSA (16 U.S.C. 1161–1169b), the MMPA, and other applicable laws, subject to further consideration after public comment. In the development of this proposed rule, NMFS worked with the ACSPI pursuant to the NMFS and ACSPI's co-management agreement under the MMPA (16 U.S.C. 1388(a)).

Executive Order 12866

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

Executive Order 14192

This proposed rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866.

Executive Order 13175

As noted in the preamble, the ACSPI and USFWS have requested that NMFS implement this rule to revise the FSA regulations to authorize rodent detection dogs to land on the Pribilof Islands. NMFS has worked collaboratively and had frequent communication with the ACSPI as part of a multi-agency invasive rodent task force and pursuant to the NMFS and ACSPI's co-management agreement under the MMPA. NMFS also contacted the local Alaska Native Corporation on St. Paul Island (Tanadgusix Corporation, TDX) about revising the regulations regarding the landing of rodent detection dogs on St. Paul Island. Neither the Alaska Native Tribe on St. Paul Island (ACSPI) nor the TDX Corporation expressed opposition to this rule. Similarly, NMFS contacted the Traditional Council of St. George Island, and their local Native Corporation (Tanaq Corporation) about revising the regulations regarding the landing of certified and trained rodent detection dogs and determined there was no opposition. Given the level of Tribal engagement in the course of responding to this issue and developing this proposed rule, Tribal consultation was not held on the proposed rule.

A Tribal summary impact statement under section (5)(b)(2)(B) and section (5)(c)(2) of E.O. 13175 was not required for this proposed rule because this action does not impose substantial direct compliance costs on Alaska Native Tribal Governments and this action does not preempt Tribal law. A Tribal summary impact statement is not required and has not been prepared.

Regulatory Impact Review (RIR)

An RIR was prepared to assess costs and benefits of available regulatory alternatives. A copy of this draft analysis is available from NMFS (see **ADDRESSES**).

Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration 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 is as follows.

The current regulation prohibits landing of all dogs on the Pribilof Islands. This proposed rule would create a limited exception for the NMFS Alaska Regional Administrator to authorize the landing of certified and trained rodent detection dogs on the Pribilof Islands for 180 days subject to certain conditions that would be imposed by the Regional Administrator to prevent the molestation of fur seals and other wildlife by such dogs. The statutory authority and the need for this action, as well as expected effects, are described in the preamble above. NMFS also prepared a Regulatory Impact Review that analyzed alternatives, including the status quo. The establishment of invasive rodents on the Pribilof Islands could result in negative environmental and ecological impacts that could in turn impact the wildlife-viewing tourist economy managed by the TDX Corporation and Tanaq Corporation and the communities of St. Paul and St. George that rely on marine and terrestrial species breeding on the Pribilof Islands for subsistence purposes and food security.

Implementing this proposed rule would help prevent the establishment of invasive rodents on the Pribilof Islands, which in turn could provide a means to protect the tourist economy, subsistence resources that contribute to food security and the mixed cash-subsistence economy, and public health costs from rodent-borne diseases. This exception proposed in this action would create the flexibility and opportunity for landowners on the Pribilof Islands to hire and utilize the services of a certified and trained rodent detection dog handler to prevent invasive rodents from establishing a population on the Pribilof Islands. Entities that would be directly regulated by this proposed rule are limited to any Pribilof Islands landowner who requests invasive rodent detection services and the service provider. Landowners on the Pribilof Islands include the Federal government, municipal governments of St. Paul and St. George, and the TDX Corporation and Tanaq Corporation. In addition to private companies, other Federal agencies, such as the U.S. Department of Agriculture, may have rodent detection dogs available.

The use of certified and trained rodent detection dogs will help to successfully locate and remove any invasive rodents from the Pribilof Islands, which will protect sensitive wildlife, subsistence resources necessary to maintain food security,

wildlife and communities that may be exposed to invasive rodent-borne diseases, and the small wildlife tourism economy on the Pribilof Islands. Therefore, it is expected that the proposed action could have a beneficial economic effect on any small entities by creating the opportunity to detect invasive rodents on the Pribilof Islands with certified and trained dogs. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

Collection-of-Information Requirements

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995. NOAA is not soliciting the information from the public and therefore is not conducting a collection of information. NOAA will respond to a request from an individual landowner on the Pribilof Islands for assistance in obtaining an exception to use a certified and trained rodent detection dog on the Pribilof Islands.

References

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- Drake, D.R., Hunt, T.L. Invasive rodents on islands: integrating historical and contemporary ecology. *Biological Invasions* 11, 1483–1487 (2009). <https://doi.org/10.1007/s10530-008-9392-1>.
- Richardson, J.L., Burak, M.K., Hernandez, C., et al. Using fine-scale spatial genetics of Norway rats to improve control efforts and reduce leptospirosis risk in urban slum environments. *Evolutionary Applications*. 2017; 10: 323–337. <https://doi.org/10.1111/eva.12449>.

List of Subjects in 50 CFR Part 216

Alaska, Pribilof Islands.

Dated: December 5, 2025.

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 216 is amended as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for 50 CFR part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

■ 2. In Section 216.82 add paragraphs (a) and (b) to read as follows:

§ 216.82 Dogs prohibited.

(a) In order to prevent molestation of fur seal herds, the landing of any dogs at Pribilof Islands is prohibited.

(b) *Exception to prevent the establishment of invasive rodents on the Pribilof Islands.* The NMFS Alaska Regional Administrator may authorize the landing of certified and trained rodent detection dogs on an island in the Pribilof Islands, subject to the following:

(1) A Pribilof Island landowner must submit a request for authorization to land a rodent detection dog on a Pribilof Island in writing to the NMFS Alaska Regional Administrator and must include the following information:

- (i) Evidence of rodent presence on a Pribilof Island;
- (ii) Certification that the dog has been trained for rodent detection;
- (iii) Certification that the dog will be under the constant voice, electronic, or leash control of a professional dog handler, or otherwise confined, while on the Pribilof Island;
- (iv) Proof that the dog has undergone any quarantine period required by the State of Alaska;
- (v) Current immunization and health certifications required by the State of Alaska;
- (vi) The number of dogs expected to be used;
- (vii) The professional dog handler's written plan for collecting and incinerating dog feces;
- (viii) The expected duration and location of rodent searches on the Pribilof Island; and
- (ix) Any other information requested by the Regional Administrator.

(2) After receipt of a complete request, within [10] days, the NMFS Alaska Regional Administrator may authorize the landing of one or more certified and trained rodent detection dogs and impose conditions on their use on the specified Pribilof Island.

(3) No certified and trained rodent detection dog authorized by the NMFS Alaska Regional Administrator may be on the specified Pribilof Island for more than 180 total days from landing on that Island.

[FR Doc. 2025–22542 Filed 12–10–25; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 90, No. 236

Thursday, December 11, 2025

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–SC–25–0386]

Vidalia Onions Grown in Georgia; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible Vidalia onion producers to determine whether they favor continuance of the marketing order regulating the handling of Vidalia onions grown in Georgia.

DATES: The referendum will be conducted from January 12 through February 3, 2026. Only current Vidalia onion producers who have grown onions within the designated production area during the period January 1, 2024, through December 31, 2024, are eligible to vote in this referendum.

ADDRESSES: Copies of the marketing order may be obtained from the office of the referendum agents at 1124 1st Street South, Winter Haven, FL 33880; telephone: (863) 324–3375; or from the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; telephone (202) 720–8085; or on the internet: <https://www.ecfr.gov/current/title-7/subtitle-B/chapter-IX/part-955>.

FOR FURTHER INFORMATION CONTACT: Delaney Fuhrmeister, Marketing Specialist, or Christian D. Nissen, Branch Chief, Southeast Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA, 1124 1st Street South, Winter Haven, FL 33880; telephone: (863) 324–3375; or email: Delaney.Fuhrmeister@usda.gov or Christian.Nissen@usda.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 955, as amended (7 CFR part 955), hereinafter referred to as the “Order,” and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act,” it is hereby directed that a referendum be conducted to ascertain whether continuance of the Order is favored by Vidalia onion producers in Georgia. The referendum will be conducted from January 12 through February 3, 2026, among Vidalia onion producers in the production area. Only current Vidalia onion producers that were engaged in the production of Vidalia onions during the period of January 1, 2024, through December 31, 2024, may participate in the continuance referendum.

USDA has determined that continuance referenda are an effective means for determining whether producers favor the continuation of marketing order programs. USDA will consider termination of the Order if less than two-thirds of the producers voting in the referendum, or producers of less than two-thirds of the volume represented in the referendum, favor continuance. In evaluating the merits of continuance versus termination, USDA will not exclusively consider the results of the continuance referendum. USDA will also consider all other relevant information concerning the operation of the Order and relative benefits and costs to producers, handlers, and consumers to determine whether continued operation of the Order would tend to effectuate the declared policy of the Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the ballot materials used in the referendum have been approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581–0178, Vegetable and Specialty Crops. It has been estimated it will take an average of 20 minutes for each of the approximately 80 Vidalia onion producers to cast a ballot. Participation is voluntary. Ballots postmarked after February 3, 2026, will not be included in the vote tabulation.

Delaney Fuhrmeister, Steven Kauffman, and Christian D. Nissen of the Southeast Region Branch, Specialty Crops Program, AMS, USDA, are hereby designated as the referendum agents of the Secretary of Agriculture to conduct

this referendum. The procedure applicable to the referendum shall be the “Procedure for the Conduct of Referenda in Connection with Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended” (7 CFR 900.400 *et seq.*).

Ballots and voting instructions will be sent by U.S. mail, or through electronic mail, to all Vidalia onion producers of record and may also be obtained from the referendum agents or their appointees.

(Authority: 7 U.S.C. 601–674.)

Erin Morris,

Administrator, Agricultural Marketing Service.

[FR Doc. 2025–22570 Filed 12–10–25; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–SC–25–0037]

Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible Walla Walla sweet onion producers to determine whether they favor continuance of the marketing order regulating the handling of sweet onions grown in the Walla Walla Valley of southeast Washington and northeast Oregon.

DATES: The referendum will be conducted from January 12 through January 30, 2026. Only current Walla Walla sweet onion producers who have grown onions within the designated production area during the period June 1, 2024, through May 31, 2025, are eligible to vote in this referendum.

ADDRESSES: Copies of the marketing order may be obtained from the office of the referendum agents at 1220 SW 3rd Avenue, Suite 305, Portland, Oregon 97204; telephone: (503) 326–2724; or from the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237,

Washington, DC 20250–0237; telephone: (202) 720–2491; or on the internet <https://www.ecfr.gov/current/title-7/subtitle-B/chapter-IX/part-956>.

FOR FURTHER INFORMATION CONTACT:

Kelsey Dugan, Marketing Specialist, or Barry Broadbent, Branch Chief, Northwest Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA, 1220 SW 3rd Avenue, Suite 305, Portland, Oregon 97204; telephone: (503) 326–2724; or email: Kelsey.Dugan@usda.gov or Barry.Broadbent@usda.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 956, as amended (7 CFR part 956), hereinafter referred to as the “Order,” and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act,” it is hereby directed that a referendum be conducted to ascertain whether continuance of the Order is favored by sweet onion producers in the Walla Walla Valley of southeast Washington and northeast Oregon. The referendum will be conducted from January 12 through January 30, 2026, among Walla Walla sweet onion producers in the production area. Only current Walla Walla sweet onion producers that were engaged in the production of Walla Walla sweet onions during the period of June 1, 2024, through May 31, 2025, may participate in the continuance referendum.

USDA has determined that continuance referenda are an effective means for determining whether producers favor the continuation of marketing order programs. USDA would consider termination of the Order if less than two-thirds of the producers voting in the referendum, or producers of less than two-thirds of the volume represented in the referendum, favor continuance. In evaluating the merits of continuance versus termination, USDA will not exclusively consider the results of the continuance referendum. USDA will also consider all other relevant information concerning the operation of the Order and the relative benefits and costs to producers, handlers, and consumers to determine whether continued operation of the Order would tend to effectuate the declared policy of the Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the ballot materials used in the referendum have been approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581–0178, Vegetable and Specialty Crops. It has been estimated that it will take an average of 20 minutes for each

of the approximately 11 Walla Walla sweet onion producers to cast a ballot. Participation is voluntary. Ballots postmarked after January 30, 2026, will not be included in the vote tabulation.

Kelsey Dugan and Barry Broadbent of the Northwest Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA, are hereby designated as the referendum agents of the Secretary of Agriculture to conduct this referendum. The procedure applicable to the referendum shall be the “Procedure for the Conduct of Referenda in Connection with Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended” (7 CFR 900.400 *et seq.*).

Ballots will be mailed to all Walla Walla sweet onion producers of record and may also be obtained from the referendum agents or their appointees.

Authority: 7 U.S.C. 601–674.

Erin Morris,

Administrator, Agricultural Marketing Service.

[FR Doc. 2025–22563 Filed 12–10–25; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: U.S. Commission on the Social Status of Black Men and Boys (CSSBMB) U.S. Commission on Civil Rights.

ACTION: Notice of CSSBMB FY25 Q4 public business meeting.

DATES: Thursday, December 11, 12:30 p.m. EDT

ADDRESSES: Meeting to take place virtually and is open to the public via livestream on the Commission’s YouTube page: www.youtube.com/usccr.

FOR FURTHER INFORMATION CONTACT: Diamond Newman, 202–339–2371, dnewman@usccr.gov.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 116–156, 1134 Stat. 700 (2020), the U.S. Commission on the Social Status of Black Men and Boys (CSSBMB) will hold its FY25 Fourth Quarter Business Meeting exploring CSSBMB business items, operations, and next steps. This business meeting is open to the public via livestream on the U.S. Commission on Civil Rights’ YouTube Page at: <https://youtube.com/live/9wG-TeEBNIE>. (*Streaming information subject to change.*)

Public participation is available for the event with view access, along with

an audio option for listening. Computer-assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on December 11 is <https://www.streamtext.net/player?event=CSSBMB>. Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

* Date and meeting details are subject to change. For more information on the CSSBMB or the upcoming public briefing, please visit www.usccr.gov/CSSBMB and CSSBMB’s Instagram, Facebook, and X.

Meeting Agenda

I. Call to Order & Opening Remarks (10 minutes)

Chair Wilson

II. Roll Call & Adoption of Agenda (5 minutes)

USCCR CSSBMB Staff

Chair Wilson

III. Framing the Theme: “Prevention Not Detention” (10 minutes)

Chair Wilson

IV. Director’s Report: Annual Report & Operations Update (20 minutes)

Director Spencer

V. Commissioners’ Clarifying Questions on Report (10 minutes)

VI. Focused Discussion: Disrupting the School-to-Prison Pipeline (25 minutes)

- Staff Data Overview (20 minutes)
- Targeted Commissioner Discussion (5 minutes)

VII. Open Floor for Commissioners (20 minutes)

- Comments, Initiatives, Brief

VIII. Adjournment

Motion to Adjourn/Vote

Zakee Martin,

Deputy Director.

[FR Doc. 2025–22544 Filed 12–9–25; 11:15 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–380–2025]

Foreign-Trade Zone 37; Application for Subzone; Oerlikon Metco (US) Inc.; Westbury, New York

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the County of Orange, grantee of FTZ 37, requesting subzone status for the facilities of Oerlikon Metco (US) Inc.,

located in Westbury, New York. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on December 5, 2025.

The proposed subzone would consist of *Site 1* (6.98 acres), 1101 Prospect Avenue, Westbury. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 37.

In accordance with the FTZ Board's regulations, Juanita Chen of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is January 20, 2026. Rebuttal comments in response to material submitted during the foregoing period may be submitted through February 4, 2026.

A copy of the application will be available for public inspection in the "Online FTZ Information Section" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Juanita Chen at juanita.chen@trade.gov.

Dated: December 5, 2025.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2025–22492 Filed 12–10–25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–49–2025]

Foreign-Trade Zone (FTZ) 075 Notification of Proposed Production Activity; Catalina Components Inc.; (Vehicle Parts); Chandler, Arizona

Catalina Components Inc. (Catalina) submitted a notification of proposed production activity to the FTZ Board (the Board) for its facilities in Chandler, Arizona within FTZ 75. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on December 4, 2025.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted notification (summarized below) and

subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished products include: pressure relief vent (PRV) flaps for motor vehicles (duty rate is 2.9%).

The proposed foreign-status materials/components include: EPDM rubber (ethylene propylene diene monomer rubber) (duty-free). The request indicates that certain materials/ components are subject to duties under section 1702(a)(1)(B) of the International Emergency Economic Powers Act (section 1702), depending on the country of origin. The applicable section 1702 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is January 20, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact John Frye at John.Frye@trade.gov.

Dated: December 5, 2025.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2025–22491 Filed 12–10–25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–50–2025]

Foreign-Trade Zone 115; Application for Subzone; Phillips 66 Company; Nederland, Texas

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Foreign Trade Zone of Southeast Texas, Inc., grantee of FTZ 115, requesting subzone status for the facility of Phillips 66 Company, located in Nederland, Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on December 9, 2025.

The proposed subzone (560 acres) is located at 128 Magnolia Avenue, Nederland, Texas. No authorization for

production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is January 20, 2026. Rebuttal comments in response to material submitted during the foregoing period may be submitted through February 4, 2026.

A copy of the application will be available for public inspection in the "Online FTZ Information Section" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Camille Evans at Camille.Evans@trade.gov.

Dated: December 9, 2025.

Elizabeth Whiteman,
Executive Secretary.

[FR Doc. 2025–22578 Filed 12–10–25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Review

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

Background

Every five years, pursuant to the Tariff Act of 1930, as amended (the Act), the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission automatically initiate and conduct reviews to determine whether revocation of an antidumping duty or countervailing duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for January 2026

Pursuant to section 751(c) of the Act, the following Sunset Reviews are scheduled for initiation in January 2026 and will appear in that month's *Notice*

of Initiation of Five-Year Sunset Reviews
(Sunset Review).

Antidumping duty proceedings	Department contact
Prestressed Concrete Steel Wire Strand from Argentina A-357-822 (1st Review)	Mary Kolberg (202) 482-1785
Passenger Vehicle and Light Truck Tires from China A-570-016 (2nd Review)	Thomas Martin (202) 482-3938
Wood Mouldings and Millwork Products from China A-570-117 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Colombia A-301-804 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Egypt A-729-804 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Indonesia A-560-837 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Italy A-475-843 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Malaysia A-557-819 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Netherlands A-421-814 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Saudi Arabia A-517-806 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from South Africa A-791-826 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Spain A-469-821 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Taiwan A-583-868 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Tunisia A-723-001 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Türkiye A-489-842 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Ukraine A-823-817 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from United Arab Emirates A-520-809 (1st Review)	Mary Kolberg (202) 482-1785
Countervailing Duty Proceedings:	
Passenger Vehicle and Light Truck Tires from China C-570-017 (2nd Review)	Mary Kolberg (202) 482-1785
Wood Mouldings and Millwork Products from China C-570-118 (1st Review)	Mary Kolberg (202) 482-1785
Prestressed Concrete Steel Wire Strand from Türkiye C-489-843 (1st Review)	Mary Kolberg (202) 482-1785
Suspended Investigations:	
No Sunset Review of suspended investigations is scheduled for initiation in January 2026.	

Commerce's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. The *Notice of Initiation of Five-Year (Sunset) Review* provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), Commerce will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact Commerce in writing within 10 days of the publication of the Notice of Initiation.

Note that if Commerce receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue.

Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹ An electronically filed document must be received successfully in its entirety via Commerce's online e-filing and document management system, Antidumping and Countervailing Duty

Electronic Service System (ACCESS) by 5:00 p.m. Eastern Time on the day on which it is due. For further information on procedures for filing information with Commerce through ACCESS, refer to User Guide found at <https://access.trade.gov/login.aspx>.

In prior proceedings we have encouraged interested parties to provide an executive summary of their comments, including footnotes. In these sunset reviews, we request that interested parties provide, at the beginning of their comments, an executive summary for each issue raised in their comments. Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the decision memorandum that will accompany the notice to be published in the **Federal Register**. Finally, we request that interested parties include footnotes for relevant citations in the public executive summary of each issue.

Notification to Interested Parties

This notice is not required by statute but is published as a service to the international trading community.

Dated: December 8, 2025.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2025-22493 Filed 12-10-25; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-135]

Certain Chassis and Subassemblies Thereof From The People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2024-2025

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

SUMMARY: The U.S. Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty (AD) order on certain chassis and subassemblies thereof (chassis) from the People's Republic of China (China) for the period of review (POR) July 1, 2024, through June 30, 2025.

DATES: Applicable December 11, 2025.

FOR FURTHER INFORMATION CONTACT: Dusten Hom, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-5075.

SUPPLEMENTARY INFORMATION:

Background

On July 8, 2021, Commerce published in the **Federal Register** the AD order on chassis from China.¹ On June 30, 2025,

¹ See *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule*, 88 FR 67069 (September 29, 2023).

¹ See *Certain Chassis and Subassemblies Thereof from the People's Republic of China: Antidumping Duty Order*, 86 FR 36093 (July 8, 2021) (*Order*).

Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order*.² On July 31, 2025, Commerce received a timely request from domestic producers of subject merchandise, the Coalition of American Chassis Manufacturers (Coalition), in accordance with 19 CFR 351.213(b)(1), to conduct an administrative review of the *Order* of the following exporters: (1) CIMC Vehicles (Group) Co., Ltd.; (2) Dongguan CIMC Vehicles Co., Ltd.; (3) Qingdao CIMC Special Vehicles Co., Ltd.; and (4) SinoTrailers.³

On August 22, 2025, Commerce published in the **Federal Register** a notice of initiation of administrative review with respect to imports of chassis exported by the above Chinese exporters, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i).⁴ On September 5, 2025, we placed on the record U.S. Customs and Border Protection (CBP) data for entries of chassis from China during the POR, showing no reviewable POR entries, and invited interested parties to comment.⁵

On September 24, 2025, Commerce notified all interested parties of its intent to rescind the instant review in full because there were no reviewable, suspended entries of subject merchandise by any of the four companies listed in the *Initiation Notice* during the POR and invited comments from interested parties.⁶ No interested party submitted comments to Commerce in response to this notice.

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days,⁷ and, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025,

Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁸ Accordingly, the deadline for the preliminary results of this review is now June 30, 2026.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of an AD order when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.⁹ Normally, upon completion of an administrative review, the suspended entries are liquidated at the AD assessment rate calculated for the review period.¹⁰ Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct CBP to liquidate at the AD assessment rate calculated for the review period.¹¹ As noted above, there were no entries of subject merchandise for the four companies listed in the *Initiation Notice* during the POR. Accordingly, in the absence of suspended entries of subject merchandise of the four companies listed in the *Initiation Notice* during the POR, we are hereby rescinding this administrative review, in its entirety, in accordance with 19 CFR 351.213(d)(3).

Cash Deposit Requirements

As Commerce has proceeded to a final rescission of this administrative review, no cash deposit rates will change. Accordingly, the current cash deposit requirements shall remain in effect until further notice.

Assessment Rates

Commerce will instruct CBP to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this rescission notice in the **Federal Register**.

⁸ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

⁹ See, e.g., *Diocetyl Terephthalate from the Republic of Korea: Rescission of Antidumping Administrative Review; 2021–2022*, 88 FR 24758 (April 24, 2023); see also *Certain Carbon and Alloy Steel Cut-to Length Plate from the Federal Republic of Germany: Rescission of Antidumping Administrative Review; 2020–2021*, 88 FR 4157 (January 24, 2023); and *Lightweight Thermal Paper from Japan: Rescission of Antidumping Administrative Review; 2022–2023*, 89 FR 18373 (March 13, 2024).

¹⁰ See 19 CFR 351.212(b)(1).

¹¹ See 19 CFR 351.213(d)(3).

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: December 9, 2025.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2025–22579 Filed 12–10–25; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; User Needs Survey by the Space Weather Advisory Group

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before February 9, 2026.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at NOAA.PRA@noaa.gov. Please reference OMB Control Number 0648–0814 in the subject line of your

² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List*, 90 FR 27841 (June 30, 2025).

³ See Coalition's Letter, "Request for Administrative Review," dated July 31, 2025.

⁴ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 90 FR 41043 (August 22, 2025) (*Initiation Notice*).

⁵ See Memorandum, "U.S. Customs and Border Protection (CBP) Data Release," dated September 5, 2025.

⁶ See Memorandum, "Notice of Intent to Rescind Review," dated September 24, 2025.

⁷ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

comments. All comments received are part of the public record and will generally be posted on <https://www.regulations.gov> without change. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or specific questions related to collection activities should be directed to Amy Macpherson, Designated Federal Officer, Space Weather Advisory Group, 7220 NW 101st Terrace, Kansas City, MO 64153, 816-584-7200, or amy.macpherson@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for renewal of an approved information collection.

The data collection is sponsored by the Department of Commerce (DOC) National Oceanic and Atmospheric Administration (NOAA) National Weather Service (NWS) Space Weather Advisory Group (SWAG). The SWAG is required under 51 U.S. Code § 60601(d)(3) to undertake a comprehensive survey of space weather product users to identify the “research, observations, forecasting, prediction, and modeling advances required to improve space weather products.” Specifically, the SWAG will (i) assess the adequacy of current Federal Government goals for lead time, accuracy, coverage, timeliness, data rate, and data quality for space weather observations and forecasting; (ii) identify options and methods to, in consultation with the academic community and the commercial space weather sector, improve upon the advancement of the goals described in clause (i); (iii) identify opportunities for collection of new data to address the needs of the space weather user community; (iv) identify methods to increase coordination of space weather research to operations and operations to research; (v) identify opportunities for new technologies, research, and instrumentation to aid in research, understanding, monitoring, modeling, prediction, forecasting, and warning of space weather; and (vi) identify methods and technologies to improve preparedness for potential space weather phenomena.

Members of the SWAG will oversee recruitment of the respondents from several sectors across the Space Weather enterprise including the general public, defined as adults ages 18+. They will be asked questions about their current use of space weather observations, information, and forecasts,

technological systems, components or elements affected by space weather, current and future risk and resilience activities, future space weather requirements, and unused or new types of measurements or observations that would enhance space weather risk mitigation. This data collection serves many purposes, including gaining a better understanding of the needs of users of space weather products. The SWAG will use the data to identify the space weather research, observations, forecasting, prediction, and modeling advances required to improve space weather products. Specifically, the information will be used to advise the National Science and Technology Council’s Space Weather Operations, Research, and Mitigation (SWORM) Subcommittee on improving the ability of the United States to prepare for, mitigate, respond to, and recover from space weather storms.

II. Method of Collection

Several methods will be used to collect the information. This includes web-based surveys, interviews, and focus groups. Determination of the appropriate method will be based on the sector in question.

III. Data

OMB Control Number: 0648-0814.

Form Number(s): None.

Type of Review: Regular submission (Extension of a current information collection).

Affected Public: Individuals or households; Business or other for-profit organizations; Not-for-profit institutions; State, Local, or Tribal government.

Estimated Number of Respondents: 300.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 300.

Estimated Total Annual Cost to Public: None.

Respondent’s Obligation: Voluntary.

Legal Authority: 51 U.S. Code § 60601, Space weather.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to

be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this information collection request. 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 may 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.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2025-22512 Filed 12-10-25; 8:45 am]

BILLING CODE 3510-KE-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and delete product(s) and service(s) previously furnished by such agencies.

DATES: Comments must be received on or before: January 10, 2026 .

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 489-1322, 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.

Additions

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice will be required to procure the product(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

5180-00-650-7821—Kit, Electrician's Tool, Quick Change, 23 PC

Authorized Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI

Mandatory For: Total Government Requirement

Contracting Activity: GENERAL SERVICES ADMINISTRATION, GSA/FSS GREATER SOUTHWEST ACQUISITI

In accordance with 41 CFR 51-5.3(b), the Committee intends to add the service listed below to the Procurement List as a mandatory purchase only for the contracting activity at the location listed with the proposed qualified nonprofit agency as the authorized source of supply. Prior to adding the service to the Procurement List, the Committee will consider other pertinent information, including information from Government personnel and relevant comments from interested parties regarding the Committee's intent to geographically limit this services requirement.

Services(s)

Service Type: Document Destruction

Mandatory for: U.S. Air Force, Oklahoma City-Air Logistics Complex, 7858 5th Street, Tinker AFB, OK

Authorized Source of Supply: The Meadows Center for Opportunity, Inc., Edmond, OK

Contracting Activity: DEPT. OF THE AIR FORCE, FA8132 AFSC PZIMC

Deletions

The following product(s) and service(s) are proposed for deletion to the Procurement List:

Product(s)

7920-01-215-6569—Cloth, Synthetic Shammy, Orange, 20" x 23"

Mandatory For: Total Government Requirement

Contracting Activity: DEPT. OF VETERANS AFFAIRS, STRATEGIC ACQUISITION CENTER

Contracting Activity: GENERAL SERVICES ADMINISTRATION, GSA/FSS GREATER SOUTHWEST ACQUISITI

Service(s)

Service Type: Warehouse and Distribution

Service

Mandatory for: National Institutes of Health, Information Resource Center, Rockville, MD, 6001 Executive Boulevard, Rockville, MD

Authorized Source of Supply: The ARC of the District of Columbia, Inc., Washington, DC

Contracting Activity: HEALTH AND HUMAN SERVICES, DEPARTMENT OF, NATIONAL INSTITUTES OF HEALTH NIDA

Service Type: Laundry Service

Mandatory for: U.S. Coast Guard, U.S. Coast Guard Base Portsmouth, Portsmouth, VA, 4000 Coast Guard Blvd., Portsmouth, VA

Authorized Source of Supply: Louise W. Eggleston Center, Inc., Norfolk, VA

Contracting Activity: DEPT. OF HOMELAND SECURITY, BASE PORTSMOUTH (00027)

Service Type: Multi-Function Support Services

Mandatory for: U.S. Army Corps of Engineers, Marine Corps Reserve Center, St. Paul, MN, 6400 Bloomington Road, St. Paul, MN

Authorized Source of Supply: AccessAbility, Inc., Minneapolis, MN

Contracting Activity: DEPT. OF DEFENSE, W074 ENDIST CHARLESTON

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2025-22507 Filed 12-10-25; 8:45 am]

BILLING CODE 6353-01-P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Extend Collection 3038-0025, Practice by Former Members and Employees of the Commission

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is announcing an opportunity for public comment on the proposed renewal of an information collection by the agency. Under the Paperwork Reduction Act ("PRA"), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments regarding the reporting requirement imposed on former members and employees of the Commission who are employed or retained by third parties to appear before the Commission.

DATES: Comments must be submitted on or before February 9, 2026.

ADDRESSES: You may submit comments, identified by "Practice by Former Members and Employees of the Commission, OMB Control No. 3038-0025," by any of the following methods:

- The Agency's website, at <https://comments.cftc.gov/>. Follow the instructions for submitting comments through the website.

- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <https://www.cftc.gov>.

FOR FURTHER INFORMATION CONTACT:

Scott Thompson, Assistant General Counsel for Ethics, Office of the General Counsel, Commodity Futures Trading Commission; phone: 202-418-6590, email: Ethics@cftc.gov, and refer to OMB Control No. 3038-0025.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.*, 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 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, the CFTC is publishing notice of a proposed extension of the currently approved information collection listed below. 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.¹

Title: Practice by Former Members and Employees of the Commission (OMB Control No. 3038-0025). This is a request for an extension of a currently approved information collection.

¹ 44 U.S.C. 3512, 5 CFR 1320.5(b)(2)(i) and 1320.8(b)(3)(vi).

Abstract: Commission Rule 140.735–6 governs the practice before the Commission of former members and employees of the Commission and is intended to ensure that the Commission is aware of any existing conflict of interest. The rule, at 17 CFR 140.735–6(e), requires former members and employees who are employed or retained to represent any person before the Commission within two years of their separation from the CFTC, to file a brief written statement with the Commission’s Office of the General Counsel. The proposed rule was promulgated pursuant to the Commission’s rulemaking authority contained in Section 8a(5) of the Commodity Exchange Act, 7 U.S.C. 12a(5) (1994), as amended.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the CFTC, including whether the information will have a practical use;
- The accuracy of the CFTC’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

You should submit only information that you wish to make available publicly. If you wish the CFTC to consider information that you believe is exempt from disclosure under the Freedom of Information Act (FOIA), then a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the CFTC’s regulations.²

The CFTC reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <https://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the

Administrative Procedure Act and other applicable laws, and may be accessible under FOIA.

Burden statement: The respondent’s burden for this collection is estimated to average 0.10 hours per response to file the brief written statement. This estimate includes the time needed to review instructions, utilize technology and systems for the purposes of collecting, validating, verifying, processing and disclosing information, and adjust/update existing methods to comply with any previously applicable instructions and requirements.

Respondents/Affected Entities:

Former Commission members, employees, and their current employers.

Estimated number of respondents: 20.

Estimated annual burden hours per respondent: 0.10 hours (or 6 minutes).

Estimated total annual burden: 2 hours.

Frequency of collection: On occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: December 8, 2025.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2025–22484 Filed 12–10–25; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

[Docket ID: ED–2025–OPE–1009]

Request for Information; Updates to the Accreditation Handbook

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Request for information.

SUMMARY: The U.S. Department of Education (Department) is issuing this request for information (RFI) to receive specific feedback on necessary updates to the Accreditation Handbook. Similar to the update to the Accreditation Handbook undertaken in 2019, the Department seeks to improve this important handbook to communicate clear and concise information to users so that the process for the Department’s recognition of an accrediting agency is transparent, efficient, and not unduly burdensome. This RFI may also inform the Department’s potential reforms to the accreditation regulatory process and may be complimentary to the public comments already received under the Department’s call for Public Feedback for the Development of Proposed Regulations and Establish Negotiated Rulemaking Committee published on April 4, 2025. Information relating to

this RFI or the Accreditation Handbook may also be discussed at future Negotiated Rulemakings held by the Department over the next year.

DATES: Comments must be received on or before January 26, 2026.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at www.regulations.gov. However, if you require an accommodation or cannot otherwise submit your comments via [regulations.gov](http://www.regulations.gov), please contact the program contact listed below under **FOR FURTHER INFORMATION**

CONTACT. The Department will not accept comments by fax or by email, or comments submitted after the comment period closes. To ensure that the Department does not receive duplicate copies, please submit your comments only once. Additionally, please include the Docket ID at the top of the comments.

The Department strongly encourages you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), the Department strongly encourages you to convert the PDF to “print-to-PDF” format, or to use some other commonly used searchable text format. Please do not submit the PDF in a scanned format. Using a print-to-PDF format allows the Department to electronically search and copy certain portions of your submissions to assist in improving the Accreditation Handbook.

Federal eRulemaking Portal: Please go to [regulations.gov](http://www.regulations.gov) to submit your comments electronically. Information on using [regulations.gov](http://www.regulations.gov), including instructions for finding a rule on the site and submitting comments, is available on the site under “FAQ.”

Privacy Note: The Department’s policy is to generally make comments received from members of the public available for public viewing on the Federal eRulemaking Portal at [regulations.gov](http://www.regulations.gov). Therefore, commenters should include in their comments only information about themselves that they wish to make publicly available. Commenters should not include in their comments any information that identifies other individuals or that permits readers to identify other individuals. The Department may not make comments that contain personally identifiable information (PII) about someone other than the commenter publicly available on [regulations.gov](http://www.regulations.gov) for privacy reasons. This may include comments where the commenter refers to a third-party individual without using their name if the Department determines that the comment provides

² 17 CFR 145.9.

enough detail that could allow one or more readers to link the information to the third party. If your comment refers to a third-party individual, to help ensure that your comment is posted, please consider submitting your comment anonymously to reduce the chance that information in your comment about a third party could be linked to the third party. The Department will also not make comments that contain threats of harm to another person or to oneself available on *regulations.gov*.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotope, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Daggett, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. Email: elizabeth.daggett@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Background

The Higher Education Act of 1965 (HEA), as amended, directs the U.S. Department of Education (Department) to determine if an accrediting agency or association is a reliable authority as to the quality of education or training for the purposes of eligibility for title IV, HEA programs or other Federal purposes. The HEA and its implementing regulations further outline criteria an accrediting agency must meet to be recognized by the Department. These include having standards to assess an institution's success with respect to student achievement and other activities, as well as having established procedures to review, evaluate, and withdraw accreditation from an institution or program. This recognition process should ideally ensure that Federal student aid funding, backed by taxpayers, is directed only to institutions or programs that provide a high-quality, high-value postsecondary education. An accrediting agency's oversight and assessment of educational quality are critical components of the program integrity triad, alongside State authorization and institutional certification at the Federal level.

The Department maintains an Accreditation Handbook ("Handbook")

(<https://www.ed.gov/sites/ed/files/admins/finaid/accred/accreditation-handbook.pdf>) to clarify requirements to receive and maintain Department recognition as an accrediting agency or association. The Handbook contains information about the Secretary's Criteria for Recognition and submission information, lists the regulatory requirements, and provides direction as to how an accrediting agency may demonstrate compliance with the requirements of a application for recognition ("petition") and file review. The Handbook does not supersede applicable law or regulations; rather, it is intended to be a useful resource to describe in plain terms how to meet the Secretary's Criteria for Recognition and submit a successful petition to the Department.

Purpose of This Request for Information

As directed by President Trump in Executive Order 14279, Reforming Accreditation to Strengthen Higher Education (April 23, 2025), the Department intends to update the Handbook to ensure that the accrediting agency recognition process is transparent, efficient, and not unduly burdensome. By updating the Handbook, the Department intends to aid reform of the accreditation process in an effort to realign accreditation with evaluating whether an institution provides a high-quality, high-value education for all students. The Executive Order signifies a historic commitment to reforming all aspects of the accreditation process and reduce unnecessary regulatory burdens associated with it. This includes the Department's renewed commitment to undertaking a critical review of the recognition process for both initial and renewing accrediting agencies and improving transparency in the Department's related resources. As such, the Department invites feedback and specific language suggestions on how the Handbook should be updated.

The Department has already implemented certain policy changes and actions it was directed to undertake in Executive Order 14279, including lifting the temporary pause on accepting and reviewing new applications for initial recognition from new accrediting agencies and associations on May 2, 2025. The Department intends to update the Handbook to reflect the resumption of these activities and thoroughly review its existing practices to address any other revisions that may be necessary due to policy position changes.

The Department believes this RFI is a critical next step to gather input on how to reform the accreditation system to improve student outcomes, and this may accompany other actions to implement Executive Order 14279. To that end, the Department particularly invites commenters to consider the following questions:

- What policies or practices should be updated in the current version of the Handbook from February 2022? Are there particular pain points that the Department should be aware of? What policies or standards are encouraging innovation or reducing college costs within the postsecondary education sector and should be retained?
- Are there any inaccuracies, inconsistencies or inclusions within the Handbook that are counter to the regulations contained in 34 CFR 602? Additionally, are there any items within the law or regulations that need further explanation?
- What policies or practices could be clearer? Do interested parties have suggestions on the process by which we update the Handbook in the event Federal regulations are further revised in future rulemakings? In what specific formats would stakeholders prefer to see clarifying information or updates, whether that be via an Electronic Announcement, in a Dear Colleague Letter, or regulations?
- Is the Handbook serving its intended purpose? How can it better assist accrediting agencies and associations in evaluating the quality of educational institutions and programs or in applying for Federal recognition?
- What might be an alternative solution to offer guiding advice to accrediting agencies and associations outside of the Handbook? How can the Handbook be designed to be less burdensome?
- How could accreditation standards be updated to incentivize intellectual diversity on campus? What guidance or standards, if any, can the Handbook provide to institutions and programs to help achieve this goal?
- Keeping in mind that the Department intends to take further action on this subject matter, what would stakeholders suggest as methods to determine appropriate assessment benchmarks, and what data sources or validation methods could be used to ensure those benchmarks reflect student competency? If new assessment methods are developed, how should the Department evaluate the feasibility and administrative burden associated with developing or administering new assessments? How do stakeholders suggest that the Department present

these benchmarks in updated guidance materials?

Commenters may also consider providing comment on the totality of the accreditation process and comment on specific proposals contained within Executive Order 14279, or other innovative ideas related to accreditation. For example, Executive Order 14279 outlines new principles of a student-oriented accreditation system, and information on how these principles may be reflected in an updated Handbook could be useful. The Department also welcomes feedback on any other provisions contained within Executive Order 14279, including how to evaluate credential inflation. This feedback may pertain either to the standards contained in regulations, and how these might be modified by rulemaking, or the Handbook, and whether commenters believe the guidance contained therein incentivizes or encourages credential inflation at institutions.

While feedback received during the previous public comment period on Title IV topics will be used to update the Handbook, the Department believes this RFI is an opportunity for commenters to focus on any specific and additional changes to the Handbook that may be necessary to improve the clarity and ease of use of the Handbook.

The Department also encourages commenters to consider the totality of the Handbook, and its overall usefulness. We invite commenters to propose bold new ideas on how this resource can better help accrediting agencies ultimately validate the highest quality in postsecondary education. Resources like the Handbook should provide clear and concise information on how to comply with the HEA and its implementing regulations but should not include additional compliance requirements or set new policy. Regularly updating the Handbook is crucial for ensuring that the guidance provided to accrediting agencies remain relevant and effective. Overall, an effective Handbook should minimize the number of questions the Department receives from stakeholders, streamline the recognition process for both initial and renewing accrediting agencies, and aid in maintaining the integrity of the accreditation process.

This is an RFI only. This RFI is not a Request for Proposal (RFP) or a promise to publish a revised Handbook in a specific timeline. This RFI does not commit any Department office to contract for any supply or service. We are not seeking contract proposals. The Department will not pay for any information or administrative costs that

you may incur in responding to this RFI. The documents and information submitted in response to this RFI become the property of the U.S. Government and will not be returned.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at govinfo.gov. At this site you can view this document, as well as all other documents ED published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents the Department published in the **Federal Register** by using the article search feature at federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by ED.

David Barker,

Assistant Secretary, Office of Postsecondary Education, U.S. Department of Education.

[FR Doc. 2025–22555 Filed 12–10–25; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. 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 information collection requests a three-year extension of its collection, titled Assistance to Foreign Atomic Energy Activities, OMB Control Number 1901–0263.

DATES: Comments regarding this proposed information collection must be received on or before February 9, 2026. 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 by email to part810@nnsa.doe.gov. Include “Paperwork Reduction Act” in the subject line. Comments can also be sent by mail to Andrew Lyman, Senior Policy Advisor, Office of Nonproliferation and Arms Control, NA–24, National Nuclear Security

Administration, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585. Due to potential delays in DOE’s receipt and processing of mail sent through the U.S. Postal Service, DOE encourages responders to submit comments electronically to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT:

Additional information on DOE’s regulation of assistance to foreign atomic energy activities pursuant to 10 CFR part 810 is available at www.energy.gov/nnsa/10-cfr-part-810. For other questions, email to part810@nnsa.doe.gov or contact Andrew Lyman, Senior Policy Advisor, Office of Nonproliferation and Arms Control, NA–24, National Nuclear Security Administration, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, telephone (202) 287–1025.

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.:* 1901–0263;
- (2) *Information Collection Request Titled:* Assistance to Foreign Atomic Energy Activities;
- (3) *Type of Review:* Extension;
- (4) *Purpose:* This collection of information from U.S. exporters is necessary in order to provide the Secretary of Energy with the appropriate information needed to make informed determinations regarding requests to directly or indirectly engage or participate in the development or production of special nuclear material outside the United States.
- (5) *Annual Estimated Number of Respondents:* 303;
- (6) *Annual Estimated Number of Total Responses:* 681;
- (7) *Annual Estimated Number of Burden Hours:* 1,127;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: \$76,397.
Statutory Authority: Sections 57 b.(2) and 161p. of the Atomic Energy Act of 1954, as amended (AEA), 10 CFR part 810.

Signing Authority

This document of the Department of Energy was signed on December 9, 2025, by Matthew Napoli, Deputy Administrator for Defense Nuclear Nonproliferation, National Nuclear Security Administration, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on December 9, 2025.

Jennifer Hartzell,

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

[FR Doc. 2025–22572 Filed 12–10–25; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2574–094]

Merimil Limited Partnership; Lockwood Holdco, LLC; Notice of Application of Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

On October 8, 2025, the Merimil Limited Partnership (transferor) filed an application with the Federal Energy Regulatory Commission (FERC or Commission) to transfer the license for the 6.92-megawatt Lockwood Hydroelectric Project (project) No. 2574. The project is located on Kennebec River in Kennebec County, Maine and does not occupy federal land.

Pursuant to 16 U.S.C. 801, the applicants seek Commission approval to transfer the license for the project from the Merimil Limited Partnership to the to-be-formed Lockwood Holdco, LLC (transferee). The transferee will be required by the Commission to comply with all the requirements of the license as though it were the original licensee.

Applicants Contacts:

William Fyfe, General Counsel—US, Brookfield Renewable US, 181 Bay Street, Suite 100, Toronto, Ontario M5J 2T3, Canada, william.fyfe@brookfieldrenewable.com.

Julia S. Wood, Rock Creek Energy Group, LLP, 1 Thomas Circle NW, Suite 700, Washington, DC 20005, jwood@rockcreekenergygroup.com.

FERC Contact: Woohee Choi, Phone: (202) 502–6336, Email: Woohee.Choi@ferc.gov.

Deadline for filing comments, motions to intervene, and protests: January 7, 2026 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

In lieu of electronic filing, you may submit a paper copy. Submissions sent via U.S. Postal Service must be addressed to, Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to, Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2574–094. Comments emailed to Commission staff are not considered part of the Commission record.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

(Authority: 18 CFR 2.1)

Dated: December 8, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–22552 Filed 12–10–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15319–001]

Jupiter Pumped Storage 1, LLC; Notice of Surrender of Preliminary Permit

Take notice that Jupiter Pumped Storage 1, LLC, permittee for the proposed Mineral Run Pumped Storage Project No. 15319, has requested that its preliminary permit be terminated. The permit was issued on March 1, 2024, and would have expired on February 29, 2028.¹ The project would have been located in Cambria County, Pennsylvania.

The preliminary permit for Project No. 15319 will remain in effect until the close of business, thirty days from the date of this notice. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.² New applications for this site may not be submitted until after the permit surrender is effective.

(Authority: 18 CFR 2.1)

Dated: December 8, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–22546 Filed 12–10–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15318–001]

Cabin Run Pumped Storage, LLC; Notice of Surrender of Preliminary Permit

Take notice that Cabin Run Pumped Storage, LLC, permittee for the proposed Cabin Run Pumped Storage Project No. 15318, has requested that its preliminary permit be terminated. The permit was issued on April 25, 2024, and would have expired on March 31, 2028.¹ The project would have been located near the Stony River and the unincorporated community of Bismarck in Tucker and Grant Counties, West Virginia.

The preliminary permit for Project No. 15318 will remain in effect until the close of business, thirty days from the

¹ *Jupiter Pumped Storage 1, LLC*, 186 FERC ¶ 62,101 (2024).

² 18 CFR 385.2007(a)(2) (2025).

¹ *Cabin Run Pumped Storage, LLC*, 187 FERC ¶ 61,036 (2024).

date of this notice. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.² New applications for this site may not be submitted until after the permit surrender is effective.

(Authority: 18 CFR 2.1)

Dated: December 8, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–22547 Filed 12–10–25; 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 Instituting Proceedings

Docket Numbers: RP26–280–000.
Applicants: ANR Pipeline Company.
Description: 4(d) Rate Filing: ANR—Neg Rate Agmts Eff 1.1.26 to be effective 1/1/2026.

Filed Date: 12/4/25.

Accession Number: 20251204–5111.

Comment Date: 5 p.m. ET 12/16/25.

Docket Numbers: RP26–281–000.
Applicants: Rendezvous Pipeline Company, LLC.

Description: 4(d) Rate Filing: Normal filing 2026 to be effective 1/4/2026.

Filed Date: 12/4/25.

Accession Number: 20251204–5148.

Comment Date: 5 p.m. ET 12/16/25.

Docket Numbers: RP26–282–000.
Applicants: Discovery Gas Transmission LLC.

Description: 4(d) Rate Filing: GT&C Section 9.9—Cashout Disposition to be effective 1/4/2026.

Filed Date: 12/4/25.

Accession Number: 20251204–5162.

Comment Date: 5 p.m. ET 12/16/25.

Docket Numbers: RP26–283–000.
Applicants: Gillis Hub Pipeline, LLC.
Description: 4(d) Rate Filing: Filing of Negotiated Rate, IW Agreements 12.5.2025 to be effective 12/8/2025.

Filed Date: 12/5/25.

Accession Number: 20251205–5271.

Comment Date: 5 p.m. ET 12/17/25.

Docket Numbers: RP26–284–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: 4(d) Rate Filing: Rate Schedule S–2 Tracker Filing Eff 1/1/2026 to be effective 1/1/2026.

Filed Date: 12/8/25.

Accession Number: 20251208–5159.

Comment Date: 5 p.m. ET 12/22/25.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP26–270–001.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Tariff Amendment: 2025 Interim Fuel Tracker Filing Amendment to be effective 1/1/2026.

Filed Date: 12/4/25.

Accession Number: 20251204–5115.

Comment Date: 5 p.m. ET 12/16/25.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: December 8, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–22550 Filed 12–10–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC26–34–000.

Applicants: Allora Solar, LLC, PGR 2021 Lessee 19, LLC, PGR 2021 Lessee 12, LLC, PGR 2021 Lessee 15, LLC, PGR 2021 Lessee 11, LLC, Cabin Creek Solar, LLC, Gunsight Solar, LLC, Phobos Solar, LLC, Foley Solar, LLC, East Atmore Solar, LLC, Summit Infrastructure LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Allora Solar, LLC, et al.

Filed Date: 12/5/25.

Accession Number: 20251205–5340.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: EC26–35–000.

Applicants: Wisconsin Electric Power Company.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Wisconsin Electric Power Company.

Filed Date: 12/5/25.

Accession Number: 20251205–5341.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: EC26–36–000.

Applicants: Entergy Power, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Entergy Power, LLC.

Filed Date: 12/5/25.

Accession Number: 20251205–5352.

Comment Date: 5 p.m. ET 12/26/25.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG26–90–000.

Applicants: Forgeview Interconnection, LLC.

Description: Forgeview Interconnection, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 12/8/25.

Accession Number: 20251208–5126.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: EG26–91–000.

Applicants: Flat Fork Interconnection, LLC.

Description: Flat Fork Interconnection, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 12/8/25.

Accession Number: 20251208–5129.

Comment Date: 5 p.m. ET 12/29/25.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3285–005; ER10–3177–003.

Applicants: UGI Energy Services, Inc., UGI Utilities Inc.

Description: Triennial Market Power Analysis for Northeast Region of UGI Utilities, Inc., et al.

Filed Date: 12/4/25.

² 18 CFR 385.2007(a)(2) (2025).

Accession Number: 20251204–5206.
Comment Date: 5 p.m. ET 2/2/26.
Docket Numbers: ER14–199–004.
Applicants: Lakewood Cogeneration, L.P.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 12/8/25.

Accession Number: 20251208–5285.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER14–1480–004.

Applicants: KMC Thermo, LLC.

Description: Compliance filing: Settlement Compliance Filing to be effective 8/11/2022.

Filed Date: 12/8/25.

Accession Number: 20251208–5292.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER18–1156–006.

Applicants: St. Joseph Energy Center, LLC.

Description: Compliance filing: Settlement Compliance Filing to be effective 11/8/2024.

Filed Date: 12/8/25.

Accession Number: 20251208–5294.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER20–2452–008.

Applicants: Hamilton Liberty LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 12/8/25.

Accession Number: 20251208–5262.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER20–2453–009.

Applicants: Hamilton Patriot LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 12/8/25.

Accession Number: 20251208–5273.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER21–1807–010.

Applicants: Hill Top Energy Center LLC.

Description: Compliance filing: Settlement Compliance Filing to be effective 4/1/2025.

Filed Date: 12/8/25.

Accession Number: 20251208–5291.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER22–291–002.

Applicants: PSEG Fossil LLC.

Description: Compliance filing: Parkway Generation Operating LLC submits tariff filing per 35: Settlement Compliance Filing to be effective 12/29/2021.

Filed Date: 12/8/25.

Accession Number: 20251208–5299.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER26–198–000.

Applicants: GCF US Holdings LLC.

Description: Response to 11/25/2025, Deficiency Letter of GCF US Holdings LLC.

Filed Date: 12/8/25.

Accession Number: 20251208–5261.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER26–198–001.

Applicants: GCF US Holdings LLC.

Description: Tariff Amendment: Response to Deficiency Notice to be effective 12/1/2025.

Filed Date: 12/5/25

Accession Number: 20251205–5329.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–678–000.

Applicants: Crowned Ridge Energy Storage I, LLC.

Description: 205(d) Rate Filing: Crowned Ridge Energy Storage I, LLC MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5284.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–679–000.

Applicants: Tuscola II Energy Storage, LLC.

Description: 205(d) Rate Filing: Tuscola II Energy Storage MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5286.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–680–000.

Applicants: Tournesol Solar, LLC.

Description: 205(d) Rate Filing: Tournesol Solar, MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5290.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–681–000.

Applicants: Dunns Bridge Solar II, LLC.

Description: 205(d) Rate Filing: Dunns Bridge Solar II, LLC MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5293.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–682–000.

Applicants: Scarborough Solar, LLC.

Description: 205(d) Rate Filing: Scarborough Solar MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5296.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–683–000.

Applicants: Reynolds Solar, LLC.

Description: 205(d) Rate Filing: Reynolds Solar MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5298.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–684–000.

Applicants: Flat Fork Interconnection, LLC.

Description: 205(d) Rate Filing: Flat Fork Interconnection MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5302.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–685–000.

Applicants: New Madrid Energy Storage, LLC.

Description: 205(d) Rate Filing: New Madrid Energy Storage MBR

Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5304.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–686–000.

Applicants: Merom Solar, LLC.

Description: 205(d) Rate Filing: Merom Solar MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5308.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–687–000.

Applicants: Forgeview Interconnection, LLC.

Description: 205(d) Rate Filing: Forgeview Interconnection MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5311.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–688–000.

Applicants: Mayhew Lake Energy Storage, LLC.

Description: 205(d) Rate Filing:

Mayhew Lake Energy Storage MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5314.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–689–000.

Applicants: Forgeview Surplus Energy Storage, LLC.

Description: 205(d) Rate Filing: Forgeview Surplus Energy Storage MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5318.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–690–000.

Applicants: Iberville Energy Storage, LLC.

Description: 205(d) Rate Filing:

Iberville Energy Storage MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5322.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–691–000.

Applicants: Geaux Energy Storage, LLC.

Description: 205(d) Rate Filing: Geaux Energy Storage MBR Application to be effective 2/4/2026.

Filed Date: 12/5/25.

Accession Number: 20251205–5326.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–692–000.

Applicants: Southwestern Public Service Company.

Description: Request for Limited Waiver, et al. of Southwestern Public Service Company.

Filed Date: 12/5/25.

Accession Number: 20251205–5331.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ER26–693–000.

Applicants: Six One Energy Corporation.

Description: 205(d) Rate Filing: Notice of Succession to be effective 12/9/2025.

Filed Date: 12/8/25.

Accession Number: 20251208–5132.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER26–694–000.

Applicants: PacifiCorp.

Description: 205(d) Rate Filing: Calpine NITSA Rev 20 (SA No. 299) to be effective 1/1/2026.

Filed Date: 12/8/25.

Accession Number: 20251208–5148.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER26–695–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: DEA, SA No. 7744 between PJM and PPL Electric Utilities Corp. to be effective 11/7/2025.

Filed Date: 12/8/25.

Accession Number: 20251208–5220.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER26–696–000.

Applicants: Dodge Flat Energy Storage, LLC.

Description: 205(d) Rate Filing: Dodge Flat Energy Storage—Application for MBR Authorization—Refile to be effective 2/7/2026.

Filed Date: 12/8/25.

Accession Number: 20251208–5268.

Comment Date: 5 p.m. ET 12/29/25.

Docket Numbers: ER26–697–000.

Applicants: Heartwood Solar, LLC.

Description: 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 1/7/2026.

Filed Date: 12/8/25.

Accession Number: 20251208–5278.

Comment Date: 5 p.m. ET 12/29/25.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES26–21–000.

Applicants: Mid-Atlantic Interstate Transmission, LLC.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Mid-Atlantic Interstate Transmission, LLC.

Filed Date: 12/4/25.

Accession Number: 20251204–5205.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ES26–22–000.

Applicants: ITC Great Plains, LLC.

Description: Application Under Section 204 of the Federal Power Act for

Authorization to Issue Securities of ITC Great Plains, LLC.

Filed Date: 12/5/25.

Accession Number: 20251205–5350.

Comment Date: 5 p.m. ET 12/26/25.

Docket Numbers: ES26–23–000.

Applicants: Entergy Arkansas, LLC.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Entergy Arkansas, LLC.

Filed Date: 12/8/25.

Accession Number: 20251208–5283.

Comment Date: 5 p.m. ET 12/29/25.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: December 8, 2025.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2025–22549 Filed 12–10–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP25–552–000]

Algonquin Gas Transmission, LLC; Notice of Schedule for the Preparation of an Environmental Assessment for the Cape Cod Canal Pipeline Relocation Project

On September 29, 2025, Algonquin Gas Transmission, LLC (Algonquin) filed an application in Docket No. CP25–552 requesting a Certificate of Public Convenience and Necessity

pursuant to Section 7(c) and Authorization pursuant to Section 7(b) of the Natural Gas Act to construct and operate, and to abandon certain natural gas pipeline facilities. The proposed project is known as the Cape Cod Canal Pipeline Relocation Project (Project). Algonquin would modify its existing interstate natural gas pipeline system facilities within the Town of Bourne, Barnstable County, Massachusetts, to accommodate the planned replacement of the Bourne Bridge and Sagamore Bridge by the Cape Cod Bridges Program while continuing to provide uninterrupted natural gas service to the National Grid distribution system on both sides of the Cape Cod Canal.¹

On October 8, 2025, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.² The EA will be issued for a 30-day comment period.

Schedule for Environmental Review

Issuance of EA—April 17, 2026
90-day Federal Authorization Decision Deadline³—July 16, 2026

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Project would consist of the following facilities and activities:

- installation of approximately 3.0 miles of 16-inch-diameter and

¹ The U.S. Army Corps of Engineers owns and operates the Bourne and Sagamore Bridges and the Cape Cod Canal and is jointly implementing the Cape Cod Bridges Program with the Massachusetts Department of Transportation.

² For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1763050824.

³ The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

approximately 2.2 miles of 18-inch-diameter pipeline to replace National Grid's existing pipelines currently attached to the existing Bourne and Sagamore Bridges;

- relocation of approximately 0.4 mile of existing 8-inch-diameter and 0.7 mile of 18-inch-diameter pipelines adjacent to the existing Sagamore and Bourne Bridges;
- abandonment by removal or in place of approximately 3.0 miles of existing 8-inch-diameter and 0.5 mile of 18-inch-diameter pipelines;
- removal and relocation of two existing mainland meter and regulating (M&R) stations—Sagamore and Bourne—that are within the footprint of the Cape Cod Bridges Program workspace; and
- installation of two new M&R stations—Pave Paws Road and Bourne Rotary.

Background

On April 3, 2025, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Planned Cape Cod Canal Bridge Relocation Project and Notice of Public Scoping Session* (Notice of Scoping).⁴ The Notice of Scoping was issued during the pre-filing review of the Project in Docket No. PF25–4 and was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the Notice of Scoping, the Commission received comments from the Cape Cod Chamber of Commerce, the Cape & Islands Bridges Coalition, the Berkshire Environmental Action Team, one landowner, and 18 other individuals. The primary and relevant issues raised by the commenters were the purpose and need for the Project; effects to sensitive resources in the Project area (e.g., wetlands, sole source aquifers, and listed species); effects to local traffic and noise during construction; and effects to air quality during operations. All substantive comments will be addressed in the EA.

The U.S. Army Corps of Engineers, U.S. Environmental Protection Agency, and the Massachusetts Army National Guard are cooperating agencies in the preparation of the EA.

⁴ During pre-filing, Algonquin changed the name of the FERC-jurisdictional Project to avoid confusion with replacement of the Bourne and Sagamore Bridges planned by the Cape Cod Bridges Program.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or request for rehearing contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Additional information about the Project is available from the FERC website (www.ferc.gov). Using the “eLibrary” link, select “General Search” from the eLibrary menu, enter the selected date range and “Docket Number” excluding the last three digits (i.e., CP25–552), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

(Authority: 18 CFR 2.1)

Dated: December 8, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–22551 Filed 12–10–25; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11286–030]

City of Abbeville; Notice of Application Tendered for Filing With The Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

- Type of Application:* New Major License.
- Project No.:* 11286–030.
- Date filed:* November 25, 2025.
- Applicant:* City of Abbeville.
- Name of Project:* Abbeville Hydroelectric Project (project).

f. *Location:* On the Rocky River in Abbeville and Anderson Counties, South Carolina.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Tim Hall, Director of Public Utilities, City of Abbeville, 306 Cambridge Street, Abbeville, SC 29620; Phone: (864) 366–5058, Email: thall@abbevillecitysc.com.

i. *FERC Contact:* Kristine Sillett at (202) 502–6575 or kristine.sillett@ferc.gov.

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. See, 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* on or before 5:00 p.m. Eastern Time on January 26, 2026.¹

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 10,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy via U.S. Postal Service to: DebbieAnne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

¹ Sixty days from the filing of the application is January 24, 2026, which is a Saturday. Therefore, the due date is the following business day.

Submissions sent via any other carrier must be addressed to: Debbie Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–11286–030.

m. The application is not ready for environmental analysis at this time.

n. *The project consists of:* (1) a 1,362-acre impoundment (Lake Secession) having a storage capacity of 25,650 acre-feet at elevation 548.0 feet National Geodetic Vertical Datum (NGVD); (2) a multi-section dam consisting of: an 80-foot east concrete abutment, a 360-foot, multiple arch buttress dam including five arches topped with wooden flashboards, a 124-foot west concrete abutment, a 910-foot earthen embankment, and an 87-foot-long

concrete gated spillway; (3) a 35.7-foot-wide by 68.3-foot-long powerhouse with two turbine generator units with a total installed capacity of 2.6 megawatts; (4) 150-foot, 2.4-kilovolt generator leads connecting the project to the project switchyard; and (5) appurtenant facilities.

o. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (e.g., license application) via the internet through the Commission’s Home Page (<http://www.ferc.gov>) using the “eLibrary” link. Enter the docket number excluding the last three digits in the docket number field to access the document (P–11286).

For assistance, contact FERC at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/FERConline.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

q. *Procedural schedule and final amendments:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Issue Deficiency Letter and Request Additional Information	February 2026.
Deficiency/Additional Information Responses Due	May 2026.
Issue Acceptance Letter and Notice	June 2026.
Issue Scoping Notice	June 2026.
Scoping Comments due	August 2026.
Issue Ready for Environmental Analysis Notice	September 2026.

r. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

(Authority: 18 CFR 2.1)

Dated: December 8, 2025.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2025–22548 Filed 12–10–25; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–SFUND–2006–0361; FRL–13108–01–OLEM]

Agency Information Collection Activities; Proposed Information Collection Request; Comment Request; Trade Secret Claims for Community Right-to-Know and Emergency Planning (Renewal), EPA ICR No. 1428.13, OMB Control No. 2050–0078

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “Trade Secrets Claims for Community Right-To-Know and Emergency

Planning” (EPA ICR No. 1428.13, OMB Control No. 2050–0078) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described in **SUPPLEMENTARY INFORMATION**. This is a proposed extension of the ICR, which is currently approved through June 30, 2026. This document allows 60 days for public comments.

DATES: Comments may be submitted on or before February 9, 2026.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–SFUND–2006–0361, to EPA online using <https://www.regulations.gov> (our preferred method), or by mail to: EPA Docket Center, U.S. Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. EPA’s policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: William Noggle, Environmental

Protection Agency, 1200 Pennsylvania Ave. NW, Mail Code 5101T, Washington, DC 20460; telephone number: (202) 566–1306; email address: noggle.william@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through June 30, 2026. 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.

This document allows 60 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at <https://www.regulations.gov> or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about EPA’s public docket, visit <https://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the

accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate forms of information technology. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** document to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This information collection request pertains to trade secrecy claims submitted under section 322 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). EPCRA contains provisions requiring facilities to report to state and local authorities, and EPA, the presence of extremely hazardous substances (section 302), inventory of hazardous chemicals (sections 311 and 312) and manufacture, process and use of toxic chemicals (section 313). Section 322 of EPCRA allows a facility to withhold the specific chemical identity from these EPCRA reports if the facility asserts a trade secret claim for that chemical identity. The provisions in section 322 establish the requirements and procedures that facilities must follow to request trade secret treatment of chemical identities, as well as the procedures for submitting public petitions to the Agency for review of the "sufficiency" of trade secret claims.

Trade secret protection is provided for specific chemical identities contained in reports submitted under each of the following sections of EPCRA: (1) Section 303(d)(2)—Facility notification of changes that have or are about to occur; (2) section 303(d)(3)—Local Emergency Planning Committee (LEPC) requests for facility information to develop or implement emergency plans; (3) section 311—Material Safety Data Sheets (MSDSs) submitted by facilities, or lists of those chemicals submitted in place of

the MSDSs; (4) section 312—Emergency and Hazardous Chemical Inventory forms (Tier I and Tier II); and (5) section 313—Toxic chemical release inventory form.

The burden estimates, numbers and types of respondents, wage rates and unit and total costs for this ICR renewal will be revised and updated if needed during the 60-day comment period while the ICR Supporting Statement is undergoing review at OMB.

Form numbers: EPA Form 9510–1.

Respondents/affected entities: Entities potentially affected by this action are manufacturer and non-manufacturer facilities subject to reporting under sections 303, 311, 312 or 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA).

Respondent's obligation to respond: Mandatory if a respondent decides to make a trade secret claim for the chemical identity for any of the chemicals in any of the reports the respondent is required to submit under EPCRA sections 303, 311, 312 or 313.

Estimated number of respondents: 283 trade secret claims.

Frequency of response: Annual, with reports submitted under sections 312 and 313.

Total estimated burden: 2,689 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$164,989 (per year). There are no capital or operation and maintenance costs associated with this ICR.

Changes in the estimates: The burden hours are likely to stay substantially the same.

Andrew Baca,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2025–22527 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0720; FRL–12989–01]

Pesticide Registration Review; Pesticide Dockets Opened for Review and Comment; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of the EPA's work plans and registration review case dockets for the following chemicals: Copper pyrrithione and urea. EPA is opening a 60-day public comment period for these work plans and case dockets.

DATES: Comments must be received on or before February 9, 2026.

ADDRESSES: Submit your comments, to the docket identification (ID) number for the specific pesticide of interest provided in Table 1 of Unit I, by one of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- **Mail:** <https://www.epa.gov/dockets/where-send-comments-epa-dockets>. OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

FOR FURTHER INFORMATION CONTACT: For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in Table 1 of Unit I.

For general questions on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0701; email address: biscoe.melanie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Purpose of This Notice

Pursuant to 40 CFR 155.50(b), this notice announces the availability of the EPA's work plans and registration review case dockets for the pesticides shown in Table 1 and opens a 60-day public comment period on the work plans and case dockets.

TABLE 1—WORK PLANS BEING MADE AVAILABLE FOR PUBLIC COMMENT

Registration review case name and number	Docket ID number	Chemical review manager and contact information
Copper Pyrrithione, Case Number 5082	EPA–HQ–OPP–2025–0018	Megan Snyderman. snyderman.megan@epa.gov (202) 566–0639.

TABLE 1—WORK PLANS BEING MADE AVAILABLE FOR PUBLIC COMMENT—Continued

Registration review case name and number	Docket ID number	Chemical review manager and contact information
Urea, Case Number 4095	EPA-HQ-OPP-2024-0218	Areej Jahangir. jahangir.areej@epa.gov (202) 566-1577.

II. Background

EPA is conducting its registration review of the chemicals listed in Table 1 of Unit I pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(g) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. FIFRA section 3(g) provides, among other things, that pesticide registrations are to be reviewed every 15 years. Consistent with 40 CFR 155.57, in its final registration review decision, EPA will ultimately determine whether a pesticide continues to meet the registration standard in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)).

Pursuant to 40 CFR 155.50, EPA initiates a registration review by establishing a public docket for a pesticide registration review case. Registration review dockets contain information that will assist the public in understanding the types of information and issues that the Agency has consider during registration review. Consistent with 40 CFR 155.50(a), these dockets may include information from the Agency’s files including, but not limited to, an overview of the registration review case status, a list of current product registrations and registrants, any **Federal Register** notices regarding any pending registration actions, any **Federal Register** notices regarding current or pending tolerances, risk assessments, bibliographies concerning current registrations, summaries of incident data, and any other pertinent data or information. EPA includes in these dockets a Preliminary Work Plan (PWP), and in some cases a continuing work plan (CWP), summarizing information EPA has on the pesticide and the anticipated path forward.

Consistent with 40 CFR 155.50(b), EPA provides for at least a 60-day public comment period on work plans and registration review dockets. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary changes to a pesticide’s workplan. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the agency should consider

during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

For additional background on the registration review program, see: <https://www.epa.gov/pesticide-reevaluation>.

III. What should I consider as I prepare a comment for EPA?

This notice is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager identified in Table 1 of Unit I. In submitting a comment to EPA, please consider the following:

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

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

All comments should be submitted using the methods in **ADDRESSES** and must be received by the EPA on or before the closing date. These comments

will become part of the docket for the pesticides included in Table 1 of Unit I. The Agency will consider all comments received by the closing date and may respond to comments in a “Response to Comments Memorandum” in the docket or the Final Work Plan (FWP), as appropriate.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 2, 2025.

Jean Anne Overstreet,
Director, Pesticide Re-Evaluation Division,
Office of Pesticide Programs.

[FR Doc. 2025-22514 Filed 12-10-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OLEM-2018-0013; FRL-13076-01-OLEM]

Agency Information Collection Activities; Proposed Information Collection Request; Comment Request; Revisions to the RCRA Definition of Solid Waste, EPA ICR No. 2310.08, OMB Control No. 2050-0202

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “Revisions to the RCRA Definition of Solid Waste” (EPA ICR No. 2310.08, OMB Control No. 2050-0202) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described in **SUPPLEMENTARY INFORMATION**. This is a proposed extension of the ICR, which is currently approved through June 30, 2026. This document allows 60 days for public comments.

DATES: Comments may be submitted on or before February 9, 2026.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-OLEM-2018-0013, to EPA online using <https://www.regulations.gov> (our preferred method), or by mail to: EPA

Docket Center, U.S. Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Mail Code 5101T, Washington, DC 20460; telephone number: (202) 566-0453; vyas.peggy@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through June 30, 2026. 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.

This document allows 60 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at <https://www.regulations.gov> or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA's public docket, visit <https://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate forms of information technology. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** document to announce the

submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: In 2018, the EPA published final revisions to the definition of solid waste that exclude certain hazardous secondary materials from regulation (83 FR 24664, May 30, 2018). The 2018 final rule was promulgated in response to orders issued by the United States Court of Appeals for the District of Columbia Circuit on July 7, 2017, and amended on March 6, 2018, vacating certain provisions of the 2015 rule and reinstated corresponding provisions from the 2008 rule. The information requirements help ensure that (1) entities operating under the regulatory exclusions are held accountable to the applicable requirements; (2) state inspectors can verify compliance with the restrictions and conditions of the exclusions when needed; and (3) hazardous secondary materials exported for recycling are handled as commodities abroad. Recordkeeping requirements include:

- Under the generator-controlled exclusion at 40 CFR 261.4(a)(23), the tolling contractor has to maintain at its facility for no less than three years records of hazardous secondary materials received pursuant to its written contract with the tolling manufacturer, and the tolling manufacturer must maintain at its facility for no less than three years records of hazardous secondary materials shipped pursuant to its written contract with the tolling contractor. In addition, facilities performing the recycling of hazardous secondary materials under the generator-controlled exclusions at 40 CFR 261.4(a)(23) must maintain documentation of their legitimacy determination onsite.

- Under the transfer-based exclusion at 40 CFR 261.4(a)(24), a generator sending secondary hazardous materials to a facility that does not have a permit, would be required to conduct a "reasonable efforts" environmental audit of the receiving facility; and a hazardous secondary materials recycler must meet the following conditions: having financial assurance in place, having trained personnel, and meeting emergency preparedness and response conditions.

- Under the export requirements of the transfer-based exclusion at 40 CFR 261.4(a)(25), exporters of hazardous secondary material must provide notice and obtain consent of the receiving country and file an annual report.

- Under the remanufacturing exclusion at 40 CFR 261.4(a)(27), both the hazardous secondary material

generator and the remanufacturer must maintain records of shipments and confirmations of receipts for a period of three years from the dates of the shipments.

- Under the revised speculative accumulation requirement in 40 CFR 261.1(c)(8), all persons subject to the speculative accumulation requirements must label the storage unit by indicating the first date that the material began to be accumulated.

Form numbers: None.

Respondents/affected entities: Entities potentially affected by this action are private business or other for-profit, as well as State, Local, or Tribal governments.

Respondent's obligation to respond: Required to obtain or retain a benefit (42 U.S.C. 6921, 6922, 6923, and 6924).

Estimated number of respondents: 4,800.

Frequency of response: On occasion.

Total estimated burden: 27,055 hours per year. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$2,933,678 (per year), which includes \$18,403 in annualized capital or operation & maintenance costs.

Changes in the estimates: The burden hours are likely to stay substantially the same.

Dated: November 13, 2025.

Andrew Baca,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2025-22529 Filed 12-10-25; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 13093-01-OA]

Farm, Ranch, and Rural Communities Advisory Committee (FRRCC); Notice of Charter Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has determined that, in accordance with the provisions of the Federal Advisory Committee Act (FACA), the Farm, Ranch, and Rural Communities Advisory Committee (FRRCC) is in the public interest and supports EPA in performing its duties and responsibilities. Accordingly, the FRRCC will be renewed for an additional two-year period. The purpose of the FRRCC is to provide advice and recommendations to the EPA

Administrator on environmental issues and policies that are of importance to agriculture and rural communities. Inquiries may be directed to Susan Park, Deputy Associate Administrator for Strategic Initiatives, Office of External Affairs, U.S. EPA, 1200 Pennsylvania Avenue NW, Washington, DC 20460, or FRRC@epa.gov.

Dated: November 20, 2025.

Henry Turner Bridgforth,
Senior Advisor for Agriculture and Rural Affairs.

[FR Doc. 2025–22561 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–13101–01–OMS]

Senior Executive Service Performance Review Board; Membership

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given of the membership of the U.S. Environmental Protection Agency (EPA) Performance Review Board for 2025.

FOR FURTHER INFORMATION CONTACT: Kyle Barja, Director, Executive Resources Staff Office, Office of the Chief Human Capital Officer, Office of Finance and Administration, U.S. Environmental Protection Agency, 109 T.W. Alexander Drive, Research Triangle Park, North Carolina 27703, telephone number: (919) 541–2477, email address: barja.kyle@epa.gov.

SUPPLEMENTARY INFORMATION: Section 4314(c)(1) through (5) of title 5, U.S.C., requires each agency to establish in accordance with regulations prescribed by the Office of Personnel Management, one or more SES performance review boards. This board shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointment authority relative to the performance of the senior executive. Members of the 2025 EPA Performance Review Board are:

Kyle Barja, (Ex-Officio) Director, Executive Resources Staff Office, Office of the Chief Human Capital Officer, Office of Finance and Administration.

Wesley Carpenter, (Ex-Officio) Deputy Chief of Staff for Management, Office of the Administrator.

Robert Coomber, Senior Advisor for Resources and Information, Office of Finance and Administration.

Michael Harris, Director, Superfund and Emergency Management Division, Region 5.

Mara J. Kamen, (Ex-Officio) Deputy Chief Human Capital Officer and Deputy Director, Office of the Chief Human Capital Officer, Office of Finance and Administration.

Javier Laureano, Director, Water Division, Region 2.

Wynne Miller, Deputy Director, Office of Wastewater Management, Office of Water.

Emma Pokon, Regional Administrator, Region 10.

Craig Pritzlaff, Principal Deputy Assistant Administrator, Office of Enforcement and Compliance Assurance.

Angel Robinson, Director, Office of Budget and Performance, Office of Finance and Administration.

Erika Sasser, Director, Impacts and Ambient Standards Division.

Cheryl Seager, Director, Enforcement and Compliance Assurance Division, Region 6.

Gregg Trembl, (Ex-Officio) Deputy Chief Financial Officer and Deputy Chief Administrative Officer, Office of Finance and Administration.

Krysti Wells, (Ex-Officio) Chief Human Capital Officer and Director, Office of the Chief Human Capital Officer, Office of Finance and Administration.

Mara J. Kamen,

EPA Deputy Chief Human Capital Officer, Office of the Chief Human Capital Officer, Office of Finance and Administration.

[FR Doc. 2025–22520 Filed 12–10–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2018–0102; FRL–13077–01–OLEM]

Agency Information Collection Activities; Proposed Information Collection Request; Comment Request; RCRA Expanded Public Participation, EPA ICR No. 1688.11, OMB Control No. 2050–0149

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “RCRA Expanded Public Participation” (EPA ICR No. 1688.11, OMB Control No. 2050–0149) to the Office of Management and Budget (OMB) for review and approval in accordance with the

Paperwork Reduction Act (PRA). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described in **SUPPLEMENTARY INFORMATION**. This is a proposed extension of the ICR, which is currently approved through June 30, 2026. This document allows 60 days for public comments.

DATES: Comments may be submitted on or before February 9, 2026.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OLEM–2018–0102, to EPA online using <https://www.regulations.gov> (our preferred method), or by mail to: EPA Docket Center, U.S. Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Mail Code 5101T, Washington, DC 20460; telephone number: (202) 566–0453; vyas.peggy@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through June 30, 2026. 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.

This document allows 60 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at <https://www.regulations.gov> or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about EPA's public docket, visit <https://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the

accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate forms of information technology. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** document to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Section 7004(b) of RCRA gives EPA broad authority to provide for, encourage, and assist public participation in the development, revision, implementation, and enforcement of any regulation, guideline, information, or program under RCRA. In addition, the statute specifies certain public notices (*i.e.*, radio, newspaper, and a letter to relevant agencies) that EPA must provide before issuing any RCRA permit. The statute also establishes a process by which the public can dispute a permit and request a public hearing to discuss it. EPA carries out much of its RCRA public involvement at 40 CFR parts 124 and 270.

Form numbers: None.

Respondents/affected entities: Entities potentially affected by this action are businesses and other for-profit.

Respondent's obligation to respond: Mandatory (RCRA 7004(b)).

Estimated number of respondents: 47.

Frequency of response: On occasion.

Total estimated burden: 4,474 hours per year. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$336,413 (per year), includes \$4,863 annualized capital or operation & maintenance costs.

Changes in the estimates: The burden hours are likely to stay substantially the same.

Dated: November 13, 2025.

Andrew Baca,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2025-22528 Filed 12-10-25; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Deputy Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than December 26, 2025.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001. Comments can also be sent electronically to KCApplicationComments@kc.frb.org:

1. *The Mary Ellen Wall 2021 Legacy Trust* dated May 11, 2021, *James N. Wall Marital Trust A*, and *James N. Wall Marital Trust B*, all of *Ada, Oklahoma*, *Mary Ellen Wall, Shawnee, Oklahoma*, and *Vision Bank, Ada, Oklahoma*, as co-trustees of each trust; the *Amy Wall Coroma Trust, Ada, Oklahoma*, *Amy Coroma, Union, Missouri*, and *Vision Bank* as co-trustees; *Laura Wall Cox Trust, Ada, Oklahoma*, *Laura Cox, Norman, Oklahoma*, and *Vision Bank* as

co-trustees; *Jamie Wall Hammons Trust, Ada, Oklahoma*, *Jamie Hammons, Shawnee, Oklahoma*, and *Vision Bank* as co-trustees; *Nancy Wall Vincent Trust, Ada, Oklahoma*, *Nancy Vincent, Tomball, Texas*, and *Vision Bank* as co-trustees; and the *Elizabeth Wall Trust, Ada, Oklahoma*, *Elizabeth Wall, Shawnee, Oklahoma*, and *Vision Bank* as co-trustees; to join the Wall Family Control Group, a group acting in concert, to retain voting shares of Vision Bancshares, Inc., Ada, Oklahoma, and thereby indirectly retain voting shares of Vision Bank, Ada, Oklahoma.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025-22568 Filed 12-10-25; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business

information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Deputy Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than December 26, 2025.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

1. *Costellis International Limited, Tortola, British Virgin Islands; and Inter & Co, Inc. and Banco Inter S.A., both of Minas Gerais, Brazil, through Inter & Co's subsidiary holding company, Inter US Holding Inc., Miami, Florida, its subsidiaries, Inter & Co Securities LLC, Inter US Finance LLC, Inter US Management LLC, and Inter & Co US Advisors LLC, all of Miami, Florida, as well as through Banco Inter S.A.'s subsidiary, Inter & Co Payments, Inc., Miami, Florida*; in connection with the establishment of a state-licensed foreign branch, to continue to engage in certain permissible nonbanking activities, including (i) extending credit and servicing loans through Inter US Finance LLC pursuant to section 225.28(b)(1), (ii) asset management and investment advisory activities through Inter US Management LLC pursuant to sections 225.28(b)(2)(vi) and 225.28(b)(6), (iii) investment advisory activities through Inter & Co US Advisors LLC pursuant to section 225.28(b)(6), (iv) securities brokerage activities through Inter & Co Securities LLC pursuant to section 225.28(b)(7), and (v) money transmission services conducted through Inter & Co Payments, Inc. pursuant to section 225.28(b)(13), all of the Board's Regulation Y.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025-22569 Filed 12-10-25; 8:45 am]

BILLING CODE P

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0024; Docket No. 2025-0054; Sequence No. 1]

Information Collection; Buy American, Trade Agreements, and Duty-Free Entry

AGENCY: Office of Federal Procurement Policy (OFPP), Office of Management and Budget (OMB); Department of Defense (DOD); General Services Administration (GSA); and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and OMB regulations, OFPP, DoD, GSA, and NASA invite the public to comment on an extension concerning Buy American, trade agreements, and duty-free entry. OFPP, DoD, GSA, and NASA invite comments on: whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through February 28, 2026. OFPP, DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: OFPP, DoD, GSA, and NASA will consider all comments received by February 9, 2026.

ADDRESSES: OFPP, DoD, GSA, and NASA invite interested persons to submit comments on this collection through <https://www.regulations.gov> and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are

difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202-501-4755 or GSARegSec@gsa.gov.

Instructions: All items submitted must cite OMB Control No. 9000-0024, Buy American, Trade Agreements, and Duty-Free Entry. 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 www.regulations.gov, approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: FARPolicy@gsa.gov or call 202-969-4075.

SUPPLEMENTARY INFORMATION:

A. OMB control number, Title, and any Associated Form(s): 9000-0024, Buy American, Trade Agreements, and Duty-Free Entry.

B. Need and Uses: This clearance covers the information that an offeror must submit in response to the requirements of the provisions and clauses in the Federal Acquisition Regulation (FAR) part 25, as codified in Chapter 1 of Title 48 of the Code of Federal Regulations, that relates to the following:

- * The Buy American statute (41 U.S.C. chapter 83) and Executive Orders 10582 and 14005.

- * The Trade Agreements Act (19 U.S.C. 2501-2515), including the World Trade Organization Government Procurement Agreement and various free trade agreements.

- * The American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act).

- * Subchapters VIII and X of Chapter 98 of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202).

FAR 52.225-2, Buy American Certificate. This provision requires the offeror to identify in its proposal supplies that do not meet the definition of domestic end product and whether those supplies exceed 55% domestic content. This provision also requires offerors to identify in its proposal domestic end products that contain a critical component.

FAR 52.225-4, Buy American—Free Trade Agreements—Israeli Trade Act Certificate. This provision requires a separate list of foreign products that are eligible under a trade agreement, and a list of all other foreign end products and whether those supplies exceed 55% domestic content. This provision also requires offerors to identify in its proposal domestic end products that contain a critical component.

FAR 52.225–6, Trade Agreements Certificate. This provision requires the offeror to certify that all end products are either U.S.-made or designated country end products, except as listed in paragraph (b) of the provision. Offerors are not allowed to provide other than a U.S.-made or designated country end product, unless the requirement is waived.

FAR 52.225–8, Duty-Free Entry. This clause requires contractors to notify the contracting officer when they purchase foreign supplies, in order to determine whether the supplies should be duty-free. The notice shall identify the foreign supplies, estimate the amount of duty, and the country of origin. The contractor is not required to identify foreign supplies that are identical in nature to items purchased by the contractor or any subcontractor in connection with its commercial business, and segregation of these supplies to ensure use only on Government contracts containing duty-free entry provisions is not economical or feasible. In addition, all shipping documents and containers must specify certain information to assure the duty-free entry of the supplies.

Construction provisions and clauses:

- FAR 52.225–9, Buy American—Construction Materials
- FAR 52.225–10, Notice of Buy American Requirement—Construction Materials
- FAR 52.225–11, Buy American—Construction Materials Under Trade Agreements
- FAR 52.225–12, Notice of Buy American Requirement—Construction Materials under Trade Agreements
- FAR 52.225–21, Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials
- FAR 52.225–23, Required Use of American Iron, Steel, and Manufactured Goods—Buy American Statute—Construction Materials Under Trade Agreements

The listed provisions and clauses provide that an offeror or contractor requesting to use foreign construction material due to unreasonable cost of domestic construction material shall provide adequate information to permit evaluation of the request.

For supplies acquisitions, the contracting officer uses some of the information to identify the offered items that comply with the requirements of the Buy American statute and trade agreements and whether the supplies should be granted duty-free entry. For construction acquisitions, the contracting officer uses the information

to evaluate requests for a determination of inapplicability of the Buy American statute.

C. Annual Burden:

Respondents: 9,279.

Total Annual Responses: 34,535.

Total Burden Hours: 29,138.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry.

Janet Fry,

*Director, Federal Acquisition Policy Division,
Office of Governmentwide Acquisition Policy,
Office of Acquisition Policy, Office of
Governmentwide Policy.*

[FR Doc. 2025–22581 Filed 12–10–25; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the reinstatement without change of the previously approved information collection project “Surveys on Patient Safety Culture Hospital Database” (OMB No. 0935–0162). This information collection was previously published in the **Federal Register** on September 15, 2025, and allowed 60 days for public comment. AHRQ received one comment from the public that was not responsive. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by January 12, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Copies of the proposed collection plans, data collection instruments, and

specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Margie Shofer, AHRQ Reports Clearance Officer, 301–427–1696 or by email at REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Surveys on Patient Safety Culture Hospital Database

Project Overview

The Surveys on Patient Safety Culture® (SOPS®) Hospital Survey is designed to enable hospitals to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. In 2004, Version 1.0 of the survey, which includes 42 items that measure 12 composites of patient safety culture, was released on the AHRQ website. AHRQ made the survey publicly available along with a Survey User’s Guide and other toolkit materials. In 2019, an updated version of the survey, Version 2.0, was released on the AHRQ website. This version includes a total of 40 items: 32 items across 10 composite measures, 2 single-item measures, and 6 background questions.

The AHRQ SOPS Hospital Database consists of data from the AHRQ SOPS Hospital Survey 2.0 and may include reportable, non-required supplemental items. Hospitals in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The SOPS Hospital Database (OMB NO. 0935–0162, last approved on October 18, 2022) was developed by AHRQ in 2006 in response to requests from hospitals interested in tracking their own survey results. Organizations submitting data receive a feedback report, as well as a report of the aggregated, de-identified findings of the other hospitals submitting data. These reports are used to assist hospital staff in their efforts to improve patient safety culture in their organizations.

AHRQ requests that OMB approve the extension, without change, of AHRQ’s collection of information for the AHRQ SOPS Hospital Database; OMB NO. 0935–0162, last approved on October 18, 2022.

The SOPS Hospital Database seeks to answer the following research questions:

1. What is the current state of patient safety culture in hospitals?
2. Has there been a change in patient safety culture scores since the previous database?

3. Are there differences in scores based on staff position and unit/work area?

This research has the following goals:

1. Produce aggregated results from hospitals that voluntarily submit their data; and

2. Provide feedback reports to hospitals that voluntarily submit their data to help them identify their strengths and areas for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ’s statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to surveys and database development [42 U.S.C 299a(a)(1) and (8)].

Method of Collection

1. Hospital Eligibility and Registration Form—The hospital point-of-contact (POC) completes several data submission forms, beginning with the completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the hospital and initiate the registration process.

2. Hospital Site Information—The purpose of the site information form, also completed by the hospital POC, is to collect background characteristics of the hospital. This information will be used to analyze data collected with the SOPS Hospital Survey.

3. Data Use Agreement—The purpose of the data use agreement, submitted by the hospital POC, is to state how data submitted by hospitals will be used and to provide privacy assurances.

4. SOPS Hospital Data File(s) Submission—The hospital POC uploads their data file(s), using the SOPS Hospital Survey data file specifications to ensure that users submit their data in a standardized way (e.g., variable names, order, coding, formatting). The number of submissions to the database is likely to vary from submission period to submission period because hospitals do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either a patient safety manager in the hospital or a survey vendor who contracts with a hospital to collect and submit their data. On average, hospital POCs submit data on behalf of 3 hospitals because many hospitals are part of a health system that includes many hospitals, or the POC is a vendor

that is submitting data for multiple hospitals.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents’ time to participate in the database. An estimated 165 POCs, each representing an average of 3 individual hospitals, will complete the database submission steps and forms annually. Each POC will submit the following:

1. Hospital Eligibility and Registration Form—Completed once by 165 hospital POCs. The form takes about 3 minutes to complete.
2. Hospital Site Information—Completed an average of three times by the 165 hospital POCs. The form takes 5 minutes to complete.
3. Data Use Agreement—Completed once by 165 hospital POCs. The form takes about 3 minutes to complete.
4. SOPS Hospital Survey Data File(s) Submission—Each of the 165 POCs will submit their SOPS Hospital Survey Data. The data submission requires an hour on average to complete.

The total annual burden hours are estimated to be 222 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents’ time to submit their data. The cost burden is estimated to be \$31,880 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
1. Hospital Eligibility/Registration Form	165	1	3/60	8
2. Hospital Site Information	165	3	5/60	41
3. Data Use Agreement	165	1	3/60	8
4. SOPS Hospital Survey Data File(s) Submission	165	1	1	165
Total	N/A	N/A	N/A	222

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Adjusted hourly rate**	Total cost burden
1. Hospital Eligibility/Registration Form	165	8	\$71.80	\$143.60	\$1,149
2. Hospital Site Information	165	41	71.80	143.60	5,888
3. Data Use Agreement	165	8	71.80	143.60	1,149
4. SOPS Hospital Survey Data File(s) Submission	165	165	71.80	143.60	23,694
Total	N/A	N/A	N/A	N/A	31,880

* Mean hourly wage of \$71.80 for Medical and Health Services Managers (SOC code 11–9111) was obtained from the May 2024 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—Hospitals, located at <https://data.bls.gov/oes/#/industry/622000>.
** The Adjusted Hourly Rate was estimated at 200% of the hourly wage.

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ’s information collection are requested with regard to

any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ’s health care research and health care information dissemination

functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) of

information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: December 1, 2025.

Mamatha Pancholi,
Deputy Director.

[FR Doc. 2025-22531 Filed 12-10-25; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2025-0651]

Draft Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among Healthcare Personnel and Patients: Conjunctivitis Section

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain comment on the *Draft Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among Healthcare Personnel and Patients: Conjunctivitis Section* ("Draft Guideline"). The *Draft Guideline* includes updates to the *Guideline for infection control in health care personnel, 1998* ("1998 Guideline"), *Part E: Epidemiology and Control of Selected Infections Transmitted Among Health Care Personnel and Patients*, and its corresponding recommendations in Part II of the 1998 *Guideline*: "2. Conjunctivitis." The updated recommendations in the *Draft Guideline* are intended for use by the leaders and staff of Occupational Health Services (OHS), as further provided herein. These updated recommendations will help facilitate the provision of occupational infection prevention and control services to healthcare personnel

(HCP) who have been exposed or infected and may be contagious to others in the workplace.

DATES: Written comments must be received on or before February 9, 2026.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2025-0651 by either of the methods listed below. *Do not submit comments by email. CDC does not accept comments by email.*

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Prevention and Response Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H16-3, Atlanta, Georgia 30329, Attn: Docket Number CDC-2025-0651.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Laura Wells, Prevention and Response Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H16-3, Atlanta, Georgia 30329; Telephone: (404) 639-4000.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data related to the *Draft Guideline*.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. *Do not submit comments by email. CDC does not accept comment by email.*

Background

The *Draft Guideline*, located in the "Supporting & Related Material" tab of the docket, includes updates to the *Guideline for infection control in health care personnel, 1998, Part E: Epidemiology and Control of Selected Infections Transmitted Among Health Care Personnel and Patients*, and its corresponding recommendations in Part II of the 1998 *Guideline*: "2. Conjunctivitis." The 1998 *Guideline* provided information and recommendations for Occupational Health Services (OHS) of healthcare facilities and systems on the prevention of transmission of infectious diseases among HCP and patients and can be found at <https://stacks.cdc.gov/view/cdc/11563>.

As described in the Executive Summary of Part I of this guideline (<https://www.cdc.gov/infection-control/hcp/healthcare-personnel-infrastructure-routine-practices/executive-summary.html>), in this document, "OHS" is used synonymously with "Employee Health," "Employee Health Services," "Employee Health and Safety," "Occupational Health," and other such programs. OHS refers to the group, department, or program that addresses many aspects of health and safety in the workplace for HCP, including the provision of clinical services for work-related injuries, exposures, and illnesses. In healthcare settings, OHS addresses workplace hazards including communicable diseases; slips, trips, and falls; patient handling injuries; chemical exposures; HCP burnout; and workplace violence.

The *Draft Guideline*, once finalized, is intended for use by the leaders and staff of OHS to guide the management of exposed or infected HCP who may be contagious to others in the workplace. The draft recommendations in the *Draft Guideline* provide current guidance on the management of HCP exposed to or infected with conjunctivitis, focusing on postexposure management, including postexposure prophylaxis, for exposed HCP and work restrictions for exposed or infected HCP.

Beginning in 2015, the Healthcare Infection Control Practices Advisory Committee (HICPAC) worked with national partners, academicians, public health professionals, healthcare providers, and other partners to develop *Infection Control in Healthcare Personnel* (Part I: <https://www.cdc.gov/infection-control/hcp/healthcare-personnel-infrastructure-routine-practices/index.html>; Part II: <https://www.cdc.gov/infection-control/hcp/>

healthcare-personnel-epidemiology-control/index.html) as a segmental update of the 1998 Guideline. HICPAC, now terminated, was a federal advisory committee appointed to provide advice and guidance to HHS and CDC regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance, and related events in United States healthcare settings. HICPAC included representatives from public health, infectious diseases, regulatory and other federal agencies, professional societies, and other stakeholders. HICPAC reviewed and voted to approve the draft recommendations in the *Draft Guideline* prior to being terminated. Additional information on HICPAC's input into the update of the *Infection Control in Healthcare Personnel Guideline* can be found in the Methods Appendix included in the "Supporting & Related Material" tab of the docket.

The updated draft recommendations in the *Draft Guideline* are informed by reviews of the 1998 Guideline; CDC resources (e.g., CDC infection control website), guidance, and guidelines, as noted more specifically in the draft document; and new scientific evidence, when available. A Methods Appendix for *Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among Healthcare Personnel and Patients* (<https://www.cdc.gov/infection-control/hcp/healthcare-personnel-epidemiology-control/index.html>) is included in the "Supporting & Related Material" tab of the docket. This information is being provided as supporting material, and CDC is not seeking comments on the Methods Appendix. The *Draft Guideline*, once finalized, will be the next section to be posted to the *Infection Control in Healthcare Personnel* website.

CDC is seeking comments on the *Draft Guideline*. Please provide references to new evidence and justification to support any suggested revisions or additions. After comments received are considered and addressed, the final recommendations will be published on CDC's website here: <https://www.cdc.gov/infection-control/hcp/healthcare-personnel-epidemiology-control/index.html>. The final recommendations will also be posted to docket CDC-2025-0651 at www.regulations.gov.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2025-22539 Filed 12-10-25; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10062 and CMS-10942]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 9, 2026.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier: ____/OMB Control Number: ____, Room C4-26-05 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments; *Use:* Section 1853 of the Social Security Act, hereafter referred to as "the Act," requires CMS to make advance monthly payments to a Medicare Advantage (MA) organization for each beneficiary enrolled in an MA plan offered by the organization for coverage of Medicare Part A and Part B benefits. Section 1853(a)(1)(C) of the Act requires CMS to adjust the monthly payment amount for each enrollee to take into account the health status of MA plan enrollees. Under the CMS Hierarchical Condition Category (HCC) risk adjustment payment methodology,

CMS determines risk scores for MA enrollees for a year and uses the appropriate enrollee risk score to adjust the monthly payment amount.

CMS used RAPS data, in combination with encounter data and Fee-For-Service (FFS) data, to develop the diagnosis-based portion of the risk scores for risk adjusted payment to MA organizations, PACE organizations, and MMPs. *Form Number:* CMS-10662 (OMB control number: 0938-0878); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 189; *Total Annual Responses:* 29,729,927; *Total Annual Hours:* 990,007. (For policy questions regarding this collection contact Sage Pasquale at 410-786-0091)

2. Type of Information Collection Request: New collection (Request for a new OMB control number); *Title of Information Collection:* State Exchange Improper Payment Measurement (SEIPM); *Use:* The Payment Integrity Information Act of 2019 (PIIA) requires Federal agencies to annually identify, review, measure, and report on the programs they administer that have been determined to be susceptible to significant improper payments. In 2016, HHS determined that payments of APTC are susceptible to significant improper payments and, as a result, are subject to the requirements of PIIA. In accordance with 45 CFR part 155, FFEs, SBE-FPs, and state Exchanges that operate their own eligibility and enrollment systems, determine the amount of APTC to be paid to qualified applicants. Starting in the FY22 Agency Financial Report (AFR), HHS began annually reporting improper payments of APTC administered through FFEs and SBE-FPs as part of the Exchange Improper Payment Measurement (EIPM) program. In 2024, HHS required State Exchanges to participate in the Improper Payment Pre-Testing and Assessment (IPPTA) to prepare State Exchanges for the future implementation of the SEIPM program.

HHS proposes to require state Exchanges to submit to HHS, a sample of tax household information from Qualified Health Plans (QHPs) that have associated APTC payments, for the purpose of being reviewed for improper payments. HHS proposes that the sample size would be of a sufficient quantity to produce a statistically valid estimate of improper payments and in accordance with requirements established by the Office of Management and Budget (OMB). HHS proposes that the measurement of all state Exchanges would occur on an annual basis unless otherwise determined by HHS. The calculated estimate of improper

payments would be reported annually in the HHS Agency Financial Report (AFR) as an aggregate rate across all state Exchanges. At HHS' discretion, contractors would be used to support these activities. The burden associated with completion and return of the proposed required information will be the time it will take each state Exchange to meet with HHS to review the information. We estimate that the burden associated with this data collection and transfer will be no more than 8 hours for each sample collected. *Form Number:* CMS-10942 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 800. (For policy questions regarding this collection contact Halina DeSantis at halina.desantis@cms.hhs.gov)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025-22478 Filed 12-10-25; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10065/10066, CMS-10637 and CMS-10338]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of

the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by January 12, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

FOR FURTHER INFORMATION CONTACT:

William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

1. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Hospital Notices: IM/DND; *Use:* This information collection applies to beneficiaries in Original Medicare and enrollees in Medicare health plans. The purpose of

the IM is to inform beneficiaries and enrollees of their rights as hospital inpatients and how to request a discharge appeal by a Quality Improvement Organization (QIO) and how to file a request. Consistent with 42 CFR 405.1205 for Original Medicare and 422.620 for Medicare health plans, hospitals must provide the initial IM within 2 calendar days of admission. A follow-up copy of the signed IM is given no more than 2 calendar days before discharge. The follow-up copy is not required if the first IM is provided within 2 calendar days of discharge. *Form Number:* CMS–10065/10066 (OMB control number: 0938–1019); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for profits, Not for profit institutions; *Number of Respondents:* 25,397,156; *Annual Responses:* 25,397,156; *Total Annual Hours:* 4,313,823. (For policy questions regarding this collection contact: Katherine Hosna at 410–786–4993 or KatherineHosna@cms.hhs.gov).

2. Type of Information Collection
Request: Reinstatement without change of a previously approved collection;
Title of Information Collection: Marketplace Operations; *Use:* On June 19, 2013, HHS published the proposed rule CMS–9957–P: Program Integrity: Exchanges, SHOP, Premium Stabilization Programs, and Market Standards (78 FR 37302) (Program Integrity Proposed Rule). Among other things, the Program Integrity Proposed Rule sets forth financial integrity provisions and protections against fraud and abuse. On January 30, 2013, CMS published Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges under the Affordable Care Act (CMS–2334–P) (E&E II Proposed Rule). On August 30, 2013, HHS published the final rule CMS–9957–F: Program Integrity: Exchanges, SHOP, Eligibility Appeals (Program Integrity Final Rule), finalizing a number of the provisions from the Program Integrity and E&E II Proposed Rules. The third-party disclosure requirements and data collections in the Program Integrity Final Rule support the oversight of qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FfEs) and other provisions. *Form Number:* CMS–10637 (OMB control number 0938–1353); *Frequency:* Annually; *Affected Public:* State, Local or Tribal Governments; Private Sector—Business or other for-profits and Not-for-profits Institutions; *Number of Respondents:* 503; *Number of Responses:* 503; *Total Annual Hours:* 2,325,320. (For questions regarding this

collection, contact Nikolas Berkobien at 667–290–9903).

3. Type of Information Collection
Request: Reinstatement without change of a previously approved collection;
Title of Information Collection: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; *Use:* PHS Act section 2719 and paragraph (b)(2)(i) of the Appeals regulation provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503–1 of the Department of Labor (DOL) claims procedure regulation, and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulation. Paragraph (b)(3)(i) requires issuers offering coverage in the individual health insurance market to also comply with the DOL claims procedure regulation as updated by the Secretary of Health and Human Services (HHS) in paragraph (b)(3)(ii) of the Appeals regulation for their internal claims and appeals processes.

The information collection requirements included in the DOL claims procedure regulation and the Appeals regulation ensure that claimants receive clear and adequate information regarding the plan's claims procedures and the plan's handling of specific benefit claims. This transparency enables claimants to understand plan procedures and decisions, allowing them to effectively request benefits and appeal denied claims when necessary. The information collected in connection with the HHS-administered federal external review process is collected by HHS and is used to provide claimants with an independent external review, ensuring a fair and impartial assessment of denied health benefit claims. *Form Number:* CMS–10338 (OMB control number: 0938–1099); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 91,355; *Total Annual Responses:* 375,202; *Total Annual Hours:* 861,785. (For policy questions regarding this collection contact Daniel Kidane at Daniel.Kidane@cms.hhs.gov.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–22482 Filed 12–10–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6743]

Food and Drug Administration Expert Panel on Testosterone Replacement Therapy for Men; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a request for information from interested parties and the public to share their perspectives with FDA on testosterone replacement therapy for men. The Agency intends to use the information submitted to help inform considerations related to testosterone therapy for men.

DATES: Either electronic or written comments on the notice must be submitted by February 9, 2026.

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 February 9, 2026. 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-2025-N-6743 for “Food and Drug Administration Expert Panel on Testosterone Replacement Therapy for Men; Request for Information.” 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>.

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: Renu Lal, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 240-753-3395, druginfo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA plans to hold an Expert Panel on December 10, 2025, on Testosterone Replacement Therapy (TRT) for Men (the panel). The purpose of the panel is to allow individual panel members to share their perspectives on TRT.

During the meeting, FDA anticipates that the panel members may discuss a range of topics related to the risks and benefits of male hormone therapy. The panel may include discussion of myths surrounding testosterone, and its perception as a lifestyle medication. FDA anticipates that panel members may review data regarding trends in average testosterone levels in men over recent decades, the potential causes, preventive strategies, and a variety of other related issues.

Patient safety remains FDA’s top priority, and any potential new indications will be based on rigorous scientific evidence and comprehensive risk-benefit analysis. The panel members may discuss safety concerns including, but not limited to, cardiovascular risks, prostate health, fertility impairment, and potential for abuse.

This multi-stakeholder panel will include healthcare professionals, researchers, industry representatives, and military health experts to ensure comprehensive perspectives. FDA recognizes the unique needs of different populations, including military personnel facing specific occupational health challenges. Evidence-based protocols that healthcare providers can confidently implement were discussed by the panel. Any potential updates to testosterone labeling, including revisions to approved indications, will undergo the FDA’s standard rigorous review process. FDA will continue robust oversight of both prescription

testosterone therapies and over-the-counter supplements.

II. Purpose of Request for Information

This request for information provides an opportunity for interested parties and the public—including commercial drug developers, health care providers, consumers, and other relevant groups—to share their perspectives with FDA on the indications, dosing, route of administration, duration of treatment, and goals of treatment. Specifically, FDA is interested in perspectives on the scientific, regulatory, and practical considerations that shape testosterone use.

III. Questions for Consideration

We seek input on the questions presented below. While the questions are aimed at gathering information most pertinent to the administration of TRT for men, we welcome any additional data and information regarding the real-world prescribing patterns and clinical uses for TRT that may improve our understanding and advance our public health mission. To help FDA review comments efficiently, please identify the question to which you are responding by its associated category and number. If you are responding to more than one question, please identify each question to which you are responding, and categorize each response by question.

A. General

1. What are the potential impacts of TRT on: cardiovascular and thromboembolic disease, genitourinary systems, musculoskeletal health, frailty, and depression?

2. How do the risks and benefits of TRT differ based on timing of hormone initiation, age of initiation of treatment, duration of use, formulation (type of testosterone replacement used), dose, and route of administration?

3. What are the biggest opportunities to improve education of providers and patients concerning the prescription of TRT?

4. How could interested parties—including, but not limited to, drug developers, health care providers, patients, consumers, and retailers—work together to further identify therapeutic uses of TRT and generate evidence supporting the safety and efficacy of these uses?

B. Scientific Considerations

1. FDA seeks input on definitions and diagnostic thresholds for age-related androgen deficiency.

2. FDA seeks input on research priorities that could enhance the

scientific understanding of TRT for men, including areas where additional evidence or data generation may be most valuable.

3. What scientific barriers might limit progress in increasing the availability of TRT?

4. What additional scientific tools, technologies, or data sources could support the availability of TRT?

5. Are there specific diseases or conditions that have not, traditionally, been treated with TRT for which testosterone could be safely and effectively used and which are currently not indicated in FDA-approved product labeling? If so, please provide the data or evidence supporting these potential uses.

(Authority: 21 U.S.C. 355.)

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22466 Filed 12–10–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Transition to Independence.

Date: January 15, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Delia Tang, MD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W602, MSC 9750, Bethesda, MD 20892, 240–276–6456, tangd@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 8, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22521 Filed 12–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIH Pathway to Independence Award (Parent K99/R00-Independent Clinical Trial Not Allowed).

Date: January 28, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Hailey P. Weerts, Ph.D., Scientific Review Officer, BG 5601 Fishers Lane Room 3G74, 5601 Fishers Lane, Rockville, MD 20852, (240) 669–5931, hailey.weerts@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 8, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22494 Filed 12–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Hepatobiliary Pathophysiology Study Section.

Date: January 8–9, 2026.

Time: 9:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jianxin Hu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2156, Bethesda, MD 20892, 301–827–4417, jianxinh@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 8, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22523 Filed 12–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–AI–24–080 Broad Spectrum Products Against Multiple Neurotoxin Botulinum Serotypes(R61/R33 Clinical Trial Not Allowed).

Date: January 14, 2026.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marcus Ferrone, Pharm.d., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–2371, marcus.ferrone@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 8, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22497 Filed 12–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program

Projects: Specialized Alcohol Research Centers.

Date: January 13, 2026.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Janetta Lun, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 827–4588, janetta.lun@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Limited Competition: National Primate Research Centers (P51).

Date: January 14–16, 2026.

Time: 12:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Zhuqing Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892–9834, (240) 669–5068, zhuqing.li@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Research Training Programs.

Date: January 21, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Manas Chattopadhyay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20872, (301) 443–7368, manasc@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 9, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22575 Filed 12–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a

meeting of the National Deafness and Other Communication Disorders Advisory Council.

This meeting is virtual and will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: January 22, 2026.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Rebecca Wagenaar-Miller, Ph.D., Director, Division of Extramural Activities, NIDCD/NIH, 6001 Executive Boulevard, Bethesda, MD 20892, (301) 496–8693, rebecca.wagenaar-miller@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <https://www.nidcd.nih.gov/about/advisory-council>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: December 9, 2025.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22577 Filed 12–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

Date: January 8–9, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W120, Bethesda, MD 20892, 240–276–6457, mh101v@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 8, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22522 Filed 12–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

This is a virtual meeting and will be open to the public. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: January 22, 2026.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: Staff Reports on Divisional, Programmatic, and Special Activities.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Rebecca Wagenaar-Miller, Ph.D., Director, Division of Extramural Activities, NIDCD/NIH, 6001 Executive Boulevard, Bethesda, MD 20892, (301) 496–8693, rebecca.wagenaar-miller@nih.gov.

Information is also available on the Institute's/Center's home page: <https://www.nidcd.nih.gov/about/advisory-council>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: December 9, 2025.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22576 Filed 12–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0350]

Notice of Availability of Record of Decision for the Hawaii-California Training and Testing Final Supplemental Environmental Impact Statement/Overseas Environmental Impact Statement

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces its decision to conduct training and testing activities within the Hawaii-California Training and Testing (HCTT) Study Area as described in Alternative 1 of the HCTT Final Environmental Impact Statement (EIS)/Overseas EIS (OEIS).

DATES: The Coast Guard's Record of Decision is dated November 28, 2025.

ADDRESSES: The complete text of the Record of Decision (ROD) is available on the project website at www.nepa.navy.mil/hctteis/. Single copies of the ROD are available upon request by contacting: 2703 Martin Luther King Jr. Ave SE, Mail Stop 7Y17–00, Washington, DC 20593–7714. The ROD is also available in the docket, which can be found by searching for docket number USCG–2025–0350 at <https://www.regulations.gov>. Supplementary and supporting documentation, including the Final

Supplementary Environmental Impact Statement, can be found at:

www.nepa.navy.mil/hctteis/.

FOR FURTHER INFORMATION CONTACT: If you have questions about the ROD, contact Andrew Haley, U.S. Coast Guard; email HQS-SMB-CG-47-POLICYREVIEW@uscg.mil.

SUPPLEMENTARY INFORMATION: Pursuant to Section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, Sections 4321 *et seq.* of Title 42 United States Code, the Coast Guard announces its decision to implement the Coast Guard's preferred Alternative, Alternative 1. Alternative 1 is representative of an annual level of training and testing activities that accounts for the natural fluctuations of training cycles, deployment schedules, and use of synthetic training opportunities.

Amy B. Grable,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Capability.

[FR Doc. 2025–22556 Filed 12–10–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number DHS–2025–0283]

Agency Information Collection Activities: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, 1601–0014

AGENCY: Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments.

SUMMARY: The Department of Homeland Security will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted until February 9, 2026. This process is conducted in accordance with 5 CFR 1320.1

ADDRESSES: You may submit comments, identified by docket number Docket # DHS–2025–0283, at:

○ *Federal eRulemaking Portal:* <http://www.regulations.gov>. Please follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number Docket # DHS–2025–0283. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

SUPPLEMENTARY INFORMATION: Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers' needs, Department of Homeland Security (hereafter "the Agency") seeks to obtain OMB approval of a generic clearance to collect qualitative feedback on our service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Improving agency programs requires ongoing assessment of service delivery, by which we mean systematic review of the operation of a program compared to a set of explicit or implicit standards, as a means of contributing to the continuous improvement of the program. The Agency will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements in service delivery based on feedback. The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the

quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, procedures outlined in Question 16 will be followed);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions ;
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study ;
- The collections are voluntary.
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government.
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
- With the exception of information needed to provide reenumeration for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

If these conditions are not met, the Agency will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, a standardized form will be submitted to OMB along with supporting documentation (e.g., a copy of the comment card). The submission will have automatic approval, unless OMB identifies issues within 5 business days.

The types of collections that this generic clearance covers include, but are not limited to:

- Customer comment cards/ complaint forms.
- Small discussion groups.

- Focus Groups of customers, potential customers, delivery partners, or other stakeholders.

- Cognitive laboratory studies, such as those used to refine questions or assess usability of a website;

- Qualitative customer satisfaction surveys (e.g., post-transaction surveys; opt-out web surveys).

- In-person observation testing (e.g., website or software usability tests).

The Agency has established a manager/managing entity to serve for this generic clearance and will conduct an independent review of each information collection to ensure compliance with the terms of this clearance prior to submitting each collection to OMB.

If appropriate, agencies will collect information electronically and/or use online collaboration tools to reduce burden.

Small business or other small entities may be involved in these efforts but the Agency will minimize the burden on them of information collections approved under this clearance by sampling, asking for readily available information, and using short, easy-to-complete information collection instruments.

Without these types of feedback, the Agency will not have timely information to adjust its services to meet customer needs.

If a confidentiality pledge is deemed useful and feasible, the Agency will only include a pledge of confidentiality that is supported by authority established in statute or regulation, that is supported by disclosure and data security policies that are consistent with the pledge, and that does not unnecessarily impede sharing of data with other agencies for compatible confidential use. If the agency includes a pledge of confidentiality, it will include a citation for the statute or regulation supporting the pledge.

There is no change in the information being collected.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security (DHS).

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 1601-0014.

Frequency: On Occasion.

Affected Public: Private Sector and Individual Household Members.

Number of Respondents: 184,902.

Estimated Time Per Respondent: 1 hour.

Total Burden Hours: 300,000.

Robert Dorr,

Executive Director, Business Management Directorate.

[FR Doc. 2025-22566 Filed 12-10-25; 8:45 am]

BILLING CODE 9112-FL-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0105]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Notice of Entry of Appearance as Attorney or Accredited Representative

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 January 12, 2026.

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-2008-0037. All submissions received must include the OMB Control Number 1615-0105 in the body of the letter, the agency name and Docket ID USCIS-2008-0037.

FOR FURTHER INFORMATION CONTACT:

USCIS, Office of Policy and Strategy, Regulatory Coordination Division, John R. Pfirrmann-Powell, Acting Deputy 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, 2025, at 90 FR 35309, allowing for a 60-day public comment period. USCIS received five 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-2008-0037 in the search box. Comments must be submitted in English, or an English translation must be provided. 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 Request: Revision of a Currently Approved Collection.

(2) Title of the Form/Collection: Notice of Entry of Appearance as Attorney or Accredited Representative; Notice of Entry of Appearance as Attorney in Matters Outside the Geographical Confines of the United States.

(3) Agency form number, if any, and the applicable component of the DHS sponsoring the collection: G-28; G-28I; USCIS.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Business or other for-profit. The data collected via the G-28 information collection instruments is used by DHS to determine eligibility of the individual to appear as a representative. Form G-28 is used by attorneys admitted to practice in the United States and accredited representatives of charitable organizations recognized by the Board of Immigration Appeals. Form G-28I is used by attorneys admitted to the practice of law in countries other than the United States and only in matters in DHS offices outside the geographical confines of the United States. If the representative is eligible, the form is filed with the case and the information is entered into DHS systems.

(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 annual respondents for the information collection G-28 (paper filed) is

4,181,229 and the estimated hour burden per response is 0.833 hours; the estimated total number of annual respondents for the information collection G–28 (online filed) is 464,581 and the estimated hour burden per response is 0.667 hours; the estimated total number of annual respondents for the information collection G–28I (paper filed) is 31,362 and the estimated hour burden per response is 0.7 hours.

(6) An estimate of the total public burden (in hours) associated with the collection: The estimated total annual hour burden associated with this collection is 3,814,793 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. Individual forms where the USCIS Form G–28 is filed would generally include a value for costs incurred for attorney services, including filing USCIS Form G–28.

Dated: December 9, 2025,

John R. Pfirrmann-Powell,

Acting Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2025–22573 Filed 12–10–25; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7106–N–10]

Privacy Act of 1974; System of Records

AGENCY: Office of Single Family Program, Office of Housing, HUD.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD) is issuing a public notice of its intent to modify the Office of Single-Family Program Development Privacy Act system of records “Credit Alert Verification Reporting System (CAIVRS).” This System of Records Notice (SORN) is being modified to update the system location, categories of record, authority for maintenance of the system, and record source categories. The updates are explained in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Comments will be accepted on or before January 12, 2026. This proposed action will be effective on the date following the end of the comment

period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number or by one of the following methods:

Federal e-Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: privacy@hud.gov.

Mail: Attention: Privacy Office; Shalanda Capehart, Acting Chief Privacy Officer; Office of the Executive Secretariat; 451 Seventh Street SW, Room 10139, Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov> including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Shalanda Capehart; 451 Seventh Street SW, Room 10139, Washington, DC 20410–0001; telephone number 202–708–3054 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION: HUD is modifying the system of records notice (SORN) for the Credit Alert Verification Reporting System (CAIVRS).

i. The “System Location” section has been updated to include Microsoft Azure Federal Cloud.

ii. The “Categories of Record” section has been revised to accurately reflect CAIVRS data components. The following data elements in the previously published SORN are not contained in CAIVRS and have been removed: Full Name, Date of Birth, Email Address, Work Address, Home Address, Mother’s Maiden Name, and FHA Case Number. Social Security Number, Taxpayer ID Number, and Employer Identification Number comprise all current data elements within CAIVRS and remain as categories of records.

iii. The “Authority for Maintenance” section has been updated for accuracy. The following authorities have been

removed: the Budget and Accounting Acts of 1921 and 1950, as amended; the Debt Collection Act of 1982, as amended; the Deficit Reduction Act of 1984, as amended, and the Debt Collection Improvement Act of 1996, as amended.

iv. The “Record Source Categories” have been revised to accurately reflect the data interfaces with CAIVRS, and to list the agencies from which record sources originate.

SYSTEM NAME AND NUMBER:

Credit Alert Verification Reporting System (CAIVRS)—HUD/HOU–04.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

CAIVRS is located and operated at NASA’s John C. Stennis Space Flight Center, located at 1100 Balch Boulevard, Stennis Space Center, MS 39529–0001, and Microsoft Azure Federal Cloud, US East Data Center in One Microsoft Way, Redmond, Washington 98052–6399.

SYSTEM MANAGER(S):

C. Brian Faux, Director, Office of Single-Family Program Development, United States Department of Housing and Urban Development, 451 7th St. SW, Washington, DC 20410–1000; Phone (202) 674–9348; Email: brian.faux@hud.gov.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 203, National Housing Act, Public Law 73–479 (12 U.S.C. 1709); Section 255, National Housing Act, Public Law 73–479 (12 U.S.C. 1701z–20); Section 165, Housing and Community Development Act of 1987, Public Law 100–242 (42 U.S.C. 3543); Section 31001, Debt Collection Act of 1996 as amended, Public Law 104–134 (31 U.S.C. 7701); Section 31001, Debt Collection Act of 1996 as amended, Public Law 104–134 (31 U.S.C. 3720B); and Office of Management and Budget (OMB) Circulars A–129 (Policies for Federal Credit Programs and Non-Tax Receivables).

PURPOSES(S) OF THE SYSTEM:

The purpose of CAIVRS is to ensure participating Federal agencies and their authorized lenders will comply with the legal requirement to verify individuals applying for a federally backed loan, or other aid, are not presently delinquent on another Federal obligation. CAIVRS is a shared, inter-agency database managed by HUD where participating agencies are required to report delinquent federal debt.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individual borrowers who have applied for Federal housing loans and have fallen delinquent.

CATEGORIES OF RECORDS IN THE SYSTEM:

Social Security Numbers, Taxpayer ID Numbers, and Employer Identification Numbers.

RECORD SOURCE CATEGORIES:

A43C—SF Insurance System—Claims Subsystem, F71—Debt Collection and Asset Management System—Title I, F71A—Debt Collection and Asset Management System—Generic Debt, A75R—Financial Data Mart, P278—Lender Electronic Assessment Portal, DOJ—Department of Justice, SBA—Small Business Administration, USDA—United States Department of Agriculture, ED—Department of Education, VA—Department of Veterans Affairs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

(1) 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.

(2) To Federal, State, and local agencies, their employees, and agents to conduct computer matching programs as regulated by the Privacy Act of 1974, as amended (5 U.S.C. 552a).

(3) To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for: (1) detection, prevention, and recovery of improper payments; (2) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (3) detection of fraud, waste, and abuse by individuals in their operations and programs; or (4) for the purpose of establishing or verifying the eligibility of, or continuing compliance with statutory and regulatory requirements by, applicants for, recipients or beneficiaries of, participants in, or providers of services with respect to, cash or in-kind assistance or payments under Federal benefits programs or recouping payments or delinquent debts under such Federal benefits programs. Records under this routine use may be disclosed only to the extent the information shared is necessary and

relevant to verify pre-award and prepayment requirements before the release of Federal funds or prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(4) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or other agreement for the purposes of statistical analysis and research in support of program operations, management, performance monitoring, evaluation, risk management, and policy development, to otherwise support the Department's mission, or for other research and statistical purposes not otherwise prohibited by law or regulation. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The results of the matched information may not be disclosed in identifiable form.

(5) To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, cooperative agreement, or other agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function.

(6) To contractors, experts, and consultants with whom HUD has a contract, service agreement, or other assignment of the Department, when necessary to utilize data to test new technology and systems designed to enhance program operations and performance.

(7) To appropriate agencies, entities, and persons when (1) HUD suspects or has confirmed that there has been a breach of the system of records; (2) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HUD (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 HUD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(8) To another Federal agency or Federal entity, when HUD 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.

(9) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would help to enforce civil or criminal laws and when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

(10) To a court, magistrate, administrative tribunal, or arbitrator while presenting evidence, including disclosures to opposing counsel or witnesses in civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; when HUD determines that use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where HUD has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

(11) To any component of the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when HUD determines that the use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where the Department of Justice or agency conducting the litigation has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is

likely to affect HUD or any of its components.

(12) To match system users for security purposes. User-provided PII may be shared with HUD departmental enforcement offices and other Federal, state, local or tribal law enforcement agencies if there is reason to believe that a user provided false information to obtain access to the system, and that providing such information would help enforce civil or criminal laws.

(13) To the United States Department of Veterans Affairs (VA), to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

(14) To the United States Small Business Administration (SBA) to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

(15) To the United States Department of Education to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

(16) To the United States Department of Agriculture (USDA) to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

(17) To the United States DOJ to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic only.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Social Security Numbers, Taxpayer ID Numbers, and Employer Identification Numbers.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

All records related to Federal Housing Administration (FHA) Mortgage Credit Alert report will be destroyed according to HUD Schedule Appendix 20 Single Family Home Mortgage Records, item 13B6 which states the following, destroyed when superseded or obsolete.

All records related to FHA Mortgage Credit Verification will be destroyed according to HUD Schedule Appendix 5 Technical Support Records, item 7

which states the following, destroy when superseded or obsolete.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

CAIVRS and its data are located on centralized servers within Federal facilities with access control in place. Physical controls include cypher and combination locks, key card-controlled access, security guards, closed circuit TV, identification badges, and safes. Administrative controls include encryption of back-up data, back-ups secured off-site, methods to ensure only authorized users have access to PII, periodic security audits, and regular monitoring of system users' behavior. Technical controls include encryption of Data at Rest and in Transit, firewalls at HUD and each reporting agency, role-based access controls, user IDs and passwords, Least Privileged access, elevated and/or administrative privileged access, PIV cards, intrusion detection systems. Additional measures to safeguard the system include role-based Privacy Act training required for HUD personnel responsible for CAIVRS system program management, IT security monitoring by the Department of Housing and Urban Development and the Department of Homeland Security.

RECORD ACCESS PROCEDURES:

Individuals requesting records of themselves should address written inquiries to the Department of Housing Urban and Development 451 7th Street SW, Washington, DC 20410-0001. For verification, individuals should provide their full name, current address, and telephone number. In addition, the requester must provide either a notarized statement, or an unsworn declaration made under 24 CFR 16.4.

CONTESTING RECORD PROCEDURES:

The HUD rule for contesting the content of any record pertaining to the individual by the individual concerned is published in 24 CFR 16.8 or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals requesting notification of records of themselves should address written inquiries to the Department of Housing Urban Development, 451 7th Street SW, Washington, DC 20410-0001. For verification purposes, individuals should provide their full name, office or organization where assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement, or an unsworn declaration made under 24 CFR 16.4.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

N/A.

HISTORY:

Docket No. FR-7077-N-16, 88 FR 58595, August 28, 2023.

Shalanda Capehart,

Acting Chief Privacy Officer, Office of Administration.

[FR Doc. 2025-22505 Filed 12-10-25; 8:45 am]

BILLING CODE 4210-67-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-748-749 and 731-TA-1726-1727 (Final)]

Float Glass Products From China and Malaysia; Revised Schedule for the Subject Proceeding

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: December 8, 2025.

FOR FURTHER INFORMATION CONTACT:

Kristina Lara (202-205-3386), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: Effective July 15, 2025, the Commission established a schedule for the conduct of the subject proceeding (90 FR 38991, August 13, 2025). Due to the lapse in appropriations and ensuing cessation of Commission operations, the Commission issued a revised schedule (90 FR 52999, November 24, 2025). Due to the Department of Commerce's tolling of case deadlines by an additional 21 calendar days, the Commission is revising its schedule as follows: the prehearing staff report will be placed in the nonpublic record on January 22, 2026; the deadline for filing prehearing briefs is January 29, 2026; requests to appear at the hearing must be filed with the Secretary to the Commission on or before January 30, 2026; a prehearing

conference will be held on February 3, 2026, if deemed necessary; parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than noon on February 4, 2026; the hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on February 5, 2026; the deadline for filing posthearing briefs and for written statements from any person who has not entered an appearance as a party is February 12, 2026; the Commission will make its final release of information on February 26, 2026; and final party comments are due on March 2, 2026.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: December 8, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-22500 Filed 12-10-25; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-752 and 731-TA-1730 (Final)]

Active Anode Material From China; Revised Schedule for the Subject Proceeding

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: December 9, 2025.

FOR FURTHER INFORMATION CONTACT:

Calvin Chang (202-205-3062), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: Effective July 22, 2025, the Commission established a schedule for the conduct of the subject proceeding (90 FR 38993,

August 13, 2025). Due to the lapse in appropriations, ensuing cessation of Commission operations, and the additional tolling of 21 days by the Department of Commerce, the Commission is revising its schedule as follows: the prehearing staff report will be placed in the nonpublic record on January 21, 2026; the deadline for filing prehearing briefs is February 2, 2026; requests to appear at the hearing must be filed with the Secretary to the Commission on February 3, 2026; a prehearing conference will be held on February 11, 2026, if deemed necessary; parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than noon on February 11, 2026; the hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on February 12, 2026; the deadline for filing posthearing briefs and for written statements from any person who has not entered an appearance as a party is February 19, 2026; the Commission will make its final release of information on March 5, 2026; and final party comments are due on March 9, 2026.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: December 9, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-22574 Filed 12-10-25; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-607]

Nonfat Milk Solids: Competitive Conditions for the United States and Major Foreign Suppliers

AGENCY: United States International Trade Commission.

ACTION: Change in filing deadline for written submissions.

SUMMARY: Due to the lapse in appropriation and ensuing cessation of Commission operations, the Commission has extended the deadline for all other written submissions from

October 14, 2025, to fourteen (14) calendar days after the date of publication of this notice.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be addressed to the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Project Leader Rudy Telles Jr. (202-205-2597 or Rodolfo.Telles@usitc.gov) or Deputy Project Leaders Kim Ha (202-205-3343 or Kim.Ha@usitc.gov) and Ivan Lee (202-205-2163 or Ivan.Lee@usitc.gov) for information specific to this investigation. For information on the legal aspects of this investigation, contact Brian Allen (202-205-3034 or Brian.Allen@usitc.gov) of the Commission's Office of the General Counsel. The media should contact Claire Huber, Office of External Relations (202-205-1819 or Claire.Huber@usitc.gov). Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810. General information concerning the Commission may be obtained by accessing its internet address (<https://www.usitc.gov>). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

SUPPLEMENTARY INFORMATION: The Commission published notice of institution of the above referenced investigation in the **Federal Register** on May 23, 2025 (90 FR 22113, May 23, 2025). Due to the lapse in appropriation and ensuing cessation of Commission operations, the Commission has changed a date announced in that notice. It has extended the deadline for filing all other written submissions from October 14, 2025, to the close of business fourteen (14) calendar days after the date of publication of this notice in the **Federal Register**. All other dates pertaining to this investigation remain the same as in the notice published in the **Federal Register** on May 23, 2025.

By order of the Commission.

Issued: December 8, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–22483 Filed 12–10–25; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1125 (Third Review)]

Electrolytic Manganese Dioxide From China; Revised Schedule for the Subject Proceeding

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: December 8, 2025.

FOR FURTHER INFORMATION CONTACT: Laurel Schwartz (202–205–2398), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: Effective September 5, 2025, the Commission established a schedule for the conduct of the subject proceeding (90 FR 48056, October 3, 2025). Due to the lapse in appropriations and ensuing cessation of Commission operations, the Commission is revising its schedule as follows: the staff report was placed in the nonpublic record on December 4, 2025; comments are due on January 21, 2026.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: December 8, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–22485 Filed 12–10–25; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1439]

Certain Polyvinylidene Fluoride Resins; Notice of Commission Determination Not To Review an Initial Determination Granting a Motion To Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (“ID”) (Order No. 19) granting a motion to amend the complaint and notice of investigation.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5468. 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 February 21, 2025, based on a complaint filed by Syensqo SA of Brussels, Belgium; Solvay Specialty Polymers, USA LLC of Alpharetta, Georgia; and Solvay Specialty Polymers Italy S.P.A. of Bollate, Italy (together, “Complainants”). 90 FR 10082–83 (Feb. 21, 2025). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain polyvinylidene fluoride resins by reason of infringement of claims 1–7, 10, and 12 of U.S. Patent No.

8,337,725. *Id.* The complaint further alleges that a domestic industry exists or is in the process of being established. *Id.* The Commission's notice of investigation named as respondents Inner Mongolia 3F Wanhao, Fluorochemical Industry Co. Ltd. of Fengzhen, China (“3F”); Zhejiang Juhua Co., Ltd. of Quzhou City, China; Zhejiang Fluorine Chemical New Material Co. Ltd. of Shaoxing, China; Hubei Fluorine New Materials Co., Ltd. of Dongtan Village, China; and Sinochem Lantian Co., Ltd. of Hangzhou, China. *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

On April 21, 2025, the Commission terminated the investigation with respect to 3F based on settlement. Order No. 8 (Mar. 28, 2025), *unreviewed by Comm'n Notice* (Apr. 21, 2025).

On November 18, 2025, Complainants moved for leave to amend the complaint and notice of investigation to change the name of two complainants to reflect corporate name changes: (1) Solvay Specialty Polymers, USA LLC to Syensqo Specialty Polymers, USA LLC; and (2) Solvay Specialty Polymers Italy S.P.A. to Syensqo Specialty Polymers Italy S.P.A. No party opposed the motion.

On November 19, 2025, the ALJ issued the subject ID (Order No. 19) granting the motion pursuant to 19 CFR 210.14(b)(1). The ALJ found that there was good cause to change the names of the two complainants to reflect their corporate name changes and that the change would not result in prejudice. No party petitioned for review of the subject ID.

The Commission has determined not to review the subject ID.

The Commission vote for this determination took place on December 5, 2025.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 9, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–22580 Filed 12–10–25; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE**[OMB Number 1103–0117]****Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery****AGENCY:** Community Oriented Policing Services, Department of Justice.**ACTION:** 60-Day notice.

SUMMARY: The Community Oriented Policing Services, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until February 9, 2026.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Marcia Jackson, U.S. Department of Justice, 145 N Street NE, Washington DC 20530.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.
2. *The Title of the Form/Collection:* CRI Customer Satisfaction, CRI Training Evaluations Surveys, and Long Impact Survey.
3. *Affected Public:* Primary: Individuals and Households, Businesses

and Organizations, State, Local or Tribal Government.

4. *Average Expected Annual Number of Activities:* 42.

5. *Average Number of Respondents per Activity:* 51,500.

6. *Annual Responses:* 309,000.

7. *Frequency:* Once.

8. *Average Minutes per Response:* 30 minutes.

9. *Total Estimated Annual Time Burden:* 99,847 hours.

10. *Total Estimated Annual Other Costs Burden:* \$176,925.

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Enterprise Portfolio Management, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: December 9, 2025.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2025–22560 Filed 12–10–25; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF LABOR**Office of Workers' Compensation Programs****[OMB Control No. 1240–0058]****Proposed Extension Without Change of a Currently Approved Collection; Request for Intervention, Longshore and Harbor Workers' Compensation Act****AGENCY:** Office of Workers' Compensation Programs, Labor.**ACTION:** Request for public comments.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, "Request for Intervention." This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA). This request helps to ensure that: requested data can be provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection requirements on respondents can be properly assessed. Currently, DLHWC is soliciting comments on the information collection for LS–4, Attorney Fee Approval Request, LS–5 Application for Special Fund Relief, LS–6

Commutation, LS-7 Request for Intervention, LS-8 Settlement Application Section, LS-9 Stipulation Approval Request by Registered or Certified Mail for Employers and/or Insurance Carriers, Attorney Fee Approval Request, Application for Special Fund Relief, Commutation Application, Request for Intervention, Settlement Application Section, and the Stipulation Approval.

DATES: Consideration will be given to all written comments received by February 9, 2026.

ADDRESSES: You may submit comment as follows. Please note that late, untimely filed comments will not be considered.

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments for WCPO-2025-0072. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket, with no changes. Because your comment will be made public, you are 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 your or anyone else's Social Security number or confidential business information.

- If your comment includes confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission.

Written/Paper Submissions: Submit written/paper submissions in the following way:

- **Mail/Hand Delivery:** Mail or visit DOL-OWCP, Division of Longshore and Harbor Workers' Compensation, 200 Constitution Avenue NW, Room S-3323, Washington, DC 20210.

- OWCP will post your comment as well as any attachments, except for information submitted and marked as confidential, in the docket at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Contact Anjanette Suggs, Office of Workers' Compensation Programs, Longshore and Harbor Workers' Compensation, OWCP/DLHWC at suggs.anjanette@dol.gov (email); by telephone at 202-354-9660.

SUPPLEMENTARY INFORMATION:

I. Background

The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed

and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Office of Workers' Compensation Programs administers the Longshore and Harbor Workers' Compensation Act. The Act provides benefits to workers injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the Longshore Act's coverage to certain other employees.

The Longshore and Harbor Workers' Compensation Act (LHWCA), at 39(a) generally authorizes the Secretary of Labor to prescribe rules and regulations to implement the Act. *See* 33 U.S.C. 939(a).

Attorney Fee Approval Request (LS-4)

When an attorney successfully obtains benefits for the injured worker or survivor, he or she may be entitled to a fee. *See* 33 U.S.C. 928; 20 CFR 702.132. In certain circumstances, the Act shifts payment of the attorney's fee to the employer (or its insurance carrier). 20 CFR 702.134. The appropriate adjudicator—an OWCP District Director, an Administrative Law Judge, the Benefits Review Board or a court—must approve the fee. The District Director rules on attorney fees for services rendered while the case is pending before him or her. 20 CFR 702.132. *See* 20 CFR 702.134. The attorney requesting the District Director's approval must file an itemized fee petition for services performed at the OWCP level. To identify and timely respond to the requests, OWCP is requiring attorneys to submit Form LS-4, Attorney Fee Approval Request. Using this form will speed the processing of attorney fee requests and the payment of such fees.

Application for Special Fund Relief (LS-5)

Under section 8(f) of the Act, 33 U.S.C. 908(f), if a pre-existing disability contributes to a disability or impairment from a subsequent work-related injury, the employer is liable for only the first 104 weeks of permanent disability compensation and the Longshore Special Fund (*see generally* 33 U.S.C. 944) is liable thereafter. *See also* 20 CFR 702.321. Hearing loss claims are different in that the Special Fund pays

for the pre-existing hearing loss and the employer for the added hearing loss. An employer/carrier must submit a request for section 8(f) relief from compensation payments to OWCP; relief may be granted by an OWCP District Director or an Administrative Law Judge.

To identify and timely respond to requests under section 8(f), OWCP is requiring employers/carriers to submit Form LS-5, Application for Special Fund Relief. Form LS-5 reflects the application requirements codified at 20 CFR 702.321.

Commutation Application (LS-6)

When compensation under the LHWCA or the Defense Base Act (DBA), an extension of the LHWCA, is payable to certain aliens who are not residents (or about to become nonresidents) of the United States or Canada, the OWCP Director may commute future periodic payments and require payment equal to one-half of the commuted amount. *See* 33 U.S.C. 909(g); 42 U.S.C. 1652; 20 CFR 702.142; 20 CFR 704.102. The Director may commute compensation payments at his or her option and must commute them upon the application of the employer or insurance carrier.

In response to its LHWCA and DBA stakeholders and to facilitate the commutation of payments to injured workers and the beneficiaries of deceased workers, OWCP is requiring employers and carriers to file Form LS-6 to request commutation.

Request for Intervention (LS-7)

Title 20 CFR 702.311 empowers the District Directors to resolve disputes with respect to claims in a manner designed to protect the rights of the parties and to resolve such disputes at the earliest practicable date. *See* 33 U.S.C. 923(a); 20 CFR 702.301 ("the District Directors are empowered to amicably and promptly resolve such problems by informal procedures"). In some cases, the best resolution method is an informal conference. *See* 20 CFR 702.312–702.316 (establishing guidelines for conducting informal conferences).

Usually, one of the parties requests an intervention or informal conference to assist with dispute resolution. Prior to scheduling an informal conference, the issues in dispute must be established and the District Director, or designee, must determine whether the type of intervention requested is the most effective means for resolving the disputed issues. The purpose of the Form LS-7, Request for Intervention, is to initiate the request for informal dispute resolution.

Settlement Application Section 8(i) (LS-8)

LHWCA section 8(i), 33 U.S.C. 908(i), allows the parties to settle claims for compensation and/or medical benefits. A Settlement Application is time sensitive because once the parties submit a settlement application, the District Director or Administrative Law Judge within thirty days must determine whether the settlement is adequate under the Act and regulations and, if so, issue a Compensation Order approving the settlement application in response.

To facilitate prompt processing of settlement applications, OWCP is requiring the parties to use Form LS-8 which outlines the terms of the settlement and provides the information required to determine the adequacy of the settlement proposal by the regulations. Title 20 CFR 702.242–702.243 authorizes this information collection.

Stipulation Approval Request (LS-9)

The regulations empower District Directors to resolve claims amicably and promptly, and issue formal compensation orders when the parties reach agreement on issues. *See* 20 CFR 702.301, 702.311, 702.315(a). To meet these goals, the District Director may issue an Order Approving Stipulations agreed to by all parties.

To facilitate prompt processing of requests to approve stipulations, OWCP is requiring the parties to use Form LS-9. The parties must attach the signed joint stipulations they wish to have approved. OWCP will prioritize handling of LS-9 forms.

This information collection is currently approved for use through March 31, 2026. Legal authority for this information collection is found at 33 U.S.C. 939(a). Regulatory authority is found at 20 CFR 702.132, 702.134, 702.321, 702.142, 704.102, 702.301, 702.312–702.316, 702.242–702.243, 702.301, 702.311 and 702.315(a).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown

in the **ADDRESSES** section. Written comments will receive consideration and summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB No. 1240–0058.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Office of Workers' Compensation Programs.

OMB Number: 1240–0058.

Type of Review: Extension of currently approved collection.

Title of Collection: Request for Intervention, Longshore and Harbor Workers' Compensation Act.

Form: LS-4, Attorney Fee Approval Request, LS-5 Application for Special Fund Relief, LS-6 Commutation, LS-7 Request for Intervention, LS-8 Settlement Application Section, LS-9 Stipulation Approval Request by Registered or Certified Mail for Employers and/or Insurance Carriers, Attorney Fee Approval Request, Application for Special Fund Relief, Commutation Application, Request for Intervention, Settlement Application Section, and the Stipulation Approval.

OMB Control Number: 1240–0058.

Affected Public: Private Sector, Individuals and Households.

Estimated Number of Respondents: 50,046.

Frequency: On occasion.

Total Estimated Annual Responses: 50,046.

Estimated Average Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 12,512 hours.

Total Estimated Annual Other Cost Burden: \$0.

(Authority: 44 U.S.C. 3506(c)(2)(A)).

Anjanette Suggs,

Agency Clearance Officer.

[FR Doc. 2025–22486 Filed 12–10–25; 8:45 am]

BILLING CODE 4510–CF–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES**National Endowment for the Arts****National Council on the Arts 218th Meeting**

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

ACTION: Notice of Meeting.

SUMMARY: Pursuant to section 10 (a) (2) of the Federal Advisory Committee Act, as amended, notice is hereby given that a meeting of the National Council on the Arts will be held open to the public via videoconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for meeting time and date.

ADDRESSES: The National Endowment for the Arts, Constitution Center, 400 Seventh Street SW, Washington, DC 20560. Please see [arts.gov](https://www.arts.gov) for the most up-to-date information.

FOR FURTHER INFORMATION CONTACT: Office of Public Affairs, National Endowment for the Arts, Washington, DC 20506, at PublicAffairs@arts.gov.

SUPPLEMENTARY INFORMATION: The meeting will take place on January 8, 2026, from 1:00 p.m. to 2:00 p.m., and will be open to the public via videoconference. If, in the course of the open session discussion, it becomes necessary for the Council to discuss non-public commercial or financial information of intrinsic value, the Council will go into closed session pursuant to subsection (c)(4) of the Government in the Sunshine Act, 5 U.S.C. 552b, and in accordance with the March 11, 2022 determination of the Chair. Additionally, discussion concerning purely personal information about individuals, such as personal biographical and salary data or medical information, may be conducted by the Council in closed session in accordance with subsection (c) (6) of 5 U.S.C. 552b.

Detailed Meeting Information*Open Session*

January 8, 2026; 1:00 p.m. to 2:00 p.m.
Location: National Endowment for the Arts, Washington, DC, via videoconference. There will be a discussion of general agency business. Please see arts.gov for the most up-to-date information, including a link to the videoconference.

Dated: December 9, 2025.

Daniel Beattie,

Director, Office of Guidelines and Panel Operations.

[FR Doc. 2025–22532 Filed 12–10–25; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION**Sunshine Act Meetings**

The National Science Board's (NSB) Committee on Science and Engineering Policy (SEP) hereby gives notice of the scheduling of a videoconference for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Monday, December 15, 2025, from 2:00 p.m.–2:30 p.m. Eastern.

PLACE: The meeting will be held by videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA, 22314. Members of the public can observe this meeting through a YouTube livestream. The YouTube link will be available from the NSB meetings web page—<https://www.nsf.gov/nsb/meetings/index.jsp>.

STATUS: Open.

MATTERS TO BE CONSIDERED: Chair's opening remarks; Discussion and vote on *Indicators 2026* special topic; update on prototype *Indicators* index.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is Chris Blair, cblair@nsf.gov, 703/292–7000.

Ann E. Bushmiller,

Senior Counsel to the National Science Board.

[FR Doc. 2025–22503 Filed 12–9–25; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2025–0049]

Information Collection: NRC Form 327, Special Nuclear Material (SNM) and Source Material (SM) Physical Inventory Summary Report, and NUREG/BR–0096, Instructions and Guidance for Completing Physical Inventory

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, NRC Form 327, “Special Nuclear Material (SNM) and Source Material (SM) Physical Inventory Summary Report, and NUREG/BR–0096, Instructions and Guidance for Completing Physical Inventory Summary Reports.”

DATES: Submit comments by February 9, 2026. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2025–0049. Address questions about Docket IDs in [Regulations.gov](https://www.regulations.gov) to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION** section of this document.

- *Mail comments to:* Heather Dempsey, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–

0856; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:**I. Obtaining Information and Submitting Comments***A. Obtaining Information*

Please refer to Docket ID NRC–2025–0049 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2025–0049. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2025–0049 on this website.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML25197A788. The supporting statement is available in ADAMS under Accession No. ML25197A787.

- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. 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 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Acting Clearance Officer, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0856 email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2025–0049, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized as follows.

1. *The title of the information collection:* NRC Form 327, Special Nuclear Material (SNM) and Source Material (SM) Physical Inventory Summary Report, and NUREG/BR-0096, Instructions and Guidance for Completing Physical Inventory Summary Reports.

2. *OMB approval number:* 3150-0139.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Form 327.

5. *How often the collection is required or requested:* Certain licensees possessing strategic SNM are required to report inventories on NRC Form 327 every 6 months. Licensees possessing SNM of moderate strategic significance must report every 9 months. Licensees possessing SNM of low strategic significance must report annually, except one licensee (enrichment facility) that must report its dynamic inventories every 2 months and its static inventory annually, and another licensee (enrichment facility) that reports its dynamic inventories every 3 months and its static inventory every 9 months.

6. *Who will be required or asked to respond:* Fuel facility licensees possessing SNM, *i.e.*, enriched uranium, plutonium, or U-233.

7. *The estimated number of annual responses:* 77.

8. *The estimated number of annual respondents:* 7.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 308.

10. *Abstract:* NRC Form 327 is submitted by certain fuel cycle facility licensees to account for SNM. The data is used by the NRC to assess licensee material control and accounting programs and to confirm the absence of (or detect the occurrence of) SNM theft or diversion. NUREG/BR-0096 provides guidance and instructions for completing the form in accordance with the requirements appropriate for a particular licensee.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: December 8, 2025.

For the Nuclear Regulatory Commission.

Heather Dempsey,

NRC Acting Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025-22476 Filed 12-10-25; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2025-0050]

Information Collection: NRC Form 748, National Source Tracking System Report

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, NRC Form 748, "National Source Tracking System Report."

DATES: Submit comments by February 9, 2026. Comments received after this date

will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0050. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301-415-1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Heather Dempsey, Office of the Chief Information Officer, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-0050 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0050. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2025-0050 on this website.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin ADAMS Public Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at

301–415–4737, or by email to PDR.Resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML25246C245, ML25246C246, ML25246C247, ML25246C248, ML25246C249, ML25246C250, ML25246C252, and ML25246C253, respectively. The supporting statement is available in ADAMS under Accession ML25206A392.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. 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 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- **NRC's Clearance Officer:** A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Acting Clearance Officer, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0856 email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2025–0050, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to

request the OMB's approval for the information collection summarized as follows.

1. *The title of the information collection:* NRC Form 748, National Source Tracking System Report.
2. *OMB approval number:* 3150–0202.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 748.
5. *How often the collection is required or requested:* On occasion (at completion of a transaction, and at inventory reconciliation).
6. *Who will be required or asked to respond:* Licensees that manufacture, receive, transfer, disassemble, or dispose of nationally tracked sources.
7. *The estimated number of annual responses:* 17,825.
8. *The estimated number of annual respondents:* 977.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 2,181.

10. **Abstract:** The NRC's National Source Tracking System (NSTS) is a secure, centralized database used to track the life cycle of certain high-risk sealed radioactive sources. Licensees are required to report key transactions involving these nationally tracked sources, including manufacture, transfer, receipt, disassembly, and disposal. These reporting requirements, first established in 2006 and fully implemented in subsequent years, support a comprehensive radioactive source control program for radioactive materials of greatest concern. Information collected through the NSTS is mandatory and plays a critical role in enhancing the NRC's and Agreement States' ability to track sources from manufacture through final disposition. The NSTS strengthens regulatory oversight by supporting inspections and investigations, enabling timely communication with other government agencies, and verifying the legitimate ownership and use of these sources.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.
2. Is the estimate of the burden of the information collection accurate? Please explain your answer.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents

be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: December 8, 2025.

For the Nuclear Regulatory Commission.

Heather Dempsey,

NRC Acting Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025–22477 Filed 12–10–25; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0064]

Information Collection: NRC Form 790, Classification Record

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, NRC Form 790, “Classification Record.”

DATES: Submit comments by February 9, 2026. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject); however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- **Federal rulemaking website:** Go to <https://www.regulations.gov> and search for Docket ID NRC–2022–0064. Address questions about Docket IDs in [Regulations.gov](https://www.regulations.gov) to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** Heather Dempsey, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:**I. Obtaining Information and Submitting Comments****A. Obtaining Information**

Please refer to Docket ID NRC-2022-0064 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website*: Go to <https://www.regulations.gov> and search for Docket ID NRC-2022-0064. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2022-0064 on this website.

- *NRC's Agencywide Documents Access and Management System (ADAMS)*: You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin ADAMS Public Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession ML25196A334. The supporting statement is available in ADAMS under Accession No. ML25196A336.

- *NRC's PDR*: The PDR, where you may examine and order copies of publicly available documents, is open by appointment. 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 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC's Clearance Officer*: A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Acting Clearance Officer, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856 email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the

Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2022-0064 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized as follows.

1. *The title of the information collection*: NRC Form 790, Classification Record.

2. *OMB approval number*: 3150-0052.

3. *Type of submission*: Extension.

4. *The form number, if applicable*: NRC Form 790.

5. *How often the collection is required or requested*: On occasion. NRC Form 790 is required each time an authorized classifier makes a classification determination to classify, declassify, or downgrade a document.

6. *Who will be required or asked to respond*: NRC licensees, licensees' contractors, and certificate holders who classify and declassify NRC information.

7. *The estimated number of annual responses*: 60.

8. *The estimated number of annual respondents*: 2.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request*: 5 hours.

10. *Abstract*: Completion of the NRC Form 790 is a mandatory requirement for NRC licensees, licensees' contractors, and certificate holders who classify and declassify NRC information in accordance with Executive Order 13526, "Classified National Security Information," the Atomic Energy Act,

and implementing directives. The NRC uses the information on the form to report statistics related to its security classification program on an annual basis to the Information Security Oversight Office.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: December 8, 2025.

For the Nuclear Regulatory Commission.

Heather Dempsey,

NRC Acting Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025-22473 Filed 12-10-25; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2025-0046]

Information Collection: NRC Form 314, Certificate of Disposition of Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, NRC Form 314, "Certificate of Disposition of Materials."

DATES: Submit comments by February 9, 2026. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website*: Go to <https://www.regulations.gov> and search

for Docket ID NRC–2025–0046. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: *Bridget.Curran@nrc.gov*. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Heather Dempsey, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0856; email: *Infocollects.Resource@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2025–0046 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2025–0046. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2025–0046 on this website.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov*. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML25171A011. The ADAMS Accession number for the supporting statement is ML25171A013.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. 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 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC’s Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC’s Acting Clearance Officer, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0856 email: *Infocollects.Resource@nrc.gov*.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2025–0046, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB’s approval for the information collection summarized as follows.

1. *The title of the information collection:* NRC Form 314, Certificate of Disposition of Materials.
2. *OMB approval number:* 3150–0028.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 314.
5. *How often the collection is required or requested:* Form 314 is required when NRC licensees wish to terminate their license.
6. *Who will be required or asked to respond:* Respondents are firms,

institutions, and individuals holding NRC license to possess and use radioactive materials who do not wish to renew those licenses.

7. *The estimated number of annual responses:* 110.

8. *The estimated number of annual respondents:* 110.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 55 hours (110 × 0.5 hour).

10. *Abstract:* NRC Form 314 is submitted by a materials licensee who wishes to terminate its license. The form provides information needed by NRC to determine whether the licensee has radioactive materials on hand which must be transferred or otherwise disposed of prior to expiration or termination of the license.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.

2. Is the estimate of the burden of the information collection accurate? Please explain your answer.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: December 8, 2025.

For the Nuclear Regulatory Commission.

Heather Dempsey,

NRC Acting Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025–22474 Filed 12–10–25; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2025–0047]

Information Collection: NRC Form 237, Request for Access Authorization

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection

is entitled, NRC Form 237, "Request for Access Authorization."

DATES: Submit comments by February 9, 2026. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0047. Address questions about Docket IDs in [Regulations.gov](https://www.regulations.gov) to Bridget Curran; telephone: 301-415-1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Heather Dempsey, Office of the Chief Information Officer, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-0047 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0047. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2025-0047 on this website.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select

"Begin ADAMS Public Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The supporting statement and NRC Form 237 are available in ADAMS under Accession Nos. ML25190A593 and ML25190A594, respectively.

- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. 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 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Acting Clearance Officer, Heather Dempsey, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0856 email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2025-0047, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the

information collection summarized as follows.

1. *The title of the information collection:* NRC Form 237, Request for Access Authorization.
2. *OMB approval number:* 3150-0050.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 237.
5. *How often the collection is required or requested:* Required with every submission for access authorization, access to special nuclear material, or access to classified information.
6. *Who will be required or asked to respond:* NRC contractors, subcontractors, licensee employees, employees of other government agencies, and other individuals who are not NRC employees who require an NRC access authorization.
7. *The estimated number of annual responses:* 922.
8. *The estimated number of annual respondents:* 77.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 184.
10. *Abstract:* A completed NRC Form 237 is required to obtain or renew access to special nuclear material (10 CFR 11.15(a)(2) and (c)(1)) or classified information (10 CFR 25.17(c) and 25.21(c)(1) and (2) for licensee personnel. It is also used to request NRC access authorizations for personnel of NRC contractors, subcontractors, or other individuals who are not applicants for employment with NRC.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.
2. Is the estimate of the burden of the information collection accurate? Please explain your answer.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: December 8, 2025.

For the Nuclear Regulatory Commission.

Heather Dempsey,

NRC Acting Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2025-22475 Filed 12-10-25; 8:45 am]

BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION**[Docket Nos. CP2024–597; MC2026–130 and K2026–130]****New Postal Products****AGENCY:** Postal Regulatory Commission.
ACTION: Notice.**SUMMARY:** The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.**DATES:** *Comments are due:* December 15, 2025.**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at <https://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.**FOR FURTHER INFORMATION CONTACT:** David A. Trissell, General Counsel, at 202–789–6820.**SUPPLEMENTARY INFORMATION:****Table of Contents**

- I. Introduction
- II. Public Proceeding(s)
- III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited

by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).*: CP2024–597; *Filing Title:* USPS Request Concerning Amendment One to Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 276, with Materials Filed Under Seal; *Filing Acceptance Date:* December 5, 2025; *Filing Authority:* 39 CFR 3035.105 and 39 CFR 3041.505; *Public Representative:* Christopher Mohr; *Comments Due:* December 15, 2025.

2. *Docket No(s).*: MC2026–130 and K2026–130; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1464 to the Competitive Product List and Notice of Filing

Materials Under Seal; *Filing Acceptance Date:* December 5, 2025; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* December 15, 2025.

III. Summary Proceeding(s)

None. See Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2025–22464 Filed 12–10–25; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION**[Release No. 34–104348; File No. SR–LTSE–2025–23]****Self-Regulatory Organizations; Long-Term Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a Co-Lead Incentive**

December 8, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder,² notice is hereby given that, on November 25, 2025, Long-Term Stock Exchange, Inc. (“LTSE” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (“Commission”) a proposed rule change to amend the LTSE Fee Schedule to adopt a Co-Lead Incentive designed to enhance market quality by incentivizing market participants to provide liquidity and increase executions on the Exchange. The Exchange proposes to implement the changes to the fee schedule pursuant to this proposal on November 25, 2025.

The text of the proposed rule change is available at the Exchange's website at <https://longtermstockexchange.com/>

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

¹ 15 U.S.C. 78a.

² 17 CFR 240.19b–4.

and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Fee Schedule to adopt a new pricing incentive, referred to by the Exchange as the "Co-Lead Incentive," designed to improve market quality on the Exchange by providing a rebate of 40 mils per share traded (\$0.40/100 shares) to any Member³ that displays a quote⁴ of at least one round lot at the National Best Bid or Offer ("NBBO")⁵ for at least 20% of the Regular Market Session⁶ in at least 2,000 securities⁷ priced at or above \$1.00 per share⁸ averaged across the month. As proposed, the Exchange will determine on a daily basis the number of securities priced at or above \$1.00 (excluding LIP Enhanced Securities) in which each of a Member's MPIDs meets

the 20% NBBO Time⁹ requirement ("quoting requirement") for that day. The Exchange will then aggregate the number of securities for each of a Member's MPIDs that have met the quoting requirement to determine the total number of securities in which such Member meets the quoting requirement for that day.¹⁰ However, a single security in which more than one of such Member's MPIDs meets the quoting requirement for that day will only be counted once for this purpose.¹¹ A Member that qualifies for the Co-Lead Incentive will receive the enhanced rebate of 40 mils per share for securities executed priced at or above \$1.00 (excluding LIP Enhanced Securities).

Co-Lead Incentive Qualification Standard

As discussed above, a Member will qualify for the Co-Lead Incentive if the Member has an NBBO Time of at least 20% on average per trading day during the month for 2000 securities priced at or above \$1.00 (excluding LIP Enhanced Securities). The proposed Co-Lead Incentive is designed to enhance market quality and increase displayed liquidity with respect to securities traded on the Exchange. In order to determine whether a Member meets the applicable 2000 Securities Requirements during a month, LTSE will determine the number of securities priced at or above \$1.00 (excluding LIP Enhanced Securities) in which each of a Member's MPIDs meets the quoting requirement for that day. LTSE will then aggregate the number of securities in which each of a Member's MPIDs meets the quoting requirement, provided that the quoting requirement with respect to a security must be met by a single MPID and LTSE will not aggregate the NBBO Time across all of the Members MPIDs to determine if the quoting requirement has been met, and provided also that a single security in which more than one of such Member's MPIDs meets the quoting requirement for that day will only be counted once for this purpose.

Each month, LTSE will calculate the average daily number of securities in

which such Member meets the quoting requirement per trading day by summing the number of securities in which each of such Member's MPIDs met the quoting requirement for each trading day during the month then dividing the resulting sum by the total number of trading days in the month.

The Exchange proposes to add notes to the Fee Schedule describing the criteria for determining whether a Member qualifies for the Co-Lead Incentive and the related calculation methodologies described above.

Qualification for the Co-Lead Incentive will be determined in the same manner as qualification for the LTSE LIP.¹² Accordingly, the Exchange will exclude: (1) Any trading day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Market Session; (2) any day with a scheduled early market close; (3) the "Russell Reconstitution Day" (typically the last Friday in June). An Exchange system disruption may occur, for example, where a certain group of securities traded on the Exchange is unavailable for trading due to an Exchange system issue. The Exchange believes that these types of Exchange system disruptions could preclude Members from participating on the Exchange to the extent that they might have otherwise participated on such days, and thus, the Exchange believes it is appropriate to exclude such days when determining whether a Member meets the applicable quoting requirements during a month to avoid penalizing Members that might otherwise have met such requirements. Additionally, the Exchange believes that scheduled early market closures, which typically are the day before, or the day after, a holiday, may preclude some Members from participating on the Exchange at the same level that they might otherwise. For similar reasons, the Exchange believes it is appropriate to exclude the Russell Reconstitution Day in the same manner, as the Exchange believes that the Russell Reconstitution Day typically has extraordinarily high, and abnormally distributed, trading volumes and the Exchange believes this change to normal activity may affect a Member's ability to meet the quoting requirement across

³ See LTSE Rule 1.160(w).

⁴ The Exchange notes that displayed quotes can include orders that rest on the LTSE Order Book and are therefore treated as displayed quotes within the System.

⁵ The term "NBB" shall mean the national best bid, the term "NBO" shall mean the national best offer, and the term "NBBO" shall mean the national best bid or offer, as set forth in Rule 600(b) of Regulation NMS under the Act, determined as set forth in LTSE Rule 11.410(b). See LTSE Rule 1.160(y).

⁶ See LTSE Rule 1.160(kk).

⁷ Liquidity Incentive Program ("LIP") Enhanced Securities are excluded. "LIP Enhanced Securities" shall mean a list of securities designated as such, that are used for the purposes of qualifying for the incentives within the LIP. The universe of these securities will be determined by the Exchange and published on the Exchange's website. See LTSE Fee Schedule and the published list of LIP Enhanced Securities is on the LTSE website available at <https://ltse.com/trading/fee-schedules>.

⁸ The Exchange determines whether a security is priced at or above \$1.00 per share by utilizing the closing price of the security on the date of execution.

⁹ The term "NBBO Time" shall mean the aggregate of the percentage of time during the Regular Market Session during which one of a Member's MPIDs has at least one round lot quote displayed at the NBBO.

¹⁰ For example, if a Member has four (4) MPIDs and each MPID has a NBBO Time of 20% in a different security, this will count as four (4) securities in which such Member has met the quoting requirement for that day.

¹¹ Thus, if a Member has two (2) MPIDs that meet the quoting requirement in the same security for a particular day, this will only count as one security for purposes of determining the total number of securities in which such Member has met the quoting requirement for that day.

¹² In determining qualification for the LTSE Liquidity Incentive Program, the Exchange excludes from its calculation of Percent Time at NBBO: (1) any trading day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during the Regular Market Session; (2) any day with a scheduled early market close; and (3) the "Russell Reconstitution Day" (typically the last Friday in June).is designed to provide greater liquidity in both LIP Enhanced Securities and LIP Standard Securities. See LTSE Fee Schedule.

various securities on that day. The Exchange notes that these exclusions mirror the approach the Exchange applies when determining eligibility for the LTSE Liquidity Incentive Program and therefore promotes consistency across its incentive programs.¹³

Co-Lead Incentive Rebate—Rate, Scope (All MPIDs), and Exclusions

A Member that qualifies for the Co-Lead Incentive by meeting the requirements described above during a particular month will receive an enhanced rebate of \$0.0040 per share for all displayed liquidity-adding executions in securities (excluding LIP Enhanced Securities) priced at or above \$1.00 per share during that month. For the avoidance of doubt, LIP Enhanced Securities are excluded from counting to the 2000 Securities Requirement and from eligibility for the Co-Lead Incentive enhanced rebate. The proposed enhanced rebate will apply to all displayed liquidity adding-executions (excluding LIP Enhanced Securities and securities priced below \$1) by each MPID of a qualifying Member; thus, if a Member's MPID qualifies for the Co-Lead Incentive during a month, the qualifying Member will receive the proposed enhanced rebate of \$0.0040 per share for all executions (excluding LIP Enhanced Securities and securities priced below \$1.00) by that MPID as well as those entered by each of its other MPIDs during that month. The Exchange notes that the proposed enhanced rebate will only apply to executions in securities priced at or above \$1.00 (excluding LIP Enhanced Securities) while a qualifying Member's executions in securities priced below \$1.00 per share will continue to receive the standard rebate applicable to executions on the Exchange (*i.e.*, 0.15% of the total dollar value of the transaction).

The Exchange is proposing to provide the enhanced rebate for executions by qualifying Members as a means of recognizing the value of market participants that consistently provide liquidity at the NBBO in a large number of securities on a displayed basis. Even when such market participants are not formally registered as market makers, they risk capital by offering immediately executable liquidity at the price most favorable to market participants on the opposite side of the market. Such activity promotes price discovery and dampens volatility and enhances the attractiveness of the Exchange as a trading venue. Given the proposed

requirements to qualify for the Co-Lead Incentive a Member must make a significant contribution to market quality by providing displayed liquidity at the NBBO in a large number of securities for a significant portion of the day.

A Member that qualifies for the Co-Lead Incentive will reflect the Member's commitment to provide meaningful and consistent support to market quality and price discovery by extensive displayed quoting at the NBBO in a large number of securities. Thus, this proposal is designed to attract displayed liquidity from firms that are willing to commit capital to support liquidity at the NBBO. Through the proposed enhanced rebate for qualifying Members, the Exchange hopes to provide improved trading conditions for all market participants through narrower bid-ask spreads and increased depth of liquidity available at the NBBO for a large number of securities. In addition, the proposal reflects an effort to use a financial incentive to encourage Members to make positive commitments to promote market quality.

The Exchange notes that the proposed Co-Lead Incentive is similar in structure and purpose to pricing programs in place at other exchanges that are designed to enhance market quality by incentivizing members to achieve minimum quoting standards, including minimum quoting at the NBBO in a large number of securities, generally, or certain designated securities, in particular.¹⁴ The Exchange further notes

¹⁴ See, *e.g.*, the MEMX fee schedule available on its public website, available at <https://info.memxtrading.com/equities-trading-resources/us-equities-fee-schedule/> and the Displayed Liquidity Incentive which provides an enhanced rebate for executions of displayed orders in securities priced at or above \$1.00 per share that add liquidity to the Exchange for Members that meet certain minimum quoting requirements across a specified number of securities; the Nasdaq equities trading fee schedule on its public website, available at <http://www.nasdaqtrader.com/trader.aspx?id=pricelisttrading2> and Nasdaq Rule Equity 7, Section 114(d) describing Nasdaq's Qualified Market Maker Program, which provides for an additional rebate (ranging from \$0.0001 to \$0.0002 per share) for executions of liquidity-providing displayed orders (other than designated retail orders) in securities across all tapes priced at or above \$1.00 per share for members that, in addition to executing transactions that represent a specified percentage of consolidated volume and avoiding inefficient order entry practices that place excessive burdens on Nasdaq's systems, quote at the NBBO at least 25% of the time during regular market hours in an average of at least 1,000 securities per day during the month; see also the Cboe BZX equities trading fee schedule on its public website available at https://markets.cboe.com/us/equities/membership/fee_schedule/bzx/, which provides for an additional rebate (ranging from \$0.0001 to \$0.0002 per share) under Cboe BZX's Liquidity Management Program for executions of liquidity-providing displayed orders in Tape B securities

that, like the proposed Co-Lead Incentive, these programs include as an incentive the provision of an enhanced rebate for executions of liquidity-adding displayed quotes for members that meet the quoting and other requirements of those programs.

In addition to the foregoing changes, the Exchange proposes to add to the Fee Schedule definitions of the terms "MPID", "quoting requirement" and "NBBO Time" that are consistent with the descriptions of those terms set forth above, as such terms are used in the notes describing the calculation methodologies and criteria for determining whether a Member qualifies for the Co-Lead Incentive.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b)¹⁵ of the Act in general and furthers the objectives of Section 6(b)(4)¹⁶ of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. Additionally, the Exchange believes that the proposed fees are consistent with the objectives of Section 6(b)(5)¹⁷ of the Act in that they are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that the proposed Co-Lead Incentive Program reflects a competitive pricing

priced at or above \$1.00 per share for members that, in addition to adding a specified percentage of total consolidated volume in Tape B securities and meeting certain other quoting requirements with respect to a specified number of securities designated as "LMP Securities" on a list determined by Cboe BZX, quote at the NBBO at least 15% of the time during regular trading hours in a specified number of such designated LMP Securities (or achieve an alternative NBBO quoting standard involving a size-setting element with respect to such designated LMP Securities).

¹⁵ 15 U.S.C. 78f(b).

¹⁶ 15 U.S.C. 78f(b)(4).

¹⁷ 15 U.S.C. 78f(b)(5).

¹³ See LTSE's fee schedule on its public website available at <https://ltse.com/trading/fee-schedules>.

structure designed to incentivize market participants to add aggressively priced displayed liquidity and direct their order flow to the Exchange, which the Exchange believes would promote price discovery and price formation and deepen liquidity that is subject to the Exchange's transparency, regulation, and oversight as an exchange, thereby enhancing market quality to the benefit of all Members and investors.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies."

In particular, the Co-Lead Incentive is reasonably designed to improve market quality on the Exchange by offering an enhanced rebate of \$0.0040 per share for executions in securities priced at or above \$1.00 (excluding LIP Enhanced Securities) where a Member meets objective, transparent qualification criteria, namely, has a displayed quote at the NBBO at least 20% of the Regular Market Session in an average of at least 2,000 securities per trading day during the month. Incentivizing significant time at the NBBO across a broad universe of symbols is reasonably expected to promote price discovery, narrow spreads, increase displayed liquidity, and enhance execution opportunities for all market participants interacting on the Exchange, thereby advancing just and equitable principles of trade and protecting investors and the public interest.

The proposal is equitable and not unfairly discriminatory because it is voluntary and available to all Members that satisfy the same quantitative standards, measured and applied uniformly. The methodology of measuring NBBO Time on a per-MPID basis, counting each security once even if multiple MPIDs meet the threshold in that symbol, aggregating across a Member's MPIDs for breadth, and applying the enhanced rebate across all of the qualifying Member's MPIDs uses objective criteria that neither target nor exclude any category of participant. Similar quoting-standard programs adopted by other exchanges (e.g., MEMX's Displayed Liquidity Incentive ("DLI")) rely on comparable NBBO-time

measurements and per-symbol counting mechanics, supporting the reasonableness of this approach.¹⁸

Additionally, the proposal's exclusion of (i) days with an Exchange system disruption exceeding 60 minutes during the Regular Market Session, (ii) scheduled early market-close days, and (iii) the Russell Reconstitution Day is reasonable and not unfairly discriminatory. These exclusions avoid penalizing Members for atypical trading sessions that can materially distort NBBO-time metrics and are consistent with practices other exchanges have described for similar programs.¹⁹

In conclusion, the Exchange submits that its proposed fee structure satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act²⁰ for the reasons discussed above in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities, does not permit unfair discrimination between customers, issuers, brokers, or dealers, and is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and in general to protect investors and the public interest, particularly as the proposal neither targets nor will it have a disparate impact on any particular category of market participant.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,²¹ the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The proposal is designed to enhance the Exchange's ability to compete for order flow by encouraging Members to add liquidity at the NBBO across a broad range of securities, thereby promoting market depth, execution quality, and price discovery on the Exchange. Other exchanges already maintain and remain free to adjust similar quoting-based incentives and tiered pricing.²² To the extent the proposal attracts additional liquidity to the Exchange, any resulting shifts in market share are the product of, and evidence of, robust intermarket

competition that Regulation NMS seeks to foster.

The Exchange also does not believe the proposal imposes an undue burden on intramarket competition. The qualification criteria and enhanced rebate apply uniformly and are available to all Members on equal terms. While some Members may more readily qualify based on quoting activity, any differences in outcomes flow from neutral, objective standards tied to quoting behavior that benefits overall market quality.

More broadly, the Exchange believes the proposal supports both intermarket and intramarket competition by encouraging order flow to a public exchange, thereby promoting transparency, efficient pricing, and enhanced execution opportunities for all Members. In this regard, the proposal furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."²³

For these reasons, the Exchange does not believe such proposed changes would impair the ability of Members or competing order execution venues to maintain their competitive standing in the financial markets, and therefore, the Exchange does not believe the proposal will impose any burden on intermarket competition. Moreover, because the proposed changes would apply equally to all Members and Non-Members, as applicable, the Exchange does not believe the proposal would impose any burden on intramarket competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

This proposed rule change establishes dues, fees or other charges among its members and, as such, may take effect upon filing with the Commission pursuant to Section 19(b)(3)(A)(ii) of the Act²⁴ and paragraph (f)(2) of Rule 19b-4 thereunder.²⁵ Accordingly, the proposed rule change would take effect upon filing with the Commission.

¹⁸ See note 14.

¹⁹ *Id.*

²⁰ 15 U.S.C. 78f(b)(4) and (5).

²¹ 15 U.S.C. 78f(b)(8).

²² See note 14.

²³ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495 (June 29, 2005) (S7-10-04) (Final Rule) ("Regulation NMS").

²⁴ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁵ 17 CFR 240.19b-4(f)(2).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-LTSE-2025-23 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-LTSE-2025-23. 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 (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR-LTSE-2025-23 and should be submitted on or before January 2, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-22472 Filed 12-10-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104347; File No. SR-PHLX-2025-64]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Phlx Options 7, Section 4

December 8, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 25, 2025, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Broker-Dealer Transaction Cap and the Floor Transaction (Open Outcry) Floor Broker Incentive Program in Options 7, Section 4, Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY and broad-based index options symbols listed within Options 7, Section 5.A).

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments become operative on December 1, 2025.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/phlx/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx proposes to amend its Pricing Schedule at Options 7, Section 4, Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY and broad-based index options symbols listed within Options 7, Section 5.A), related to the Broker-Dealer³ Transaction Cap and the Floor Transaction⁴ (Open Outcry) Floor Broker⁵ Incentive Program.

Broker-Dealer Transaction Cap

Today, the Exchange offers a Broker-Dealer Transaction Cap whereby each Broker-Dealer Floor Options Transaction Charge is capped at \$15,000 per transaction (including FLEX and Cabinet Options Transaction Charges).

At this time, the Exchange proposes to specify in the rule text that for purposes of this cap, the term "per transaction" includes simple orders or with respect to complex orders, all legs of the same complex order that are Floor Options Transaction Charges. This is the manner in which the term "per transaction" is applied today by the Exchange. The Exchange believes that this additional rule text will make the application of the cap transparent to members and member organizations.

Floor Transaction (Open Outcry) Floor Broker Incentive Program

Currently, Floor Brokers are paid rebates for transactions executed on the trading floor in open outcry on qualifying volume at each threshold level based on the below tiers. The following transactions are not considered qualifying volume: (1) dividend, merger, short stock interest, reversal and conversion, jelly roll, and box spread strategy executions as defined in this Options 7, Section 4; (2) Firm Floor Options Transactions for members executing facilitation orders pursuant to Options 8, Section 30 when such members are trading in their own proprietary account (including Cabinet Options Transaction Charges); and (3)

³ The term "Broker-Dealer" applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category. See Options 7, Section 1(c).

⁴ The term "floor transaction" is a transaction that is effected in open outcry on the Exchange's Trading Floor. See Options 7, Section 1(c).

⁵ The term "Floor Broker" means an individual who is registered with the Exchange for the purpose, while on the Options Floor, of accepting and handling options orders. See Phlx Options 7, Section 1(c).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

²⁶ 17 CFR 200.30-3(a)(12).

Customer-to-Customer transactions. Currently, Floor Qualified Contingent Cross Orders (“QCC”) Orders, as defined in Options 8, Section 30(e), and electronic QCC Orders, as defined in

Options 3, Section 12, are considered qualifying volume but are not paid rebates based on the schedule, rather Floor QCC Orders and electronic QCC Orders are paid the QCC Rebates noted

in Options 7, Section 4. Rebates are paid on qualifying volume at each threshold level based on the schedule below.

	Qualifying contracts	Per contract rebate (customer on one side)	Per contract rebate (non-customer on both sides)
Tier 1	0–500,000	\$0.04	\$0.10
Tier 2	500,001–5,000,000	0.07	0.18
Tier 3	5,000,001–10,000,000	0.09	0.18
Tier 4	Greater than 10,000,000	0.10	0.22

At this time, the Exchange proposes to specify that Broker-Dealer Floor Options Transactions that are capped pursuant to the Broker-Dealer Transaction Cap will be considered qualifying volume but would not be paid rebates pursuant to the Floor Transaction (Open Outcry) Floor Broker Incentive Program. While the Exchange would not pay rebates for the capped Broker-Dealer Floor Options Transactions, these transactions would continue to be capped and count toward qualifying volume, therefore the Exchange believes members and member organizations will continue to be incentivized to transact Broker-Dealer Floor Options Transactions on Phlx.

Further, the Exchange recently amended the Floor Transaction (Open Outcry) Floor Broker Incentive Program at Options 7, Section 4.⁶ At the time of those changes, the Exchange did not amend the examples that follow the rebate table to reflect changes to the examples as a result of the amendments to add electronic QCC as qualifying volume and to amend the per contract rebates in the two proposals.⁷ This proposal seeks to revise examples 1 through 4 to reflect the current Floor Transaction (Open Outcry) Floor Broker

Incentive Program qualifications and rebates and replace the outdated examples. Examples 1 through 4 would be revised as follows:

Example 1: A Floor Broker that executes a total of 2,000,000 qualified contracts in a month comprised of (1) Floor QCC Order volume of 600,000 contracts; (2) Floor Transaction Open Outcry Customer volume of 400,000 contracts; and (3) Floor Transaction Open Outcry volume with Non-Customers on both sides of 1,000,000 contracts, will be paid \$0.07 per contract for the 400,000 or \$28,000 for the Floor Transaction Open Outcry Customer volume and \$0.18 per contract for the 1,000,000 or \$180,000 for the Floor Transaction Open Outcry volume with Non-Customers on both sides, equaling a total Floor Broker Incentive Program Rebate of \$208,000 for that month. The 600,000 contracts of executed Floor QCC Orders would be paid the applicable QCC Rebate as described in Options 7, Section 4 above.

Example 2: A Floor Broker that executes floor transactions with a mix of Customer on one side and Non-Customer on both sides in a given month totaling 2,000,000 contracts (with no Floor QCC volume) will be paid a rebate tied to the requisite rebate schedule based on timestamp of the execution. Utilizing Example 1, assume: (1) 100,000 contracts had a Customer on one side, those transactions would be paid at \$0.04 per contract (\$4,000); (2) 400,000 contracts had a Non-Customer on both sides, those transactions would be paid at \$0.10 per contract (\$40,000); (3) 400,000 contracts had a Customer on one-side, those transactions would be paid at \$0.07 per contract (\$28,000); and (4) 1,100,000 contracts had a Non-Customer on both sides, those transaction would be paid at \$0.18 per contract (\$198,000), for a total rebate of \$270,000 for that month.

Example 3: A Floor Broker that executes floor transactions with a Customer on one side in a given month totaling 10,500,000 contracts (with no Floor QCC volume) will be paid \$0.04 per contract for the first 500,000 contracts (\$20,000), \$0.07 per contract for the next 4,500,000 floor transaction contracts (\$315,000), \$0.09 per contract for the next 5,000,000 floor transaction contracts (\$450,000), and \$0.10 per contract for the final 500,000 floor transaction contracts (\$50,000), for a total rebate of \$835,000 for that month.

Example 4: A Floor Broker that executes floor transactions with Non-Customer on both sides in a given month totaling 10,500,000 contracts (with no Floor QCC volume) will be paid \$0.10 per contract for the first 500,000 contracts (\$50,000), \$0.18 per contract for the next 4,500,000 floor transaction contracts (\$810,000), \$0.18 per contract for the next 5,000,000 floor transaction contracts (\$900,000), and \$0.22 per contract for the final 500,000 floor transaction contracts (\$110,000) for a total rebate of \$1,870,000 for that month.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹⁰

Likewise, in *NetCoalition v. Securities and Exchange Commission*¹¹ (“NetCoalition”) the D.C. Circuit upheld the Commission’s use of a market-based approach in evaluating the fairness of

⁶ See Securities Exchange Act Release Nos. 104034 (September 24, 2025), 90 FR 46674 (September 29, 2025) (SR-Phlx-2025-49); and 104128 (September 29, 2025), 90 FR 47441 (October 1, 2025) (SR-Phlx-2025-55).

⁷ SR-Phlx-2025-49 amended the Tier 2 rebate from \$0.12 to \$0.16 per contract for Non-Customer on both sides. SR-Phlx-2025-50 increased the rebates in all tiers by \$0.02 per contract. The Exchange previously offered a per contract rebate if a Customer is on one side of \$0.04 per contract for Tier 1 (0–500,000 qualifying contracts), a \$0.07 per contract rebate for Tier 2 (500,001–5,000,000 qualifying contracts), a \$0.09 per contract rebate for Tier 3 (5,000,001–10,000,000 qualifying contracts) and a \$0.10 per contract rebate for Tier 4 (Greater than 10,000,000 qualifying contracts). As amended, the Exchange now offers a per contract rebate if a Non-Customer is on both sides of \$0.10 per contract for Tier 1 (0–500,000 qualifying contracts), a \$0.18 per contract rebate for Tier 2 (500,001–5,000,000 qualifying contracts), a \$0.18 per contract rebate for Tier 3 (5,000,001–10,000,000 qualifying contracts) and a \$0.22 per contract rebate for Tier 4 (Greater than 10,000,000 qualifying contracts).

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(4) and (5).

¹⁰ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (“Regulation NMS Adopting Release”).

¹¹ *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

market data fees against a challenge claiming that Congress mandated a cost-based approach.¹² As the court emphasized, the Commission “intended in Regulation NMS that ‘market forces, rather than regulatory requirements’ play a role in determining the market data . . . to be made available to investors and at what cost.”¹³

Further, “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution’; [and] ‘no exchange can afford to take its market share percentages for granted’ because ‘no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers’”¹⁴ Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

Broker-Dealer Transaction Cap

The Exchange’s proposal to state that the term “per transaction” as it relates to the Broker-Dealer Transaction Cap would include simple orders or with respect to complex orders, all legs of the same complex order that are Floor Options Transaction Charges is reasonable because the additional rule text brings transparency to the manner in which the cap is currently applied by the Exchange. Specifically, all simple orders are included and the legs of the same complex order are included.

The Exchange’s proposal to state that the term “per transaction” as it relates to the Broker-Dealer Transaction Cap would include simple orders or with respect to complex orders, all legs of the same complex order that are Floor Options Transaction Charges is equitable and not unfairly discriminatory because the Exchange would apply the cap uniformly to all eligible Phlx members and member organizations.

Floor Transaction (Open Outcry) Floor Broker Incentive Program

The Exchange’s proposal to specify that Broker-Dealer Floor Options Transactions that are capped pursuant to the Broker-Dealer Transaction Cap will be considered qualifying volume but would not be paid rebates pursuant

to the Floor Transaction (Open Outcry) Floor Broker Incentive Program is reasonable. While the Exchange would not pay rebates for the capped Broker-Dealer Floor Options Transactions, these transactions would continue to be capped and count toward qualifying volume, therefore the Exchange believes members and member organizations will continue to be incentivized to transact Broker-Dealer Floor Options Transactions on Phlx.

The Exchange’s proposal to specify that Broker-Dealer Floor Options Transactions that are capped pursuant to the Broker-Dealer Transaction Cap will be considered qualifying volume but would not be paid rebates pursuant to the Floor Transaction (Open Outcry) Floor Broker Incentive Program is equitable and not unfairly discriminatory because the Exchange would uniformly count the capped Broker-Dealer Floor Options Transactions as qualifying volume and uniformly would not pay rebates pursuant to the Floor Transaction (Open Outcry) Floor Broker Incentive Program to any Phlx member or member organization.

The Exchange’s proposal to replace examples 1 through 4 in the Floor Transaction (Open Outcry) Floor Broker Incentive Program with updated examples that reflect the current qualifying volume and rates is reasonable because the examples will provide members and member organizations with clear examples as to the manner in which the Exchange currently calculate the rebates.

The Exchange’s proposal to replace examples 1 through 4 in the Floor Transaction (Open Outcry) Floor Broker Incentive Program with updated examples that reflect the current qualifying volume and rates is equitable and not unfairly discriminatory because the Exchange uniformly applies the rebate methodology to calculate the rebates and, therefore, the revised examples could therefore apply to all members and member organizations.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants with another choice

of where to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intra-Market Competition

The Exchange’s proposal to state that the term “per transaction” as it relates to the Broker-Dealer Transaction Cap would include simple orders or with respect to complex orders, all legs of the same complex order that are Floor Options Transaction Charges does not impose an undue burden on competition because the Exchange would apply the cap uniformly to all eligible Phlx members and member organizations.

The Exchange’s proposal to specify that Broker-Dealer Floor Options Transactions that are capped pursuant to the Broker-Dealer Transaction Cap will be considered qualifying volume but would not be paid rebates pursuant to the Floor Transaction (Open Outcry) Floor Broker Incentive Program does not impose an undue burden on competition because the Exchange would uniformly count the capped Broker-Dealer Floor Options Transactions as qualifying volume and uniformly would not pay rebates pursuant to the Floor Transaction (Open Outcry) Floor Broker Incentive Program to any Phlx member or member organization.

The Exchange’s proposal to replace examples 1 through 4 in the Floor Transaction (Open Outcry) Floor Broker Incentive Program with updated examples that reflect the current qualifying volume and rates does not impose an undue burden on competition because the Exchange uniformly applies the rebate methodology to calculate the rebates and, therefore, the revised examples could therefore apply to all members and member organizations.

¹² See *NetCoalition*, at 534–535.

¹³ *Id.* at 537.

¹⁴ *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-Phlx-2025-64 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-Phlx-2025-64. 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 (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is

obscene or subject to copyright protection. All submissions should refer to file number SR-Phlx-2025-64 and should be submitted on or before January 2, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-22471 Filed 12-10-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104343; File No. SR-IEX-2025-32]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend IEX's Fee Schedule Concerning the Supplemental Market Quality Program

December 8, 2025.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Act") ² and Rule 19b-4 thereunder, ³ notice is hereby given that, on November 26, 2025, the Investors Exchange LLC ("IEX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act, ⁴ and Rule 19b-4 thereunder, ⁵ the Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members ⁶ (the "Fee Schedule") ⁷ pursuant to IEX Rule 15.110(a) and (c) to lower the barriers to qualification for the Supplemental Market Quality Program incentive payments. Changes to the Fee Schedule pursuant to this proposal are effective

¹⁶ 17 CFR 200.30-3(a)(12).

¹⁵ U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ 15 U.S.C. 78s(b)(1).

⁵ 17 CFR 240.19b-4.

⁶ See IEX Rule 1.160(s).

⁷ See Investors Exchange Fee Schedule, available at <https://www.iexexchange.io/resources/trading/fee-schedule>.

upon filing, ⁸ and will be operative beginning on December 1, 2025.

The text of the proposed rule change is available at the Exchange's website at <https://www.iexexchange.io/resources/regulation/rule-filings> and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to modify the Supplemental Market Quality Program ("SMQ" or the "Program") ⁹ to lower the barriers to qualify for the incentive payments by counting qualifying activity in any eligible security when determining if a Member satisfied the Program's requirements for that month. The Exchange also proposes to make conforming changes to the Fee Schedule to reflect the changes to the SMQ. As described below, this proposed rule change is designed to make it easier for Members to qualify for the SMQ.

Background

The Program is intended to increase displayed liquidity and promote order flow to the Exchange by offering a financial incentive (the "SMQ Incentive Payment") for Members to enter displayed orders or quotes (*i.e.*, displayed trading interest) priced at the NBBO ¹⁰ on the Exchange for a significant portion of the day in certain securities designated by the Exchange as either SMQ Level 1 Securities or SMQ Level 2 Securities (collectively "SMQ Securities"). ¹¹

⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

⁹ The Exchange filed the proposed rule change establishing the SMQ on May 16, 2025. See Securities Exchange Act Release No. 103131 (May 27, 2025), 90 FR 23397 (June 2, 2025) (SR-IEX-2025-07) ("SMQ Product Filing").

¹⁰ See IEX Rule 1.160(u).

¹¹ Information about the objective criteria applied by the Exchange in determining which securities to

¹⁵ 15 U.S.C. 78s(b)(3)(A)(ii).

To qualify for the SMQ Incentive Payment, a Member must enter displayed trading interest of at least one round lot at either the NBB, the NBO, or the NBBO, for at least 40% of the time during regular market hours in at least 100 of the SMQ Level 1 Securities or at least 20 of the SMQ Level 2 Securities (based on an average daily number) during the month. IEX defines these quoting requirements as “Percent Time at NBB”¹² and “Percent Time at NBO”,¹³ which added together are called “NBBO Time.”¹⁴ Members that qualify for the SMQ based upon their quoting activity in SMQ Level 1 Securities receive an “SMQ Incentive Payment” of \$125 per qualified security, and Members that qualify for the SMQ based upon their quoting activity in SMQ Level 2 Securities receive an “SMQ Incentive Payment” of \$400 per qualified security. As set forth in the Fee Schedule, a Member that satisfies the Program’s requirements receives an “SMQ Payout”, which is a lump sum payment determined by multiplying the applicable SMQ Incentive Payment times the number of qualified securities in which the Member had “SMQ Qualifying Activity.”¹⁵ The following examples demonstrate how a Member can earn SMQ Payouts based upon its quoting activity in either SMQ Level 1 Securities, SMQ Level 2 Securities, or both:

Example 1

- Member has NBBO Time of at least 40% in 110 SMQ Level 1 Securities and NBBO Time of at least 40% in 10 SMQ Level 2 Securities.
- Member qualifies for an SMQ Payout of \$13,750 for its quoting activity in SMQ Level 1 Securities (\$125 SMQ

designate as SMQ Level 1 or SMQ Level 2 Securities can be found in the rule filing that established the two SMQ tiers. See Securities Exchange Act Release No. 104221 (November 19, 2025), 90 FR 53037 (November 24, 2025) (SR-IEX–2025–27).

¹² As set forth in the Fee Schedule, “Percent Time at NBB” means the aggregate of the percentage of time during Regular Market Hours where a Member has a displayed order of at least one round lot at the national best bid (“NBB”).

¹³ As set forth in the Fee Schedule, “Percent Time at NBO” means the aggregate of the percentage of time during Regular Market Hours where a Member has a displayed order of at least one round lot at the national best offer (“NBO”).

¹⁴ IEX notes that if a Member enters displayed trading interest of at least one round lot at both the NBB and the NBO, each of those quotes will be counted towards the Member’s NBBO Time.

¹⁵ As set forth in the Fee Schedule, “SMQ Qualifying Activity” is calculated at the end of the month by taking the average (rounded to the nearest whole number) of the number of SMQ Level 1 and/or Level 2 Securities for which the Member’s NBBO Time was at least the threshold value set forth in the SMQ Calculation Tables below.

Incentive Payment per qualified security times 110 SMQ Level 1 Securities).

- Member does not qualify for an SMQ Payout for its quoting activity in SMQ Level 2 Securities (because it did not have SMQ Qualifying Activity for at least 20 SMQ Level 2 Securities).
- Member’s monthly SMQ Payout is \$13,750.

Example 2

- Member has NBBO Time of at least 40% in 90 SMQ Level 1 Securities and NBBO Time of at least 40% in 22 SMQ Level 2 Securities.
- Member qualifies for an SMQ Payout of \$8,800 for its quoting activity in SMQ Level 2 Securities (\$400 SMQ Incentive Payment per qualified security times 22 SMQ Level 2 Securities).
- Member does not qualify for an SMQ Payout for its quoting activity in SMQ Level 1 Securities (because it did not have SMQ Qualifying Activity for at least 100 SMQ Level 1 Securities).
- Member’s monthly SMQ Payout is \$8,800.

Example 3

- Member has NBBO Time of at least 40% in 110 SMQ Level 1 Securities and NBBO Time of at least 40% in 22 SMQ Level 2 Securities.
- Member qualifies for an SMQ Payout of \$13,750 for its quoting activity in SMQ Level 1 Securities (\$125 SMQ Incentive Payment per qualified security times 110 SMQ Level 1 Securities).
- Member qualifies for an SMQ Payout of \$8,800 for its quoting activity in SMQ Level 2 Securities (\$400 SMQ Incentive Payment per qualified security times 22 SMQ Level 2 Securities).
- Member’s monthly SMQ Payout is \$22,550.

However, if a Member does not meet the quoting threshold for either SMQ Level 1 or Level 2 Securities, the Member will not receive an SMQ Payout for that month, as demonstrated in the following example:

Example 4

- Member has NBBO Time of at least 40% in 90 SMQ Level 1 Securities and in 15 SMQ Level 2 Securities.
- Member does not qualify for an SMQ Payout for its quoting activity in SMQ Level 1 Securities (because it did not have SMQ Qualifying Activity for at least 100 SMQ Level 1 Securities).
- Member does not qualify for an SMQ Payout for its quoting activity in SMQ Level 2 Securities (because it did not have SMQ Qualifying Activity for at least 20 SMQ Level 2 Securities).
- Member does not receive an SMQ Payout for that month.

Proposal

IEX proposes to lower the barriers for qualifying for the SMQ by counting a Member’s quoting activity in either SMQ Level 1 or SMQ Level 2 Securities towards that Member’s SMQ Qualifying Activity for the month. As proposed, a Member could qualify for the SMQ Payout by entering displayed trading interest of at least one round lot at either the NBB, the NBO, or the NBBO, for at least 40% of the time during regular market hours in 100 or more SMQ Level 1 or Level 2 Securities. Thus, the Member described in Example 4 would now qualify for an SMQ Payout as follows:

Example 4—A

- Member has NBBO Time of at least 40% in 90 SMQ Level 1 Securities and in 15 SMQ Level 2 Securities.
- Member satisfies the Program’s requirements, because it had SMQ Qualifying Activity in 105 SMQ Securities (counting Level 1 and Level 2 together), which exceeds the Program requirement to have SMQ Qualifying Activity in at least 100 SMQ Securities.
- Member qualifies for an SMQ Payout of \$11,250 for its quoting activity in SMQ Level 1 Securities (\$125 SMQ Incentive Payment per qualified security times 90 SMQ Level 1 Securities).
- Member qualifies for an SMQ Payout of \$6,000 for its quoting activity in SMQ Level 2 Securities (\$400 SMQ Incentive Payment per qualified security times 15 SMQ Level 2 Securities).
- Member’s monthly SMQ Payout is \$17,250.

IEX makes this proposal to further incentivize Members to enter displayed interest in SMQ Level 2 Securities, which, by design, are more difficult securities in which to meet the quoting requirements for the Program.¹⁶ As a result, IEX expects there will typically be many more securities on the SMQ Level 1 list than on the SMQ Level 2 list, which means Members have more opportunities to qualify for the SMQ based upon quoting activity in SMQ Level 1 Securities.¹⁷ Thus, a Member that enters qualified displayed trading interest in at least 100 of the 650 SMQ Level 1 Securities will both receive SMQ Incentive Payments for that quoting activity and for any qualifying quoting activity in SMQ Level 2 Securities.

¹⁶ See *supra* note 11.

¹⁷ For example, since October 1, 2025, IEX has designated 650 securities as SMQ Level 1 Securities and 100 securities as SMQ Level 2 securities. See SMQ Security List, <https://www.iexexchange.io/resources/trading/supplemental-market-quality-program>.

To make this change, IEX proposes to remove the SMQ Level 2 Calculation Table from the Fee Schedule and to

revise the SMQ Level 1 Calculation Table so that it applies to all SMQ

Qualifying Activity. As proposed, the table will now read as follows:

SMQ CALCULATION TABLE

SMQ Qualifying Activity: average daily number of SMQ Securities with an NBBO time of at least 40%	SMQ incentive payment
0–99	\$0 per qualified security per month.
100 or more SMQ Securities *	\$125 per qualified SMQ Level 1 Security per month.
	\$400 per qualified SMQ Level 2 Security per month.

* SMQ Payouts will be made for all qualified securities if Member had SMQ Qualifying Activity in at least 100 SMQ Securities during the month.

IEX also proposes to make the following conforming changes to the SMQ section of the Fee Schedule:

- In the bullet describing “SMQ Qualifying Activity”, remove the references to “Level 1 and/or Level 2” and revise “Calculation Tables” to read “SMQ Calculation Table”.

- In the bullet describing “SMQ Payout” remove the “s” from “Calculation Tables” to reflect that there is now only one Calculation Table and revise the final sentence by adding “for the qualified securities in which the Member had SMQ Qualifying Activity” to the end.

Finally, as noted in the SMQ Product Filing, the SMQ Program is similar to quote incentive programs at other national securities exchanges.¹⁸

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b) ¹⁹ of the Act in general, and furthers the objectives of Sections 6(b)(4) ²⁰ of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange believes that the proposed fee change is reasonable, fair and equitable, and is not designed to permit unfair discrimination.

The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. IEX believes that it will be able to more effectively compete with other exchanges for order flow by lowering the barriers to qualify for the SMQ. IEX believes that Members and other market participants may be more

willing to send displayed trading interest to IEX if the proposed rule change is adopted.

IEX believes that an increase in displayed liquidity and order flow to the Exchange will, in turn, improve the quality of the IEX market and increase its attractiveness to existing and prospective participants. In addition, the proposal is equitable and not designed to permit unfair discrimination as the proposal would equitably allocate SMQ Payouts among Members by paying Members based on their total quoting activity in SMQ Level 1 Securities and SMQ Level 2 Securities in any given month.

As noted in the Purpose section, the Exchange believes the proposed incentive payments in the SMQ will incentivize Members to direct additional displayed liquidity-providing orders to the Exchange in SMQ Securities, thereby promoting price discovery and market quality in the SMQ Securities and more generally on the Exchange, and, further, that the resulting increased displayed liquidity and narrower spreads will benefit all investors by deepening the Exchange’s liquidity pool, supporting the quality of price discovery, enhancing quoting competition across all exchanges, and promoting market transparency.

As discussed above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The SMQ is comparable to quote incentive programs at other exchanges and thus IEX does not believe that the proposal raises any new or novel issues not already considered by the Commission in the context of other exchanges’ fees.²¹ To the extent this proposed fee change is successful in incentivizing the entry and execution of displayed trading interest on IEX, such greater liquidity will benefit all market participants by increasing price discovery and price

formation as well as market quality and execution opportunities.

Finally, the Exchange believes that the proposed conforming changes to the Fee Schedule are consistent with the requirements above. These proposed changes are designed to reduce any potential confusion for market participants using IEX’s Fee Schedule and to provide clarity, accuracy, and consistency between the Fee Schedule and the Rule Book. Further, IEX believes these changes would contribute to reasonably ensuring that the requirements of the SMQ Program, and any other activity-based incentive or rebate described in the Fee Schedule, are clear, accurate, and consistent with the Rule Book.

B. Self-Regulatory Organization’s Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if fee schedules at other venues are viewed as more favorable. Consequently, the Exchange believes that the degree to which IEX fees could impose any burden on competition is extremely limited and does not believe that such fees would burden competition between Members or competing venues. Moreover, as noted in the Statutory Basis section, the Exchange does not believe that the proposed changes raise any new or novel issues not already considered by the Commission.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act

¹⁸ See SMQ Product Filing, *supra* note 9, 90 FR at 23400 (comparing the SMQ to the Enhanced Market Quality Program offered by Nasdaq BX, the Market Quality program offered by MIAX PEARL, and Choe EDGA’s NBBO Setter Program); see also LTSE’s Liquidity Incentive Program, available at <https://ltse.com/trading/fee-schedules>.

¹⁹ 15 U.S.C. 78f.

²⁰ 15 U.S.C. 78f(b)(4).

²¹ See *supra* note 18.

because, while different Members may qualify for different amounts of SMQ Payouts, these payments are not based on the type of Member entering the displayed trading interest, but rather on the amount of displayed trading interest in a wide range of eligible securities that each Member submits to the Exchange. Further, the proposed fee changes are intended to incentivize market participants to bring increased order flow to the Exchange, which benefits all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii)²² of the Act.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)²³ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form <https://www.sec.gov/rules/sro.shtml>; or
- Send an email to rule-comments@sec.gov. Please include File Number SR-IEX-2025-32 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-IEX-2025-32. 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 (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-IEX-2025-32 and should be submitted on or before January 2, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁴

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-22468 Filed 12-10-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104346; File No. SR-NASDAQ-2025-093]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to NOM Options 7, Section 2

December 8, 2025.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 25, 2025, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed

rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend The Nasdaq Options Market LLC ("NOM") Rules at Options 7, Section 2, Nasdaq Options Market—Fees and Rebates.

While the changes proposed herein are effective upon filing, the Exchange has designated the amendments become operative on February 2, 2026.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NOM's Pricing Schedule at Options 7, Section 2, Nasdaq Options Market—Fees and Rebates, related to the Penny Symbol Fee for Removing Liquidity.

Background

Today, NOM assesses certain fees and rebates for execution of contracts on NOM as follows:

	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
Rebates to Add Liquidity in Penny Symbols						
Customer	(\$0.20)	(\$0.25)	(\$0.43)	(\$0.44)	(\$0.45)	(\$0.48)
Professional	(0.20)	(0.25)	(0.43)	(0.44)	(0.45)	(0.47)
Broker-Dealer	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)

²² 15 U.S.C. 78s(b)(3)(A)(ii).

²³ 15 U.S.C. 78s(b)(2)(B).

²⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6
Firm	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)
Non-NOM Market Maker	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)	(0.10)
NOM Market Maker	(0.20)	(0.25)	(0.30)	(0.32)	(0.46)	(0.48)

Fees and Rebates to Add Liquidity in Non-Penny Symbols

Customer		(\$0.80)
Professional		(0.80)
Broker-Dealer		0.45
Firm		0.45
Non-NOM Market Maker		0.45
NOM Market Maker		0.35/0.00/ (0.30)/(0.40)

Fees to Remove Liquidity in Penny and Non-Penny Symbols

	Penny symbols	Non-penny symbols
Customer	\$0.49	\$0.85
Professional	0.49	0.85
Broker-Dealer	0.50	1.25
Firm	0.50	1.25
Non-NOM Market Maker	0.50	1.25
NOM Market Maker	0.50	1.25

Today, NOM offers Participants the ability to lower their Penny Symbol Fee for Removing Liquidity in note 2 of Options 7, Section 2. Specifically, Participants that add 1.10% of Customer, Professional, Firm, Broker-Dealer or Non-NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of total industry customer equity and ETF option ADV contracts per day in a month are subject to the following pricing applicable to executions: a \$0.48 per contract Penny Symbols Fee for Removing Liquidity when the Participant is (i) both the buyer and the seller or (ii) the Participant removes liquidity from another Participant under Common Ownership.

Also, today, Participants that add 1.30% of Customer, Professional, Firm, Broker-Dealer or Non-NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of total industry customer equity and ETF option ADV contracts per day in a month and meet or exceed the cap for The Nasdaq Stock Market Opening Cross during the month are subject to the following pricing applicable to executions less than 10,000 contracts: a \$0.38 per contract Penny Symbols Fee for Removing Liquidity when the Participant is (i) both the buyer and seller or (ii) the Participant removes liquidity from another Participant under Common Ownership.

Finally, today, Participants that add 1.55% of Customer, Professional, Firm, Broker-Dealer or Non-NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of total industry customer equity and ETF option ADV

contracts per day in a month are subject to the following pricing applicable to executions less than 10,000 contracts: a \$0.38 per contract Penny Symbols Fee for Removing Liquidity when the Participant is (i) both the buyer and seller or (ii) the Participant removes liquidity from another Participant under Common Ownership.

At this time, the Exchange proposes to remove the note 2 incentive of Options 7, Section 2 that provides:

Participants that add 1.30% of Customer, Professional, Firm, Broker-Dealer or Non-NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of total industry customer equity and ETF option ADV contracts per day in a month and meet or exceed the cap for The Nasdaq Stock Market Opening Cross during the month will be subject to the following pricing applicable to executions less than 10,000 contracts: a \$0.38 per contract Penny Symbols Fee for Removing Liquidity when the Participant is (i) both the buyer and seller or (ii) the Participant removes liquidity from another Participant under Common Ownership.

With this proposal, despite the removal of part of the note 2 incentive described above, the Exchange would continue to incentivize Participants through the remaining two incentives within note 2 of Options 7, Section 2 to add a greater amount of liquidity on NOM in an effort to lower their Penny Symbol Fee for Removing Liquidity. Participants that currently qualify for the lower \$0.38 per contract Penny Symbol Fee for Removing Liquidity may continue to lower their Penny Symbol Fees for Removing Liquidity by qualifying for one of the remaining two incentives in note 2 of Options 7, Section 2.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,³ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁴ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”⁵

Likewise, in *NetCoalition v. Securities and Exchange Commission*⁶ (“NetCoalition”) the D.C. Circuit upheld the Commission’s use of a market-based approach in evaluating the fairness of market data fees against a challenge

³ 15 U.S.C. 78f(b).

⁴ 15 U.S.C. 78f(b)(4) and (5).

⁵ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (“Regulation NMS Adopting Release”).

⁶ *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

claiming that Congress mandated a cost-based approach.⁷ As the court emphasized, the Commission “intended in Regulation NMS that ‘market forces, rather than regulatory requirements’ play a role in determining the market data . . . to be made available to investors and at what cost.”⁸

Further, “[n]o one disputes that competition for order flow is ‘fierce.’ . . . As the SEC explained, ‘[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution’; [and] ‘no exchange can afford to take its market share percentages for granted’ because ‘no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers’”⁹ Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

The Exchange’s proposal to remove one of the three note 2 incentives of Options 7, Section 2 that lowers the Penny Symbol Fee for Removing Liquidity is reasonable because despite the removal of part of the note 2 incentive,¹⁰ the Exchange would continue to incentivize Participants through the remaining two incentives within note 2 of Options 7, Section 2 to add a greater amount of liquidity on NOM in an effort to lower their Penny Symbol Fee for Removing Liquidity. Participants that currently qualify for the lower \$0.38 per contract Penny Symbol Fee for Removing Liquidity may continue to lower their Penny Symbol Fees for Removing Liquidity by qualifying for one of the remaining two incentives in note 2 of Options 7, Section 2.

The Exchange’s proposal to remove one of the three note 2 incentives of Options 7, Section 2 that lowers the

Penny Symbol Fee for Removing Liquidity is equitable and not unfairly discriminatory because no Participant would be able to qualify for the second incentive within note 2 of Options 7, Section 2 that pays a \$0.38 per contract Penny Symbols Fee for Removing Liquidity, applicable to executions less than 10,000 contracts, when a Participant adds 1.30% of Customer, Professional, Firm, Broker-Dealer or Non-NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of total industry customer equity and ETF option ADV contracts per day in a month and meet or exceed the cap for The Nasdaq Stock Market Opening Cross and the Participant is (i) both the buyer and seller or (ii) the Participant removes liquidity from another Participant under Common Ownership.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants with another venue in which to submit orders. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, to which fee changes in this market may impose any burden on competition is extremely limited.

Intra-Market Competition

The Exchange’s proposal to remove one of the three note 2 incentives of Options 7, Section 2 that lowers the Penny Symbol Fee for Removing Liquidity does not impose an undue burden on competition because no Participant would be able to qualify for the second incentive within note 2 of Options 7, Section 2 that pays a \$0.38 per contract Penny Symbols Fee for

Removing Liquidity, applicable to executions less than 10,000 contracts, when a Participant adds 1.30% of Customer, Professional, Firm, Broker-Dealer or Non-NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of total industry customer equity and ETF option ADV contracts per day in a month and meet or exceed the cap for The Nasdaq Stock Market Opening Cross and the Participant is (i) both the buyer and seller or (ii) the Participant removes liquidity from another Participant under Common Ownership.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹¹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR–NASDAQ–2025–093 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.
- All submissions should refer to file number SR–NASDAQ–2025–093. This

⁷ See NetCoalition, at 534–535.

⁸ *Id.* at 537.

⁹ *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

¹⁰ The Exchange proposes to remove the second incentive from note 2 of Options 7, Section 2 that states, Participants that add 1.30% of Customer, Professional, Firm, Broker-Dealer or Non-NOM Market Maker liquidity in Penny Symbols and/or Non-Penny Symbols of total industry customer equity and ETF option ADV contracts per day in a month and meet or exceed the cap for The Nasdaq Stock Market Opening Cross during the month will be subject to the following pricing applicable to executions less than 10,000 contracts: a \$0.38 per contract Penny Symbols Fee for Removing Liquidity when the Participant is (i) both the buyer and seller or (ii) the Participant removes liquidity from another Participant under Common Ownership.

¹¹ 15 U.S.C. 78s(b)(3)(A)(ii).

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 (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NASDAQ-2025-093 and should be submitted on or before January 2, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-22470 Filed 12-10-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-104342; File No. SR-IEX-2025-33]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fee Schedule Pursuant to IEX Rules 15.110(a) and (c) To Delete Obsolete Language

December 8, 2025.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the "Act") ² and Rule 19b-4 thereunder,³ notice is hereby given that, on December 2, 2025, the Investors Exchange LLC ("IEX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,⁴ and Rule 19b-4 thereunder,⁵ the Exchange is filing with the Commission a proposed rule change to amend its Fee Schedule,⁶ pursuant to IEX Rules 15.110(a) and (c), to delete obsolete language referring to fee changes that became operative on October 1, 2025. The text of the proposed rule change is available at the Exchange's website at <https://www.iexexchange.io/resources/regulation/rule-filings> and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

IEX is proposing to amend the Connectivity section of its Fee Schedule, pursuant to IEX Rules 15.110(a) and (c), to delete certain obsolete language in the Connectivity Fees and Market Data Fees sections of the Fee Schedule. Currently the Connectivity Fees and Market Data Fees sections of the Fee Schedule contain the following sentence under each section sub-heading: "New underlined and bracketed deleted text will be operative October 1, 2025." In September 2025, the Exchange filed to amend the Connectivity Fee section of the Fee Schedule to change the monthly fees for Logical Order Entry Ports, and to amend the Market Data section of the Fee Schedule to establish a fee for real-time access to DEEP+ market data product.⁷

⁴ 15 U.S.C. 78s(b)(1).

⁵ 17 CFR 240.19b-4.

⁶ See IEX Fee Schedule—Connectivity Fees table, available at <https://www.iexexchange.io/resources/trading/fee-schedule#connectivity-fees>.

⁷ See Securities Exchange Act Release No. 103947 (September 11, 2025), 90 FR 44730 (September 16, 2025) (SR-IEX-2025-22); Securities Exchange Act

In order to inform readers of the Fee Schedule of the upcoming fee changes, in September 2025 the Exchange added the sentence "[n]ew underlined and bracketed deleted text will be operative October 1, 2025" to the beginning of the Connectivity Fees and Market Data Fees sections of the Fee Schedule.

These fee changes became operative on October 1, 2025 and the Exchange removed the underlining and brackets from the respective fee columns in the Connectivity and Market Data sections of the Fee Schedule at that time. The Exchange, however, left the sentence "[n]ew underlined and bracketed deleted text will be operative October 1, 2025" under the "Connectivity Fees" and "Market Data Fees" subheadings because it had not yet submitted this proposed rule change to the Commission pursuant to Section 19(b)(3) of the Act⁸ and paragraph (f)(6) of Rule 19b-4 thereunder.⁹

The Exchange now proposes to remove the sentence "[n]ew underlined and bracketed deleted text will be operative October 1, 2025" under the "Connectivity Fees" and "Market Data Fees" subheadings because this language is obsolete in light of the fact that the fee changes referred to therein became operative on October 1, 2025. The Exchange believes that removing this obsolete language will make the Fee Schedule easier to read and understand, and will reduce potential confusion that could result from outdated references to fee changes that have already taken effect. The proposed changes are not intended to address any other changes to the Fee Schedule.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) ¹⁰ of the Act in general and furthers the objectives of Section 6(b)(5) ¹¹ of the Act, in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general to protect investors and the public interest.

The Exchange believes that the proposed rule change deleting obsolete language from the Connectivity Fees and Market Data Fees sections of the Fee

Release No. 104060 (September 25, 2025), 90 FR 46955 (September 30, 2025) (SR-IEX-2025-25).

⁸ 15 U.S.C. 78s(b)(3).

⁹ 17 CFR 240.19b-4(f)(6).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

¹² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

Schedule is consistent with the requirements above. Specifically, the Exchange believes the proposed change is designed to alleviate any potential confusion regarding the connectivity and market data fees that became effective on October 1, 2025 and have been reflected in the Fee Schedule since that date. When the fees became operative, the Exchange removed the underlining and brackets that appeared in the fees column and that had previously indicated the pending fee changes that would be operative on October 1, 2025. The Exchange believes the proposed change protects investors and the public interest by eliminating obsolete information and thereby providing more clarity and consistency with respect to those sections of the Fee Schedule.

The Exchange also believes that the proposed change would remove impediments to, and perfect the mechanism of a national market system because removing the outdated language would make the Fee Schedule more streamlined, avoid confusion, and make it easier to read and understand.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal to remove obsolete language from the Connectivity Fees and Market Data Fees sections of the Fee Schedule will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.¹² The proposed rule change is not designed to address any competitive issues but rather is designed to enhance the clarity of the Fee Schedule and alleviate possible confusion that may arise from leaving obsolete language in the Fee Schedule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act¹³ and Rule 19b-4(f)(6)¹⁴ thereunder. Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii)

impose any significant burden on competition; or (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and Rule 19b-4(f)(6)¹⁶ thereunder.

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹⁷ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹⁸ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any novel regulatory issues and waiver will allow the Exchange to provide clarity to market participants by deleting obsolete language from its Fee Schedule. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.¹⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁷ 17 CFR 240.19b-4(f)(6).

¹⁸ 17 CFR 240.19b-4(f)(6)(iii).

¹⁹ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-IEX-2025-33 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-IEX-2025-33. 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 (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-IEX-2025-33 and should be submitted on or before January 2, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025-22467 Filed 12-10-25; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Rule 32a-4

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 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (SEC or

²⁰ 17 CFR 200.30-3(a)(12).

¹² 15 U.S.C. 78f(b)(8).

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 17 CFR 240.19b-4(f)(6).

“Commission”) is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget (“OMB”) for extension and approval.

Section 32(a)(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–31(a)(2)) (“Act”) requires that the selection of a registered management investment company’s or registered face-amount certificate company’s (collectively, “funds”) independent public accountant be submitted to shareholders for ratification or rejection. Rule 32a–4 under the Investment Company Act (17 CFR 270.32a–4) (“rule”) exempts a fund from this requirement if, among other things, the fund has an audit committee consisting entirely of independent directors. The rule permits continuing oversight of a fund’s accounting and auditing processes by an independent audit committee in place of a shareholder vote.

Among other things, to rely on rule 32a–4, a fund’s board of directors must adopt an audit committee charter and must preserve that charter, and any modifications to the charter, permanently in an easily accessible place. The purpose of these conditions is to ensure that Commission staff will be able to monitor the duties and responsibilities of an audit committee of a fund relying on the rule.

Commission staff estimates that on average the board of directors takes 15 minutes to adopt the audit committee charter. Commission staff has estimated that with an average of 9 directors on the board,¹ total director time to adopt the charter is 2.25 hours. Combined with an estimated ½ hour of paralegal time to prepare the charter for board review, the staff estimates a total one-time collection of information burden of 2.75 hours for each fund. Once a board adopts an audit committee charter, the charter is preserved as part of the fund’s records. Commission staff estimates that there is no annual hourly burden associated with preserving the charter in accordance with this rule.²

Because virtually all existing funds have now adopted audit committee charters, the annual one-time collection of information burden associated with adopting audit committee charters is limited to the burden incurred by newly

established funds. Commission staff estimates that fund sponsors establish approximately 88 new funds each year,³ and that all of these funds will adopt an audit committee charter to rely on rule 32a–4. Thus, Commission staff estimates that the annual one-time hour burden associated with adopting an audit committee charter under rule 32a–4 is approximately 242 hours.⁴

When funds adopt an audit committee charter to rely on rule 32a–4, they also may incur one-time costs related to hiring outside counsel to prepare the charter. Commission staff estimates that those costs average approximately \$2,086 per fund.⁵ As noted above, Commission staff estimates that approximately 88 new funds each year will adopt an audit committee charter in order to rely on rule 32a–4. Thus, Commission staff estimates that the ongoing annual cost burden associated with rule 32a–4 in the future will be approximately \$183,568.⁶

These estimates of average costs are made solely for the purposes of the Paperwork Reduction Act. The estimates are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. The collections of information required by rule 32a–4 are necessary to obtain the benefits of the rule.

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.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC’s estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize

the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to PaperworkReductionAct@sec.gov by February 9, 2026. There will be a second opportunity to comment on this SEC request following the **Federal Register** publishing a 30-Day Submission Notice.

Dated: December 9, 2025.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2025–22535 Filed 12–10–25; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–104344; File No. SR–NASDAQ–2025–066]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Certain Initial Listing Requirements for de-SPAC Transactions

December 8, 2025.

On August 22, 2025, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² a proposed rule change to modify the rules applicable to de-SPAC transactions (as defined below) to align the treatment of over-the-counter (“OTC”) trading SPACs (as defined below) with similarly situated exchange-listed SPACs. The proposed rule change was published for comment in the **Federal Register** on September 9, 2025.³

On September 25, 2025, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the

¹ This estimate is based on staff experience and on discussions with a representative of an entity that surveys funds and calculates fund board statistics based on responses to its surveys.

² This estimate is based on staff experience and discussions with funds regarding the hour burden related to maintenance of the charter.

³ This estimate is based on the average annual number of notifications of registration on Form N–8A filed from 2022 to 2024.

⁴ This estimate is based on the following calculation: (2.75 burden hours for establishing charter × 88 new funds = 242 burden hours).

⁵ Costs may vary based on the individual needs of each fund; however, based on the staff’s experience and conversations with outside counsel that prepare these charters, legal fees related to the preparation and adoption of an audit committee charter usually average \$2,086 or less; the Commission also understands that model audit committee charters are available, which reduces the costs associated with drafting a charter.

⁶ This estimate is based on the following calculations: (\$2,086 cost of adopting charter × 88 newly established funds = \$183,568).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 103864 (Sept. 4, 2025), 90 FR 43493 (“Notice”).

⁴ 15 U.S.C. 78s(b)(2).

proposed rule change.⁵ The Commission received comments on the proposal.⁶ On December 4, 2025, the Exchange submitted Amendment No. 1 to the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. Amendment No. 1 replaced and superseded the proposed rule change as originally filed.⁷ The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

I. Self-Regulator Organization's Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Exchange proposes to modify the rules applicable to de-SPAC transactions to align the treatment of OTC trading SPACs with similarly situated exchange-listed SPACs.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq is filing this amendment to SR-NASDAQ-2025-066⁸ in order to: (i) specify that the proposed changes will apply only to a de-SPAC transaction involving a SPAC, as defined below, which was previously listed on a national securities exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; (ii) address a commentator's technical concern regarding the proposed rule language for the timing of the effectiveness of a registration statement as it relates to the listing of a de-SPAC transaction, as defined below;⁹ and (iii) make minor technical changes to improve the structure, clarity and readability of the proposed rules and this proposal. This amendment supersedes and replaces the Initial Proposal in its entirety.

Nasdaq is proposing to modify the definition of a "Reverse Merger" in Listing Rule 5005(a)(39)¹⁰ to exclude the security of a special purpose acquisition company, as that term is defined in Item 1601(b) of Regulation S-

K ("SPAC"),¹¹ which was previously listed on a national securities exchange, and is listing in connection with a de-SPAC transaction, as that term is defined in Item 1601(a) of Regulation S-K ("de-SPAC transaction"), in connection with an effective 1933 Securities Act registration statement ("Registration Statement"). Nasdaq also proposes to modify Listing Rules 5315(e)(4), 5405(a)(4), and 5505(a)(5) (the "ADV Requirement") to exclude the security of a company listing in connection with a de-SPAC transaction, involving a SPAC which was previously listed on a national securities exchange, in connection with an effective Registration Statement, from the minimum trading volume requirement applicable to newly listing companies that previously traded in the over-the-counter ("OTC") market. The effect of these changes will be to treat a de-SPAC transaction by such SPAC trading in the OTC market in the same way as a de-SPAC transaction with a listed SPAC and, in each case, subject these transactions to the same rules applicable to an initial public offering.¹²

Reverse Merger Rule

Under Nasdaq Listing Rule 5110(c), a security issued by a Company formed by a Reverse Merger, as defined in Listing Rule 5005(a)(39), is eligible for initial listing only if it satisfies additional listing conditions, including, among other requirements, that immediately before the filing of the initial listing application, the combined entity traded for at least one year in the U.S. over-the-counter market, on another national securities exchange, or on a regulated

⁵ See Securities Exchange Act Release No. 104046, 90 FR 47110 (Sept. 30, 2025) (designating Dec. 8, 2025 as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

⁶ Comments received on the proposed rule change are available at: <https://www.sec.gov/comments/sr-nasdaq-2025-066/srnasdaq2025066.htm>.

⁷ Amendment No. 1 is available on the Commission's website at: <https://www.sec.gov/comments/sr-nasdaq-2025-066/srnasdaq2025066.htm>. Amendment No. 1: (i) specifies that the proposed changes will apply only to a de-SPAC transaction involving a SPAC, as defined below, which was previously listed on a national securities exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; (ii) address a commentator's suggestion for a technical revision regarding the proposed rule language for the timing of the effectiveness of a registration statement as it relates to the listing of a company in connection with a de-SPAC transaction, as defined below; and (iii) makes minor technical changes to improve the structure, clarity and readability of the proposed rules and this proposal.

⁸ Securities Exchange Act Release No. 94592 (September 4, 2025), 90 FR 43493 (September 9, 2025) (the "Initial Proposal").

⁹ See Letter from Penny Somer-Greif, Chair, and Gregory T. Lawrence, Co-Chair, Committee on Securities Law of the Business Law Section of the Maryland State Bar Association to Secretary, Securities and Exchange Commission (September 30, 2025), available at <https://www.sec.gov/comments/sr-nasdaq-2025-066/srnasdaq2025066-665487-1989414.pdf>. While the commentators expressed overall support for the proposed changes, they noted that "the proposed changes to the Rules would apply with respect to 'a de-SPAC transaction . . . where the [issuer applying to list its securities on Nasdaq] is listing upon effectiveness of a 1933 Act registration statement.' Technically, though, such a company could not actually list upon the effectiveness of the applicable registration statement."

¹⁰ Rule 5005(a)(39) defines a "Reverse Merger" as "any transaction whereby an operating company becomes an Exchange Act reporting company by combining, either directly or indirectly, with a shell company which is an Exchange Act reporting company, whether through a reverse merger, exchange offer, or otherwise." However, the definition currently excludes from being a Reverse Merger "the acquisition of an operating company by a listed company satisfying the requirements of IM-5101-2 or a business combination described in Rule 5110(a)."

¹¹ The term special purpose acquisition company (SPAC) means a company that has: (1) Indicated that its business plan is to: (i) Conduct a primary offering of securities that is not subject to the requirements of § 230.419 of this chapter (Rule 419 under the Securities Act); (ii) Complete a business combination, such as a merger, consolidation, exchange of securities, acquisition of assets, reorganization, or similar transaction, with one or more target companies within a specified time frame; and (iii) Return proceeds from the offering and any concurrent offering (if such offering or concurrent offering intends to raise proceeds) to its security holders if the company does not complete a business combination, such as a merger, consolidation, exchange of securities, acquisition of assets, reorganization, or similar transaction, with one or more target companies within the specified time frame; or (2) Represented that it pursues or will pursue a special purpose acquisition company strategy. 17 CFR 229.1601

¹² An OTC SPAC can also structure its de-SPAC transaction such that the operating company, and not the SPAC, is the surviving entity. In a transaction structured in this manner, the de-SPAC transaction would not be subject to the Reverse Merger or ADV Requirements because the listing applicant is a new registrant and not the OTC traded entity. The proposed rule change will therefore also align the treatment of these various structures.

foreign exchange; and timely filed all required periodic financial reports with the SEC or other regulatory authority (Forms 10-Q, 10-K or 20-F) for the prior year, including at least one annual report (the “Reverse Merger Requirement”).¹³

Listing Rule 5005(a)(39) defines a “Reverse Merger” as a transaction whereby an operating company becomes an Exchange Act reporting company by combining with a shell company. While a SPAC is a shell company, the rule specifically excludes from the definition of a Reverse Merger the acquisition of an operating company by a “listed” SPAC.¹⁴ The Reverse Merger rule also provides an exception for a company that lists in connection with a firm commitment underwritten public offering where the gross proceeds to the company will be at least \$40 million.¹⁵

The Reverse Merger Requirement was designed to prevent an operating company from becoming an Exchange Act reporting company in a so-called “backdoor registration”¹⁶ and immediately accessing public markets without any of the vetting from investors and/or underwriters that companies typically undergo when they perform a traditional IPO. Moreover, in these transactions, the newly public company typically is not required to file a 1933 Act registration statement, which is subject to the SEC Staff review.

The Commission recently adopted new rules to align the legal obligations of companies in de-SPAC transactions with those in traditional IPOs and mandated additional disclosures for both SPAC IPOs and de-SPAC transactions (the “SPAC Release”).¹⁷ In

the SPAC Release the Commission explained that “[w]hile structured as an M&A transaction, the de-SPAC transaction also is the functional equivalent of the private target company’s IPO, because it results in the target company becoming part of a combined company that is a reporting company and provides the private target company with access to cash proceeds that the SPAC had previously raised from the public.”¹⁸

As described above, Listing Rule 5005(a)(39) already excludes a de-SPAC transaction by a currently listed SPAC from the definition of a Reverse Merger, as do the comparable rules of other exchanges.¹⁹ This exception was premised on the fact that Nasdaq initially listed the SPAC knowing it would seek to conduct a de-SPAC transaction, and investors invested with that knowledge and with the benefit of the additional disclosure and redemption possibilities that come at the time of the de-SPAC transaction, and so it would be inconsistent to require the company to delist and trade in the OTC market at the time it completes the very transaction it was formed to pursue. Nasdaq believes that modifying this definition to also exclude other de-SPAC transactions, involving SPACs which were previously listed on a national securities exchange, from the rule is similarly reasonable where the de-SPAC is listing in connection with an effective Registration Statement. The Commission treats a de-SPAC transaction as the functional equivalent of an IPO;²⁰ and given the proposed requirement that a de-SPAC transaction occurs in connection with an effective Registration Statement, such transaction is subject to a level of investor protection, rigorous disclosure requirements, and SEC review similar to that of an IPO. Accordingly, prior to the closing of the de-SPAC transaction, SPAC shareholders will have an opportunity to review an effective Registration Statement which would allow them to make an informed decision whether to remain a shareholder of the surviving company after the business combination or redeem their shares prior to the de-SPAC transaction. Similarly, a company conducting a firm commitment underwritten offering is also currently excluded from the Reverse Merger rules,

because such an offering involves an underwriter and requires a Registration Statement, which includes issuer disclosure and can be reviewed by the Commission. Thus, Nasdaq believes that regardless of where the SPAC is trading, a company listing on Nasdaq in connection with a de-SPAC transaction involving a SPAC, which was previously listed on a national securities exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; in connection with an effective Registration Statement should be excluded from the Reverse Merger Requirement.²¹

To effect this change, Nasdaq proposes to modify Listing Rule 5005(a)(39) to revise the existing de-SPAC exclusion from the definition of a Reverse Merger to exclude any de-SPAC transaction, as that term is defined in Item 1601(a) of Regulation S-K, involving a SPAC, which is listed or was previously listed on a national securities exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; where the company is listing in connection with an effective Registration Statement.

²¹ Following its IPO, a SPAC places all or substantially all of the IPO proceeds into a trust or escrow account. The SPAC typically registers its shares and warrants under Section 12(b) of the Securities Exchange Act of 1934 and lists the units (typically consisting of a common share and a fraction of a warrant) for trading on a national securities exchange. Next, the SPAC seeks to identify a target company for a de-SPAC transaction within the time frame specified in its governing documents. If the SPAC does not complete a de-SPAC transaction within that time frame, it may seek an extension (often requiring approval from its shareholders) or dissolve and liquidate. SPAC shareholders typically also have a redemption right in connection with any votes to extend the duration of the SPAC. Nasdaq generally expects that an OTC-trading SPAC, which was previously listed on a national securities exchange, will retain the investor protection features it had at the time of its IPO, including providing its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities. See e.g., Listing Rule IM-5101-2(a) (“At least 90% of the gross proceeds from the initial public offering and any concurrent sale by the company of equity securities must be deposited in a trust account . . .”).

¹³ See Listing Rule 5110(c).

¹⁴ See Listing Rule 5005(a)(39).

¹⁵ See Listing Rule 5110(c)(3).

¹⁶ See former Commissioner Aguilar speech: Facilitating Real Capital Formation, citing release No. 33-8587, (July 15, 2005) [70 FR 42233] (stating that “These transactions generally take one of two forms: In the most common type of transaction, a “reverse merger,” the private business merges into the shell company, with the shell company surviving and the former shareholders of the private business controlling the surviving entity. In another common type of transaction, a “back door registration,” the shell company merges into the formerly private company, with the formerly private company surviving and the shareholders of the shell company becoming shareholders of the surviving entity.”).

¹⁷ Securities Exchange Act Release No. 99418 (January 24, 2024), 89 FR 14158 (February 26, 2024). In the SPAC Release the Commission also adopted a definition for a “de-SPAC transaction” that Nasdaq Staff proposes to utilize. See 17 CFR 229.1601 (Item 1601 of Regulation S-K): “The term de-SPAC transaction means a business combination, such as a merger, consolidation, exchange of securities, acquisition of assets, reorganization, or similar transaction, involving a special purpose acquisition company and one or more target companies (contemporaneously, in the case of more than one target company).”

¹⁸ SPAC Release at 14160.

¹⁹ See e.g., NYSE Listed Company Manual Section 102.01F (“However, a Reverse Merger does not include the acquisition of an operating company by a listed company which qualified for initial listing as an acquisition company under Section 102.06.”).

²⁰ See footnote 13, above.

Average Daily Trading Volume Requirement

In 2019, the Commission approved Nasdaq's proposed changes to enhance its initial listing standards related to liquidity ("Initial Liquidity Amendments").²² Under the revised standards, the ADV Requirement provides that securities that traded in the OTC market prior to the application to list such securities on Nasdaq, must have a minimum average daily trading volume over the 30 trading days prior to listing of at least 2,000 shares a day, with trading occurring on more than half of those 30 days. Nasdaq adopted the ADV Requirement to help ensure a liquid trading market, promote price discovery, and help establish an appropriate market price for the OTC securities listing on Nasdaq.

Since implementing the Initial Liquidity Amendments, Nasdaq has determined that the ADV Requirement is neither necessary nor appropriate for the listing of a Company in connection with a de-SPAC transaction, involving a SPAC, which was previously listed on a national securities exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; in connection with an effective Registration Statement.

Historically, SPACs listed and traded primarily, if not exclusively, on national securities exchanges while pursuing a business combination, and, at the time, the ADV Requirement was adopted SPACs were neither targeted nor immediately affected by the ADV Requirement. Recently, however, Nasdaq observed an increase in a number of SPACs that have been delisted from an exchange and then trade as SPACs in the OTC market. When an OTC-trading SPAC enters into a business combination and applies to list on Nasdaq in connection with the de-SPAC transaction the ADV Requirement applies because the primary equity security "is trading in the U.S. over-the-counter market as of the date of application . . ." ²³

For an operating company, investors determine a valuation of the company based on its revenues, future cash flow

expectations, business activities, and peer valuations, among other metrics. Nasdaq believes that imposing the ADV Requirement on operating companies trading in the OTC market helps ensure that once listed these companies will have sufficient investor base and trading interest to provide the depth and liquidity necessary to promote fair and orderly markets. In contrast, in the Exchange's view, the value of a SPAC prior to a business combination typically is not based on investor interest in the operating company or analysis of its metrics, but instead is based primarily on the value of the cash held in the trust account and supported by the potential redemption ability at the time of the de-SPAC transaction. Nasdaq therefore believes that the ADV Requirement for OTC-trading SPACs is not relevant to help establish the legitimacy of the SPAC market price.

Further, Nasdaq believes that the investor base in the SPAC, typically, changes significantly at the time of the de-SPAC transaction and investors interested in the operating company will first purchase the securities following that transaction. As a result, trading in the SPAC prior to the de-SPAC transaction is not indicative of how the company will trade after the transaction and, therefore, the de-SPAC transaction more closely resembles an IPO of the target company than an OTC uplisting, thus rendering the ADV Requirement not meaningful in helping establish whether the new company will trade well once listed. Accordingly, Nasdaq proposes to modify Listing Rules 5315(e)(4), 5405(a)(4), and 5505(a)(5), on the Nasdaq Global Select, Global and Capital Markets, accordingly, to exclude from the ADV Requirement the security of a company listing in connection with a de-SPAC transaction, as that term is defined in Item 1601(a) of Regulation S-K, which was previously listed on a national securities exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; in connection with an effective Registration Statement.

Although OTC-trading SPACs ²⁴ will be excluded from the ADV Requirement at the time of their application, the post business combination company will be required to satisfy all of Nasdaq's other initial listing standards, as would any IPO or other new listing. Nasdaq believes that this will continue to help

ensure that securities of the post business combination companies have sufficient public float, investor base, and trading interest likely to generate depth and liquidity to support exchange listing and trading, which will help to protect investors and the public interest.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁶ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by (1) excluding the security of certain OTC-trading SPACs listing in connection with a de-SPAC transaction in connection with an Registration Statement, as described above, from the definition of a Reverse Merger, and (2) removing a listing requirement applicable to certain OTC-trading SPACs, as described above, that is not an appropriate measure of investor base and trading interest. In both cases, based on the unique characteristics of a de-SPAC transaction, the changes will align the requirements for listing a de-SPAC transaction with those for listing an IPO, consistent with the treatment by the Commission in other contexts, eliminating an impediment to a free and open market, while ensuring adequate distribution, shareholder interest, a liquid trading market and investor protections through other listing standards.

Nasdaq believes that excluding a de-SPAC transaction by an OTC-trading SPAC, which is listed or was previously listed on a national securities exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; from the Reverse Merger definition avoids imposing an unnecessary impediment to the mechanism of a free and open market and is not unfairly discriminatory. Specifically, as noted above, the Reverse Merger Requirement was designed to prevent an operating company from becoming an Exchange Act reporting company and immediately accessing public markets without proper disclosure and vetting opportunities by the Commission and investors. Nasdaq

²² See Securities Exchange Act Release No. 86314 (July 5, 2019), 84 FR 33102 (July 11, 2019) (approving SR-NASDAQ-2019-009).

²³ See Listing Rules 5315(e)(4), 5405(a)(4), and 5505(a)(5): "[i]f the security is trading in the U.S. over-the-counter market as of the date of application, such security must have a minimum average daily trading volume of 2,000 shares over the 30 trading day period prior to listing . . ."

²⁴ See footnote 16, above.

²⁵ 15 U.S.C. 78f(b).

²⁶ 15 U.S.C. 78f(b)(5).

believes that a de-SPAC transaction with such OTC-trading SPAC where the post-transaction entity lists in connection with an effective Registration Statement does not present the same concerns as a typical Reverse Merger transaction. The Commission in the SPAC Release explained that “[w]hile structured as an M&A transaction, the de-SPAC transaction also is the functional equivalent of the private target company’s IPO, because it results in the target company becoming part of a combined company that is a reporting company and provides the private target company with access to cash proceeds that the SPAC had previously raised from the public.” Unlike the historical “backdoor registrations” that the Reverse Merger rule was designed to capture, a de-SPAC transaction would be required to file a 1933 Act registration statement to avail itself of the proposed rule change.

Nasdaq believes that excluding a de-SPAC transaction by such OTC-trading SPACs from the definition of a Reverse Merger is reasonable because it aligns the treatment of such transactions with the treatment of a de-SPAC transaction by a Nasdaq-listed SPAC because both cases represent the functional equivalent of an IPO, as the Commission explained in the SPAC Release, and, therefore, these cases differ from a typical Reverse Merger where a public shell merges into a private company, in a so-called “backdoor registration”²⁷ without a Registration Statement which is subject to review by Commission staff.²⁸

The proposed requirement that a de-SPAC transaction by a previously listed OTC-trading SPAC, as described above, or a listed SPAC, is excluded from the definition of Reverse Merger only where the Company is listing in connection with an effective Registration Statement is designed to protect investors and the public interest, because it will ensure such companies satisfy the rigorous disclosure requirements under the Securities Act of 1933 and are subject to review by Commission staff. In addition, as noted above, SPACs that are listed or were previously listed²⁹ on a national securities exchange, generally have established certain investor protection safeguards.³⁰ Accordingly, prior to the

closing of the de-SPAC transaction, SPAC shareholders will have an opportunity to review an effective Registration Statement allowing them to make an informed decision whether to remain a shareholder of the surviving company after the business combination or redeem their shares prior to the de-SPAC transaction.

Nasdaq also believes that excluding the security of a company listing in connection with a de-SPAC transaction, in connection with an effective Registration Statement, as described above, from the ADV Requirement applicable to newly listing companies that previously traded in the OTC market is designed to avoid imposing an unnecessary impediment to the mechanism of a free and open market and is not unfairly discriminatory.

Specifically, as noted above, the ADV Requirement was adopted to help ensure a liquid trading market, promote price discovery, and establish an appropriate market price for the OTC securities listing on Nasdaq. However, since implementing the Initial Liquidity Amendments, Nasdaq has determined that the ADV Requirement is neither necessary nor appropriate for the listing of de-SPAC transactions, involving a SPAC, which was previously listed on a national securities exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities, because trading in the SPAC is not indicative of trading in the merged operating company because shareholders, typically, have the opportunity to redeem their shares in the SPAC for a pro rata portion of the trust at the time of the business combination.

For an operating company, investors determine a valuation of the company based on its revenues, future cash flow expectations, business activities, and peer valuations, among other metrics. Nasdaq believes that imposing the ADV Requirement on operating companies trading in the OTC market helps ensure that once listed these companies will have sufficient investor base and trading interest to provide the depth and liquidity necessary to promote fair and orderly markets. In contrast, in the Exchange’s view, the value of a SPAC prior to a business combination is not based solely on investor demand for the security but is based primarily on the

value of the cash held in the trust account. In that regard, the Exchange has observed that SPACs generally have historically traded close to the value in the trust during the period between its public offering and the consummation of a business combination. This suggests that the value of a SPAC’s security derives from the value of the underlying trust. Nasdaq therefore believes that assessing the average daily trading volume of the SPAC before the transaction is not relevant to help establish the trading characteristics of the post transaction entity.

Further, Nasdaq believes that the investor base in the SPAC, typically, changes significantly at the time of the de-SPAC transaction and investors interested in the operating company will first purchase the securities following that transaction. As a result, trading in the SPAC prior to the de-SPAC transaction is not indicative of how the company will trade after the transaction and, therefore, the de-SPAC transaction more closely resembles an IPO of the target company than an OTC uplisting rendering the ADV Requirement not meaningful in helping establish whether the new company will trade well once listed.³¹

The Exchange believes that other listing standards will help it ensure adequate distribution, shareholder interest and a liquid trading market of a de-SPAC transaction security following a business combination. In all cases, a de-SPAC transaction must satisfy Nasdaq’s initial listing standards which will continue to help ensure that securities of the post business combination entity have sufficient public float, investor base, and trading interest likely to generate depth and liquidity to support exchange listing and trading, which should help to protect investors and the public interest.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule changes are designed to avoid imposing an unnecessary impediment to the mechanism of a free and open market and does not limit the ability of companies to list on any other national securities exchange. Furthermore, while the rule change may

²⁷ See footnote 11, above.

²⁸ Nasdaq notes that a de-SPAC transaction where the SPAC is not the surviving entity is not subject to the Reverse Merger Requirement because the entity to be listed is a new registrant, and, therefore a de-SPAC transaction can already be structured so as not to implicate the Reverse Merger Requirement.

²⁹ See, footnote 16, above.

³⁰ See, Listing Rule IM-5101–2. Listing of Companies Whose Business Plan is to Complete

One or More Acquisitions. See also, Section 102.06 Minimum Numerical Standards—Acquisition Companies; of the NYSE Listed Company Manual.

³¹ Nasdaq notes that a de-SPAC transaction where the SPAC is not the surviving entity is not subject to the ADV Requirement because the entity to be listed is a new registrant, and, therefore a de-SPAC transaction can already be structured not to implicate the ADV Requirement.

permit more companies to list on Nasdaq in connection with de-SPAC transactions, other exchanges could adopt similar rules to compete for such listings. In addition, the proposed rule change could help facilitate competition amongst OTC-trading SPACs with other SPACs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Discussion and Commission Findings

After careful review of the proposed rule change, as modified by Amendment No. 1 ("Amended Proposal"), and the comments received, the Commission finds that the Amended Proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.³² In particular, the Commission finds that the Amended Proposal is consistent with Section 6(b)(5) of the Act,³³ which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, and not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Nasdaq proposes to enable a previously listed OTC SPAC to re-list on the Exchange upon a de-SPAC transaction by treating the de-SPAC transaction in the same way as a de-SPAC transaction with a listed SPAC and, in each case, applying the Exchange rules that are applicable to an initial public offering as opposed to the Reverse Merger process. Two commenters expressed support for the proposal. One commenter stated its full agreement with the Exchange's rationale for the proposal and specifically stated that the Reverse Merger rule makes no exception for de-SPAC transactions where an OTC-traded SPAC is applying to list on Nasdaq as the continuing publicly listed entity following the closing.³⁴ The commenter stated that the

Reverse Merger rule imposes an unnecessary regulatory burden on OTC-traded SPACs whereby the SPAC remains the continuing publicly listed entity following the closing of the de-SPAC transaction³⁵ and that the proposed rule change would eliminate an obstacle to capital formation for OTC-traded SPACs.³⁶ This commenter also stated that the proposed rule change would not compromise investor protection because the OTC-traded SPACs would be required to file a Registration Statement that would be reviewed by the Commission and to satisfy all applicable Nasdaq initial listing requirements.³⁷ The commenter further stated that the one-year seasoning requirement forces OTC-traded SPACs to delay their Nasdaq listing for an entire year even if they have satisfied every other Nasdaq initial listing requirement.³⁸ The other commenter supported the proposal but suggested a technical revision to the proposed rule's language that a company lists "upon effectiveness" of the registration statement, stating that such a company could not actually list "upon" the effectiveness of the applicable registration statement.³⁹

The Amended Proposal will enable SPACs previously listed on a national securities exchange but trading in the OTC market to re-list on Nasdaq following a de-SPAC transaction, if they meet certain conditions. In particular, these conditions require a previously listed SPAC to (1) provide its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; and (2) list in connection with an effective Registration Statement. These conditions require the previously listed SPAC that is engaging in a de-SPAC transaction to provide substantially similar investor protections in connection with the de-SPAC transaction that a listed SPAC engaging in a de-SPAC transaction provides pursuant to Nasdaq IM-5101-2(a), (d),

Acquisition Corp., dated Oct. 9, 2025 ("Welsbach Letter"), at 2.

³⁵ See Welsbach Letter at 2.

³⁶ See Welsbach Letter at 2.

³⁷ See Welsbach Letter at 1-2.

³⁸ See Welsbach Letter at 2.

³⁹ See letter from Penny Somer-Greif, Chair, and Gregory T. Lawrence, Co-Chair, Committee on Securities Law of the Business Law Section of the Maryland State Bar Association, dated Sept. 30, 2025, at 3. In response to this commenter, the Exchange modified the language to state, "where the Company is listing in connection with an effective 1933 Securities Act registration statement."

and (e). Furthermore, an OTC SPAC that was previously listed on a national securities exchange was subject to listing standards tailored to this type of listing and the Exchange notes that an OTC SPAC generally is expected to retain the investor protection features established at the time of its IPO. Moreover, a re-listing following a de-SPAC transaction must meet Nasdaq's initial listing standards. Once re-listed on Nasdaq, the company will be subject to Nasdaq's continued listing standards and will be subject to delisting procedures if it fails to meet those standards.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views and arguments concerning whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2025-066 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2025-066. 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 filing will be available for inspection and copying at the principal office of Nasdaq. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR-NASDAQ-2025-066 and should be submitted on or before January 2, 2026.

V. Accelerated Approval of Proposed Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the Amended Proposal prior to

³² 15 U.S.C. 78f. In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³³ 15 U.S.C. 78f(b)(5).

³⁴ See letter from Christopher Clower, Chief Operating Officer, Welsbach Technology Metals

the 30th day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. Amendment No. 1, without altering the purpose of the original proposal, provides additional investor protection, and clarity and justification for the proposal's consistency with the Act. Specifically, Amendment No. 1: (i) specifies that the proposed changes will apply only to a de-SPAC transaction involving a SPAC that was previously listed on an exchange and provides its public shareholders the opportunity to redeem or tender their shares in connection with the de-SPAC transaction in exchange for a pro rata share of the IPO proceeds and concurrent sale by the company of equity securities; (ii) address a commenter's suggestion for a technical revision regarding the proposed rule language for the timing of the effectiveness of a registration statement as it relates to the listing of a company in connection with a de-SPAC transaction; and (iii) makes minor technical changes to improve the structure, clarity and readability of the proposed rules and this proposal.

The Commission therefore finds that Amendment No. 1 raises no novel regulatory issues and is reasonably designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest. Accordingly, pursuant to Section 19(b)(2) of the Act,⁴⁰ the Commission finds good cause to approve the Amended Proposal on an accelerated basis prior to the 30th day after publication of notice of the filing of Amendment No. 1 in the **Federal Register**.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁴¹ that the proposed rule change (SR-NASDAQ-2025-066), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴²

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2025-22469 Filed 12-10-25; 8:45 am]

BILLING CODE 8011-01-P

⁴⁰ 15 U.S.C. 78s(b)(2).

⁴¹ *Id.*

⁴² 17 CFR 200.30-3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before January 12, 2026.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection request by selecting "Small Business Administration"; "Currently Under Review," then select the "Only Show ICR for Public Comment" checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at Shauniece.carter@sba.gov; (202) 205-6536, or from www.reginfo.gov/public/do/PRAMain.

SUPPLEMENTARY INFORMATION: SBA Form 912 is used to collect basic identifying information needed to make character and eligibility determinations with respect to applicants and borrowers for monetary loan assistance or for participation in SBA loan programs during servicing of the disaster loan program. The form is being revised to streamline and align with current SBA regulations.

Solicitation of Public Comments: Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control No: 3245-0178.

Title: Statement of Personal History.

Description of Respondents: Applicants/Principals/Borrowers participating in SBA programs.
Estimated Annual Responses: 10,000.
Estimated Annual Hour Burden: 2,500.

Shauniece Carter,

Interim Agency Clearance Officer.

[FR Doc. 2025-22498 Filed 12-10-25; 8:45 am]

BILLING CODE 8026-09-P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA-2025-0618]

Rate for Assessment on Direct Payment of Fees to Representatives in 2026

AGENCY: Social Security Administration (SSA).

ACTION: Notice.

SUMMARY: We are announcing the assessment percentage rate under the Social Security Act (Act) is 6.3 percent for 2026.

FOR FURTHER INFORMATION CONTACT:

Mona B. Ahmed, Head of Program, Fiscal, & Disclosure Law, Law and Policy, Social Security Administration, 1961 Stout Street 4th Floor, Suite 4169, Denver, CO 80294. Phone: (303) 844-7108, email Mona.Ahmed@ssa.gov.

SUPPLEMENTARY INFORMATION: A claimant may appoint a qualified individual as a representative to act on their behalf in matters before the Social Security Administration (SSA). If the claimant is entitled to past-due benefits and was represented either by an attorney or by a non-attorney representative who has met certain prerequisites, the Act provides that we shall withhold up to 25 percent of the past-due benefits and use that money to pay the representative's approved fee directly to the representative.

When we pay the representative's authorized fee directly to the representative, we must collect from that fee payment an assessment to recover the costs we incur in determining and paying representatives' fees. The Act provides that the assessment we collect will be the lesser of two amounts: a specified dollar limit; or the amount determined by multiplying the fee we are paying by the assessment percentage rate. (Sections 206(d), 206(e), and 1631(d)(2) of the Act, 42 U.S.C. 406(d), 406(e), and 1383(d)(2).)

The Act initially set the dollar limit at \$75 in 2004 and provides that the limit will be adjusted annually based on changes in the cost-of-living. (Sections

206(d)(2)(A) and 1631(d)(2)(C)(ii)(I) of the Act, 42 U.S.C. 406(d)(2)(A) and 1383(d)(2)(C)(ii)(I).) The maximum dollar limit for the assessment currently is \$123, as we announced in the **Federal Register** on November 3, 2025 (90 FR 49047).

The Act requires us each year to set the assessment percentage rate at the lesser of 6.3 percent or the percentage rate necessary to achieve full recovery of the costs we incur to determine and pay representatives' fees. (Sections 206(d)(2)(B)(ii) and 1631(d)(2)(C)(ii)(II) of the Act, 42 U.S.C. 406(d)(2)(B)(ii) and 1383(d)(2)(C)(ii)(II).)

Based on the best available data, we have determined that the current rate of 6.3 percent will continue for 2026. We will continue to review our costs for these services on a yearly basis.

Thomas J. Holland,
Chief Financial Officer for Finance, and
Management, Social Security Administration.

[FR Doc. 2025-22534 Filed 12-10-25; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF STATE

[Public Notice 12880]

30-Day Notice of Proposed Information Collection: Statement of Political Contributions, Fees, and Commissions Relating to Sales of Defense Articles and Defense Services

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to January 12, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection

listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Andrea Battista, who may be reached at BattistaAL@state.gov or 202-992-0973.

SUPPLEMENTARY INFORMATION:

• *Title of Information Collection:* Statement of Political Contributions, Fees, and Commissions Relating to Sales of Defense Articles and Defense Services.

• *OMB Control Number:* 1405-0025.

• *Type of Request:* Renewal of an Approved Information Collection.

• *Originating Office:* Directorate of Defense Trade Controls (DDTC).

• *Form Number:* No Form.

• *Respondents:* Persons requesting a license or other approval for the export, reexport, or retransfer of USML-regulated defense articles or defense services valued in an amount of \$500,000 or more that are being sold commercially to or for the use of the armed forces of a foreign country or international organization or persons who enter into a contract with the Department of Defense for the sale of defense articles or defense services valued in an amount of \$500,000 or more under section 22 of the AECA.

• *Estimated Number of Respondents:* 57.

• *Estimated Number of Responses:* 450.

• *Average Time per Response:* 1 hour.

• *Total Estimated Burden Time:* 450 hours.

• *Frequency:* On Occasion.

• *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

DDTC regulates the export and temporary import of defense articles and defense services enumerated on the United States Munitions List (USML) in accordance with the Arms Export Control Act (AECA) (22 U.S.C. 2751 *et seq.*) and the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120-130). In accordance with section 39 of the AECA, the Secretary of State must require, in part, adequate and timely reporting of political contributions, gifts, commissions and fees paid, or offered or agreed to be paid in connection with the sales of defense articles or defense services licensed or approved under AECA sections 22 and 38. Pursuant to ITAR § 130.9(a), any person applying for a license or approval required under section 38 of the AECA for sale to the armed forces of a foreign country or international organization valued at \$500,000 or more (see ITAR § 130.2) must inform DDTC, and provide certain specified information, when they have paid, offered to, or agreed to pay, (1) political contributions in an aggregate amount of \$5,000 or greater; or (2) fees or commissions in an aggregate amount equaling or exceeding \$100,000. Similarly, ITAR § 130.9(b) requires any person who enters into a contract with the Department of Defense under section 22 of the AECA, valued at \$500,000 or more (see ITAR § 130.7), to inform DDTC and provide the specified information, when they or their vendors, have paid, or offered or agreed to pay, in respect to any sale (1) political contributions in an aggregate amount of \$5,000 or greater; or (2) fees or commissions in an aggregate amount equaling or exceeding \$100,000. Respondents are also required to collect information pursuant to Sections 130.12 and 130.13 prior to submitting their report to DDTC.

Methodology

Respondents will submit information as attachments to relevant license applications or requests for other approval.

Michael J. Vaccaro,

Deputy Assistant Secretary for Defense Trade Controls, U.S. Department of State.

[FR Doc. 2025-22525 Filed 12-10-25; 8:45 am]

BILLING CODE 4710-25-P

DEPARTMENT OF STATE**[Public Notice 12879]****30-Day Notice of Proposed Information Collection: Nontransfer and Use Certificate**

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to January 12, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Andrea Battista, SA–1, 12th Floor, Directorate of Defense Trade Controls, Bureau of Political Military Affairs, U.S. Department of State, Washington, DC 20522–0112, via phone at (202) 663–3136, or via email at battistaal@state.gov.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Nontransfer and Use Certificate.
- *OMB Control Number:* 1405–0021.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–83.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.
- *Estimated Number of Respondents:* 2,947.
- *Estimated Number of Responses:* 2,947.
- *Average Time per Response:* 1 hour.
- *Total Estimated Burden Time:* 2,947.
- *Frequency:* On occasion.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Pursuant to ITAR § 123.10, a completed “Nontransfer and Use Certificate” (OMB No. 1405–0021, Form DSP–83) must be received by DDTC for the export of significant military equipment and classified articles, including classified technical data. Pursuant to ITAR § 124.10, a completed “Nontransfer and Use Certificate” must be submitted with any manufacturing license agreement or technical assistance agreement that relates to significant military equipment or classified defense articles, including classified technical data. In both cases, the foreign consignee (if applicable), foreign end-user, and applicant execute this form. By signing the certificate the foreign end-user certifies that they will not, except as specifically authorized by prior written approval of the Department of State, re export, resell or otherwise dispose of the defense articles enumerated in the application (1) outside the foreign country named as the country of ultimate destination; or (2) to any other person. With respect to agreements that involve classified articles or classified technical data, an authorized representative of the foreign government must also sign the form.

Methodology

This information collection may be sent to the Directorate of Defense Trade

Controls via the following methods: electronically or mail.

Michael J. Vaccaro,

Deputy Assistant Secretary for Defense Trade Controls, U.S. Department of State.

[FR Doc. 2025–22524 Filed 12–10–25; 8:45 am]

BILLING CODE 4710–25–P

SURFACE TRANSPORTATION BOARD**[Docket No. 36869]****Iowa Northern Railway Company—Trackage Rights Exemption—Cedar River Railroad Company**

Iowa Northern Railway Company (IANR) has filed a verified notice of exemption under 49 CFR 1180.2(d)(7) to acquire limited local trackage rights on a line of railroad of Cedar River Railroad Company (CEDR) ¹ between milepost 0.0 at Mona Junction in Cedar Falls, Iowa, and milepost 85.0 in London Township, Minn. (the Line), a distance of approximately 85.0 miles.²

According to the verified notice, on November 3, 2025, IANR and CEDR entered into a written trackage rights agreement that permits IANR to operate trains with its own crews to and from an ethanol facility of Absolute Energy LLC (or any successor entity) on CEDR’s line at Mona/St. Ansgar, Iowa, as well as to serve other facilities on CEDR’s line that tender or receive “co-load” traffic in blocks of at least 25 cars that are combined into unit trains for movement to or from a single off-line location. IANR states that the trackage rights are intended to provide operational flexibility and reliability in service to customers.³

¹ The verified notice states that IANR and CEDR are indirect rail carrier subsidiaries of Canadian National Railway Company (CNR), whose U.S. rail carrier subsidiaries (including IANR and CEDR) are held directly or indirectly by CNR’s wholly owned subsidiary Grand Trunk Corporation (GTC). See *Can. Nat’l Ry.—Control—Iowa N. Ry.*, FD 36744 (STB served Jan. 14, 2025); see also *Can. Nat’l Ry.—Control—Ill. Cent. Corp.*, 4 S.T.B. 122 (1999); *Ill. Cent. Corp.—Control—CCP Holdings, Inc.*, FD 32858 (STB served May 14, 1996).

² In its verified notice of exemption, IANR states that it owns, leases, or operates approximately 218 miles of rail line extending generally from Cedar Rapids, Iowa, through Waterloo, Iowa, and Cedar Falls, Iowa, to Manly, Iowa, and that CEDR owns approximately 100 miles of rail line extending north from Cedar Falls through Charles City, Iowa, to Glenville, Minn. The verified notice states that IANR and CEDR connect at Cedar Falls.

³ The verified notice states that the parties’ agreement is in the form of an amendment to an existing trackage rights agreement, previously submitted to the Board, between CEDR and Chicago, Central & Pacific Railroad Company (CCP), another GTC affiliate. See *Chi., Cent. & Pac. R.R.—Trackage Rts. Exemption—Cedar River R.R.*, FD 36722 (STB served Sept. 15, 2023). In a related proceeding, CCP has filed a verified notice of

The transaction may be consummated on or after December 25, 2025, the effective date of the exemption (30 days after the verified notice was filed).

As a condition to this exemption, any employees affected by the acquisition of the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad*, 360 I.C.C. 653 (1980).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 18, 2025 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36869, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on IANR's representative, Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606-3208.

According to IANR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: December 8, 2025.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2025-22502 Filed 12-10-25; 8:45 am]

BILLING CODE 4915-01-P

exemption under 49 CFR 1180.2(d)(7) to extend its existing trackage rights on CEDR's rail line, pursuant to the same amendment to the trackage rights agreement. See *Chi., Cent. & Pac. R.R.—Trackage Rts. Exemption—Cedar River R.R.*, Docket No. FD 36722 (Sub-No. 1). According to the verified notice, the amended trackage rights agreement admits IANR to the same CEDR line over which CCP holds or is obtaining trackage rights.

SURFACE TRANSPORTATION BOARD

[Docket No. 36722 (Sub-No. 1)]

Chicago, Central & Pacific Railroad Company—Amended Trackage Rights Exemption—Cedar River Railroad Company

Chicago, Central & Pacific Railroad Company (CCP) has filed a verified notice of exemption under 49 CFR 1180.2(d)(7) to acquire limited local trackage rights over a line of railroad of Cedar River Railroad Company (CEDR),¹ between milepost 41.5 in Charles City, Iowa, and milepost 85.0 in London Township, Minn. (the Line), a distance of approximately 43.5 miles.²

According to the verified notice, CCP acquired overhead trackage rights on CEDR's rail line between Mona Junction and Charles City in 2023.³ CCP states that, on November 3, 2025, it entered into an amended trackage rights agreement with CEDR to permit CCP to acquire extended, limited local trackage rights over the Line so that CCP may operate trains with its own crews to and from an ethanol facility of Absolute Energy LLC (or any successor entity) on CEDR's line at Mona/St. Ansgar, Iowa, as well as to serve other facilities on CEDR's line that tender or receive "co-load" traffic in blocks of at least 25 cars that are combined into unit trains for movement to or from a single off-line location. CCP states that the trackage rights are intended to provide operational flexibility and reliability in service to customers.⁴

The transaction may be consummated on or after December 25, 2025, the

¹ The verified notice states that CCP and CEDR are indirect rail carrier subsidiaries of Canadian National Railway Company (CNR), whose U.S. rail carrier subsidiaries (including CCP and CEDR) are held directly or indirectly by CNR's wholly owned subsidiary Grand Trunk Corporation. See *Can. Nat'l Ry.—Control—Ill. Cent. Corp.*, 4 S.T.B. 122 (1999); see also *Ill. Cent. Corp.—Control—CCP Holdings, Inc.*, FD 32858 (STB served May 14, 1996).

² As explained by CCP in its verified notice, CCP operates approximately 725 miles of rail line between Chicago, Ill., and Council Bluffs/Sioux City, Iowa, and CEDR owns approximately 100 miles of rail line extending north from Cedar Falls, Iowa, through Charles City, to Glenville, Minn. The verified notice states that CEDR and CCP connect at Mona Junction in Cedar Falls.

³ See *Chi., Cent. & Pac. R.R.—Trackage Rts. Exemption—Cedar River R.R.*, FD 36722 (STB served Sept. 15, 2023) (acquiring overhead trackage rights over approximately 41.5 miles of rail line owned by CEDR between milepost 0.0 at Mona Junction and milepost 41.5 in Charles City).

⁴ CCP states that the amended trackage rights agreement also provides for Iowa Northern Railway Company (IANR), a CCP/CEDR affiliate, to obtain new trackage rights over CEDR's line that overlap with the trackage rights currently held and to be obtained by CCP. The IANR trackage rights transaction is the subject of a separate proceeding. See *Iowa N. Ry.—Trackage Rts. Exemption—Cedar River R.R.*, Docket No. 36869.

effective date of the exemption (30 days after the verified notice was filed).

As a condition to this exemption, any employees affected by the acquisition of the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad*, 360 I.C.C. 653 (1980).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 18, 2025 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36722 (Sub No. 1), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423-0001. In addition, a copy of each pleading must be served on CCP's representative, Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606-3208.

According to CCP, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at www.stb.gov.

Decided: December 8, 2025.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2025-22504 Filed 12-10-25; 8:45 am]

BILLING CODE 4915-01-P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR-2025-0243]

Request for Comments and Notice of a Public Hearing Regarding the 2026 Special 301 Review

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments and notice of public hearing.

SUMMARY: Each year, the Office of the United States Trade Representative (USTR) conducts a review to identify countries that deny adequate and effective protection of intellectual

property (IP) rights or deny fair and equitable market access to U.S. persons who rely on IP protection. Based on this review, the U.S. Trade Representative determines which, if any, of these countries to identify as Priority Foreign Countries. USTR requests written comments that identify acts, policies, or practices that may form the basis of a country's identification as a Priority Foreign Country or placement on the Priority Watch List or Watch List.

DATES:

January 28, 2026 at 11:59 p.m. EST: Deadline for submission of written comments, hearing statements, and notices of intent to appear at the hearing from the public.

February 11, 2026 at 11:59 p.m. EST: Deadline for submission of written comments, hearing statements, and notices of intent to appear at the hearing from foreign governments.

February 18, 2026: The Special 301 Subcommittee (Subcommittee) will hold a public hearing at the Office of the United States Trade Representative, 1724 F Street NW, Rooms 1&2, Washington, DC. If necessary, the hearing may continue on the next business day. Those who intend to testify at the public hearing must submit a notice of intent to appear by the deadlines stated above. Please consult the USTR website at <https://ustr.gov/issue-areas/intellectual-property/Special-301>, for confirmation of the date and location and the schedule of witnesses.

February 25, 2026 at 11:59 p.m. EST: Deadline for submission of post-hearing written comments from persons who testified at the public hearing.

On or about April 30, 2026: USTR will publish the 2026 Special 301 Report within 30 days of the publication of the National Trade Estimate Report.

ADDRESSES: USTR strongly encourages electronic submissions made through the Federal eRulemaking Portal: <https://www.regulations.gov> (Regulations.gov). Follow the submission instructions in section IV below. The docket number is USTR-2025-0243. For alternatives to on-line submissions, please contact USTR at Special301@ustr.eop.gov before transmitting a comment and in advance of the relevant deadline.

FOR FURTHER INFORMATION CONTACT: Claire Avery-Page, Director for Innovation and Intellectual Property, at Special301@ustr.eop.gov or (202) 395-6862. You can find information about the Special 301 Review at <https://www.ustr.gov>.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 182 of the Trade Act of 1974 (Trade Act) (19 U.S.C. 2242), commonly known as the Special 301 provisions, requires the U.S. Trade Representative to identify countries that deny adequate and effective IP protections or fair and equitable market access to U.S. persons who rely on IP protection. The Trade Act requires the U.S. Trade Representative to determine which, if any, of these countries to identify as Priority Foreign Countries. Acts, policies, or practices that are the basis of a country's identification as a Priority Foreign Country can be subject to the procedures set out in sections 301–305 of the Trade Act (19 U.S.C. 2411–2415).

In addition, USTR has created a Priority Watch List and Watch List to assist in pursuing the goals of the Special 301 provisions. Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IP protection, enforcement, or market access for persons who rely on intellectual property protection. Trading partners placed on the Priority Watch List are the focus of increased bilateral engagement concerning the problem areas.

USTR chairs the Subcommittee, which reviews information from many sources, and consults with and makes recommendations to the U.S. Trade Representative on issues arising under Special 301. Written submissions from the public are a key source of information for the Special 301 review process. In 2026, USTR will conduct a public hearing as part of the review process and will allow hearing participants to provide additional information relevant to the review. At the conclusion of the process, USTR will publish the results of the review in a Special 301 Report.

USTR requests that interested persons identify through the process outlined in this notice those countries whose acts, policies, or practices deny adequate and effective protection for IP rights or deny fair and equitable market access to U.S. persons who rely on IP protection. The Special 301 provisions also require the U.S. Trade Representative to identify any act, policy, or practice of Canada that affects cultural industries, was adopted or expanded after December 17, 1992, and is actionable under Article 32.6 of the United States-Mexico-Canada Agreement (USMCA) (as defined in section 3 of the USMCA Implementation Act). USTR invites the public to submit views relevant to this aspect of the review.

The Special 301 provisions require the U.S. Trade Representative to identify all such acts, policies, or practices within 30 days of the publication of the National Trade Estimate Report. In accordance with this statutory requirement, USTR will publish the annual Special 301 Report on or about April 30, 2026.

II. Public Comments

To facilitate this year's review, written comments should be as detailed as possible and provide all necessary information to identify and assess the effect of the acts, policies, and practices. USTR invites written comments that provide specific references to laws, regulations, policy statements, including innovation policies, executive, presidential, or other orders, and administrative, court, or other determinations that should factor into the review. USTR also requests that, where relevant, submissions mention particular regions, provinces, states, or other subdivisions of a country in which an act, policy, or practice is believed to warrant special attention. Finally, submissions proposing countries for review should include data, loss estimates, and other information regarding the economic impact on the United States, U.S. industry, and the U.S. workforce caused by the denial of adequate and effective intellectual property protection. Comments that include quantitative loss claims should include the methodology used to calculate the estimated losses.

III. Public Hearing

The Special 301 Subcommittee will convene a public hearing on February 18, 2026, in Rooms 1 and 2, 1724 F Street NW, Washington, DC, at which interested persons, including representatives of foreign governments, may appear to provide oral testimony. If necessary, the hearing may continue on the next business day. Because the hearing will take place in federal facilities, attendees must present REAL ID-compliant state-issued identification or other acceptable identification and will be screened for security purposes. Please consult the USTR website at <https://ustr.gov/issue-areas/intellectual-property/Special-301>, to confirm the date and location of the hearing and to obtain copies of the hearing schedule. USTR also will post the transcript and recording of the hearing on the USTR website as soon after the hearing as possible.

Witnesses must deliver prepared oral testimony, which is limited to five minutes, before the Special 301 Subcommittee in person and in English.

Subcommittee member agencies may ask questions following the prepared statement. Witnesses not from foreign governments must submit a notice of intent to testify and a hearing statement by January 28, 2026, and foreign government witnesses must submit a notice of intent to testify and a hearing statement by February 11, 2026. The submissions must be in English and must include: (1) The name, address, telephone number, email address, and firm or affiliation of the individual wishing to testify, and (2) a hearing statement that is relevant to the Special 301 review.

IV. Submission Instructions

All submissions must be in English and sent electronically via *Regulations.gov* using docket number USTR–2025–0243. To submit comments, locate the docket (folder) by entering the number USTR–2025–0243 in the ‘search for dockets and documents on agency actions’ window at the *Regulations.gov* home page and click ‘search.’ The site will provide a search-results page listing all documents associated with this docket. Locate the reference to this notice by selecting ‘notice’ under ‘document type’ on the left side of the search-results page, and click on the link entitled ‘comment’.

USTR requests that you provide comments in an attached document, and that you name the file according to the following protocol: Commenter Name or Organization_2026 Special 301_Review_Comment, or Notice of Intent to Testify or Hearing Statement. Please include the following information in the ‘start typing comment here’ field: ‘2026 Special 301 Review’ and whether the submission is a comment, a request to testify at the hearing, or a hearing statement. Please submit documents prepared in (or compatible with) Microsoft Word (.doc) or Adobe Acrobat (.pdf) formats. If you prepare the submission in a compatible format, please indicate the name of the relevant software application in the ‘start typing comment here’ field. For further information on using *Regulations.gov*, please select ‘FAQ’ on the bottom of any page.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the comment itself, rather than submitting them as separate files.

For any comments that contains BCI, the file name of the business confidential version should begin with

the characters ‘BCI’. Any page containing BCI must be clearly marked ‘BUSINESS CONFIDENTIAL’ on the top of that page and the submission should clearly indicate, via brackets, highlighting, or other means, the specific information that is business confidential. A filer requesting business confidential treatment must certify that the information is business confidential and that they would not customarily release it to the public. Additionally, the filer should type ‘business confidential’ in the ‘start typing comment here’ field. Filers of comments containing BCI also must submit a public version of their comments. The file name of the public version should begin with the character ‘P’. The ‘BCI’ and ‘P’ should be followed by the name of the person or entity submitting the comments. Filers submitting comments containing no BCI should name their file using the name of the person or entity submitting the comments.

As noted, USTR strongly urges commenters to submit comments through *Regulations.gov*. You must make any alternative arrangements before transmitting a document and in advance of the relevant deadline by contacting USTR at *Special301@ustr.eop.gov*.

USTR will place comments in the docket and they will be open to public inspection, except properly designated BCI. You can view comments on *Regulations.gov* by entering Docket Number USTR–2025–0243 in the ‘search’ field on the home page.

Daniel Lee,

Assistant U.S. Trade Representative for Innovation and Intellectual Property, Office of the United States Trade Representative.

[FR Doc. 2025–22571 Filed 12–10–25; 8:45 am]

BILLING CODE 3390–F3–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket # FAA–2025–1056]

Airport Terminal Program; FY 2026 Funding Opportunity

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

ACTION: Notice of funding opportunity.

SUMMARY: The Department of Transportation (DOT), Federal Aviation Administration (FAA) announces the opportunity to apply for approximately \$1 billion in Fiscal Year (FY) 2026 competitive funds for the Airport Terminal Program (ATP), made

available under the Infrastructure Investment and Jobs Act of 2021 (IIJA), Pub. L. 117–58. The FY 2026 ATP announcement will be the final announcement for this program. The purpose of the ATP is to make annual grants available to eligible airports for airport terminal and airport-owned Airport Traffic Control Tower (ATCT) development projects that address the aging infrastructure of our nation’s airports.

DATES: Airport sponsors seeking consideration for FY 2026 ATP Competitive Grant Program funding should submit FAA Form 5100–144 as soon as possible, but no later than 5:00 p.m. Eastern Time on, January 15, 2026.

ADDRESSES: Submit applications electronically at <https://www.faa.gov/iija/airport-terminals> by following the instructions under Frequently Asked Questions, “How to apply.”

FOR FURTHER INFORMATION CONTACT: Dan Neumann, Acting Manager, FAA Office of Airports IJA Infrastructure Branch (APP–540), at (202)267–8328 or IIJA.Airports@faa.gov.

SUPPLEMENTARY INFORMATION: IIJA established the ATP as a competitive grant program which provides approximately \$1 billion in grant funding annually for five years (FYs 2022–2026) to upgrade, modernize, and rebuild our nation’s airport terminals and airport-owned ATCTs. This funding opportunity (FY 2026) is for the final year in which ATP will be available.

The full text of the Notice of Funding Opportunity (NOFO) is available on the FAA’s website at <https://www.faa.gov/iija/airport-terminals>. For more information applicants may also search *Grants.gov* using Funding Opportunity Number FAA–ARP–IIJA–G–26–001 or Assistance Listing Number 20.118. Mail and fax submissions will not be accepted.

Issued in Washington, DC, on December 9, 2025

Dan Neumann,

Acting Manager, FAA Office of Airports IJA Infrastructure Branch, APP–540.

[FR Doc. 2025–22526 Filed 12–10–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****[Docket No. FHWA–2025–0335]****Request for Information on Expediting Delivery of the American Legion Memorial Bridge**

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice; request for information (RFI).

SUMMARY: FHWA invites public input and proposals on innovative project delivery methods to ensure cost-effective and efficient reconstruction of the American Legion Memorial Bridge (the Bridge) connecting Montgomery County, Maryland and Fairfax County, Virginia and the Interstate 495 (I–495) & Interstate 270 (I–270) Managed Lane Project.

DATES: Comments must be received on or before February 9, 2026. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure you do not duplicate your docket submissions, please submit comments by only one of the following means:

- *Federal eRulemaking Portal:* Go to www.regulations.gov and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590;
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

• *Instructions:* You must include the agency name and docket number at the beginning of your comments. Except as described below under the heading “Confidential Business Information,” all submissions received, including any personal information provided, will be posted without change or alteration to www.regulations.gov. For more information, you may review the U.S. Department of Transportation’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 Brian Hogge, FHWA Office of Infrastructure, (334) 399–0081, or via email at brian.hogge@dot.gov. For legal

questions, please contact Mariya Tikhonova, FHWA Office of the Chief Counsel, (202) 366–1356, or via email at mariya.tikhonova@dot.gov. Office hours for FHWA are from 8:00 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:**Electronic Access and Filing**

A copy of this notice, all comments received on this notice, and all background material may be viewed online at www.regulations.gov using the above listed docket number. Electronic retrieval assistance and guidelines are also available at www.regulations.gov. An electronic copy of this document may also be downloaded from the Office of the Federal Register’s website at: www.FederalRegister.gov and the U.S. Government Publishing Office’s website at: www.GovInfo.gov.

Confidential Business Information

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 notice 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 notice, it is important for you to clearly designate the submitted comments as CBI.

You may ask FHWA to give confidential treatment to information you give to the Agency by taking the following steps: (1) mark each page of the original document submission containing CBI as “Confidential”; (2) send FHWA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. FHWA will protect confidential information, complying with the CBI requirements to the extent required under applicable law. If DOT receives a FOIA request for the information the applicant has marked in accordance with this notice, DOT will follow the procedures described in its FOIA regulations at 49 CFR 7.29. Only information marked in accordance with this notice and ultimately determined to be exempt from disclosure under FOIA and 49 CFR 7.29 will not be released to a requester or placed in the public docket of this notice. Submissions containing CBI should be sent to: Mr. Brian Hogge, FHWA, 1200 New Jersey Avenue SE, Washington, DC 20590, via mail or brian.hogge@dot.gov via email.

Any comment submissions FHWA receives that are not specifically designated as CBI will be placed in the public docket for this matter.

Purpose

The I–495 & I–270 Managed Lane Project is designed to address severe, worsening congestion throughout this vital interstate corridor serving the National Capital Region, which is the most congested region in the nation based on annual delay and congestion per auto commuter. I–495 west of I–270 had an Average Annual Daily Traffic (AADT) of 255,000 vehicles per day and I–270 had an AADT over 265,000 vehicles per day in 2019. The I–495 & I–270 corridor functions as the primary east coast bypass for long-distance travelers on I–95. The Project will feature express toll lanes in addition to the free general purpose lanes. Virginia’s I–495 Express Lanes Northern Extension project will extend the existing Express Lanes on I–495 in Virginia by approximately three miles to the American Legion Memorial Bridge. In 2019, Maryland and Virginia announced a “Capital Beltway Accord” that worked in a bipartisan fashion to build express lanes into Maryland. The pervasive congestion across the entire I–495 & I–270 corridor complicates daily trips, causes chronic delays, and increases safety risks and costs for all users.

The American Legion Memorial Bridge is the most significant bottleneck in the I–495 & I–270 corridor. As a nationally significant connector, the severe congestion on the Bridge and its approaches affects the normal everyday life of the traveling public and imposes additional costs and delays to the flow of commerce. For local commuters, it is a daily struggle to traverse the American Legion Memorial Bridge, requiring the need to build in additional time for commutes, face the uncertainty of unanticipated delays, and navigate various safety challenges. In addition, the location of the Bridge in serving our nation’s capital, a thriving metropolitan area attracting a mix of other drivers including Federal and military personnel, diplomatic and international drivers, tourists, and other visitors, poses its own unique challenges in terms of managing congestion. On the freight side, both short-haul and long-haul freight operations are impeded by congestion leading to costly delays in meeting delivery schedules, unnecessary wear on both drivers and equipment, and again, safety challenges associated with competing traffic. Whether a driver is commuting to their office, transporting goods, visiting

friends or family, or simply traveling through the area enroute to another place, congestion on the American Legion Memorial Bridge is complicating the trip, causing delays, and increasing safety risks and costs.

This RFI is an invitation to assist in identifying or proposing solutions or ideas to best advance bridge reconstruction, and ensure reconstruction advances safety, mobility, and technological innovation on the American Legion Memorial Bridge. The purpose is to enable interested stakeholders to provide input, submit proposals, facilitate dialogue, and galvanize action towards resolving a serious transportation challenge on the national transportation network. Ideas can be broad in nature, or specific actions such as project proposals or engineering solutions. Although FHWA does not own the American Legion Memorial Bridge, in its responsibility to ensure America's roads and highways remain safe and technologically sound, it is compelled to initiate this exercise and will share submissions with the Maryland Department of Transportation (MDOT) for consideration.

Background

Decades of rapid population growth and surging travel demand have transformed the American Legion Memorial Bridge into one of the Nation's most congested and freight-critical crossings. Since the Bridge was last improved in 1992, Fairfax and Montgomery Counties combined have added more than half a million residents, placing extraordinary strain on this key connection.

The American Legion Memorial Bridge connects two major population centers in Maryland and Virginia along I-495. It is a crucial connector for transportation needs in the National Capital Region, including access to jobs and essential services. It is also a nationally significant connector for interstate commerce. The American Legion Memorial Bridge is the only high-volume crossing between Montgomery County, Maryland and Fairfax County, Virginia. It is also the only major crossing between Maryland and Virginia between the Point of Rocks Bridge, more than 30 miles (50 km) upstream, and the Chain Bridge downstream between Virginia and the District of Columbia. The Bridge is also one of the two locations at which the Capital Beltway crosses the Potomac River. The other crossing is the Woodrow Wilson Memorial Bridge, both spans of which were replaced with the Inner Loop span being open to traffic in 2008.

The American Legion Memorial Bridge now carries an AADT of over 216,000 vehicles and 21,400 heavy trucks per day, and peak commuting speeds frequently fall to roughly 15 miles per hour. Congestion at the Bridge is prolonged and recurring, which translates directly into measurable costs. Several converging pressures make timely action urgent:

- *Growing demand and constrained capacity:* The National Capital Region continues to grow in both population and employment. Over the next 25 years, the Metropolitan Washington Council of Governments projects a 23 percent increase in population (adding approximately 1.3 million residents) and a 29 percent increase in jobs, or about 1 million additional positions. Traffic volumes at the American Legion Memorial Bridge are already at or above the original design capacity during peak periods. Without modernization, continued regional growth will only magnify delay and unreliability.

- *Bottleneck network impacts:* The corridor is identified on the 2024 National List of Major Freight Highway Bottlenecks and Congested Corridors, with an estimated annual congestion cost due to truck delay of \$43 million. Several major routes converge onto I-495 at the American Legion Memorial Bridge, concentrating regional traffic demand. When capacity is exceeded, the Bridge operates as a critical choke point, generating delays that ripple throughout the regional highway network rather than remaining localized to the crossing.

- *Economic and freight significance:* I-495 is a Tier-1 corridor within the Regionally Significant Highway Freight Network for the National Capital Region. Freight-dependent industries (transportation, wholesale and retail trade, manufacturing support) represent a major component of the regional economy, collectively contributing about 19 percent of the region's Gross Domestic Product (over \$660 billion in 2022). Recurring congestion along this high-volume freight corridor drives up business operating costs, reduces economic competitiveness, and ultimately increases costs for consumers.

As part of its broader I-495 and I-270 Managed Lanes Study, the State of Maryland seeks to fully replace the more than 60-year-old bridge. As stated in the June 17, 2022, Final Environmental Impact Statement (FEIS) and in the Record of Decision (ROD) issued on August 25, 2022, the reconstruction is expected to relieve congestion, and improve reliability and roadway performance.

FHWA is committed to improving safety and mobility on our nation's highways through national leadership, innovation, and program delivery. Through financial and technical assistance to State and local governments, FHWA helps ensure America's roads and highways are among the safest and most technologically sound in the world. To this end, FHWA seeks public input on how to best advance bridge reconstruction, and ensure reconstruction advances safety, mobility, and technological innovation.

As noted in the FEIS, the State does not possess the necessary revenue to independently fund replacement of the Bridge, nor to obtain the requisite bonding capacity. These challenges have held up construction on the project. So, to assist in cost-effective delivery of this regionally significant project, FHWA requests public input on innovative project delivery methods to ensure the project is constructed to the highest safety standards and without any further delay. Public-private partnerships (P3) help address public funding constraints by enabling projects to be financed over longer periods, transferring appropriate risks to the private sector, reducing lifecycle costs through private-sector efficiencies, and leveraging private capital to support upfront construction. Secretary Duffy has emphasized a commitment to making the United States the world's leading destination for private infrastructure investment. Collaboration with the private sector also introduces additional due diligence and diversifies funding sources, enhancing both accountability and project delivery.

As the ROD was issued in August 2022, FHWA is not seeking public input on environmental impacts of bridge reconstruction. Instead, this RFI is seeking public input on innovative project delivery approaches to accelerate reconstruction, the level of industry interest and capabilities, and how congestion affects travel, safety, and economic activity.

Nature of Information Request

This RFI is being conducted to inform and develop ideas, thoughts, and proposals on how to best advance bridge reconstruction, and ensure reconstruction advances safety, mobility, and technological innovation on the American Legion Memorial Bridge. FHWA's goal is to solicit information to assist FHWA's internal reviews of the issue and to provide the same to MDOT, the owner of the Bridge, for further consideration. FHWA may use this information to assist, inform,

and identify solutions to one of the worst bottlenecks in the Nation. Specifically, the information will be used by FHWA to:

- Obtain information and data to better understand the congestion-related impacts across the spectrum of the traveling public and residents.
- Collect statements of interest and capabilities from qualified industry partners capable of addressing these issues.
- Learn more about potential designs or business proposals which would address the issue.
- Solicit feedback on the public's interest in the use of private-sector partnerships and support.
- Gather cost and timeline information associated with these solutions.

Request for Comments and Information

FHWA requests information from the public on innovative project proposals and delivery methods to support the timely and efficient reconstruction of the American Legion Memorial Bridge and the I-495 & I-270 Managed Lane Project to the highest safety standards and without any further delay. FHWA is also seeking information on the impact of increasing congestion and project delivery delays on individuals, businesses, and communities. Questions #1–5 are focused on the American Legion Memorial Bridge. Question #6 is about the I-495 & I-270 Managed Lane Project.

When providing this information, FHWA requests that all respondents clearly identify: the respondent type (individual, business, public agency, non-profit, etc.); any relevant geographic area affected; and supporting data where available. Please include any relevant rendering, designs, or descriptions to provide additional clarity.

1. General Questions

- a. What are the primary challenges or barriers preventing completion of the American Legion Memorial Bridge reconstruction?
- b. What specific actions, project proposals, or strategies could help accelerate project delivery of the American Legion Memorial Bridge reconstruction?
- c. What additional support, resources, or coordination would help advance the American Legion Memorial Bridge reconstruction to completion?

2. Innovative Project Delivery Methods To Accelerate Reconstruction

- a. What innovative delivery mechanisms, such as P3s, could be applied to accelerate the American

Legion Memorial Bridge reconstruction to minimize short-term and long-term financial burden on taxpayers?

- b. What potential revenue sources could be generated to cover all or part of the project's costs?
- c. If the American Legion Memorial Bridge reconstruction is not delivered via P3, which alternative contracting methods (e.g., design-build, construction manager/general contractor, progressive design-build) are best suited to accelerate delivery while achieving safety and quality standards for this project?
- d. What accelerated construction methods (e.g., precast concrete systems, slide-in bridge replacement, prefabricated bridge elements and systems) could be applied to minimize lane closures and maximize safety?
- e. Are there other projects in other States which can be used as a helpful case study or reference point?
- f. What is a reasonable amount of time and cost for a project of this size and complexity?

3. Industry Interest and Capabilities

- a. What industry qualifications and experiences would be helpful in taking on a project at this level?
- b. Are there specific companies or industries which are well-equipped to take on projects at this level?
- c. If a specific company is interested, please submit: company name and address; link to the company website (if applicable); and points of contact including telephone number and email address.
- d. What steps can be taken to enhance competition and deliver better value for taxpayers?

4. Impacts of Congestion

- a. How has congestion around the American Legion Memorial Bridge affected your daily commute, fuel consumption, travel time, and reliability?
- b. Has the congestion around the American Legion Memorial Bridge affected your stress levels, health, and overall quality of life?
- c. Has the congestion caused a loss of leisure time or otherwise reduced the amount of time spent with friends, family, hobbies, or rest?
- d. What direct and indirect economic impacts have you observed (e.g., reduced productivity, increased freight or delivery costs, missed appointments or shipments, lost sales, increased vehicle operating costs)?
- e. Which travel patterns (work-based trips, school routes, emergency services, chores, errands) are most disrupted by the congestion?

f. Are there specific days, times, or circumstances in which the congestion is acutely observed?

- g. What kind of wear and tear on your vehicle have you had to address as a result of the congestion?

h. In your experience, how effectively do managed lanes (like Express Lanes or managed lanes) reduce overall traffic congestion and improve reliability on the corridor?

5. Project Proposals

a. Interested parties are invited to submit proposals that would advance bridge reconstruction, and ensure such reconstruction advances safety, mobility, and technological innovation. Such proposals need only be general concepts. Any proposals submitted to FHWA will be used for the purpose of informing and developing ideas, thoughts, and proposals on how to best advance bridge reconstruction. In addition, any such proposals will be shared with MDOT for consideration.

6. I-495 & I-270 Corridor

- a. What are the most significant challenges or barriers preventing the timely completion of the I-495 & I-270 Managed Lane Project?
- b. What specific actions, project proposals, or strategies could be implemented to accelerate delivery of the I-495 & I-270 Managed Lane Project?
- c. What additional support, resources, or coordination would help to advance the I-495 & I-270 Managed Lane Project to completion?
- d. What innovative project delivery methods are best suited to accelerate the completion of the I-495 & I-270 Managed Lane Project?
- e. What is the industry interest and capacity to undertake a project of the scale and complexity of the I-495 & I-270 Managed Lane Project?
- f. What other impacts does congestion on the I-495 & I-270 corridor cause?

Timeline and Delivery of Submittal

Submittals should be submitted within 60 days after this announcement is published in the **Federal Register**. FHWA may request additional clarification to responses directly related to this RFI through direct contact with respondents.

Sean McMaster,
Administrator, Federal Highway
Administration.

[FR Doc. 2025–22506 Filed 12–10–25; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****Notice of Final Federal Agency Actions on Proposed Transportation Project in Florida**

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review.

SUMMARY: The FHWA, on behalf of the State Department of Transportation (FDOT), is issuing this notice to announce actions taken by FDOT and other Federal agencies that are final agency actions. These actions relate to the proposed Project Development and Environment (PD&E) Study to evaluate alternatives to widen US 17–92 (State Road (SR) 600) from two to four lanes from Ivy Mist Lane to Avenue A, a distance of 3.8 miles, in Osceola County.

DATES: By this notice, the FHWA, on behalf of FDOT, 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 listed highway project will be barred unless the claim is filed on or before May 11, 2026. 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.

ADDRESSES: The Type 2 Categorical Exclusion and additional project documents can be viewed and downloaded from the project website at: <https://www.cflroads.com/project/437200-2>, or by contacting FDOT Office of Environmental Management, 605 Suwannee Street, MS 37, Tallahassee, Florida 32399, during normal business hours: 8 a.m. to 5 p.m. (Eastern Standard Time), Monday through Friday, except State holidays.

FOR FURTHER INFORMATION CONTACT: Katasha Gruver, Interim Director, Office of Environmental Management, FDOT; telephone (850) 414–5260; email: Katasha.Gruver@dot.state.fl.us.

SUPPLEMENTARY INFORMATION: Effective December 14, 2016, and as subsequently renewed on May 26, 2022, the FHWA assigned, and the FDOT assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that FDOT and other Federal agencies have taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, or approvals for the proposed improvement highway project. The actions by FDOT and other Federal

agencies on the project, and the laws under which such actions were taken are described in the Type 2 Categorical Exclusion approved on October 29, 2025, and in other project records for the listed project. Additionally, Programmatic Section 4(f) Evaluations were approved for the project. The Type 2 Categorical Exclusion and other documents for the listed project are available by contacting FDOT at the address provided above.

The project subject to this notice is:

Project Location: The project limits include US 17–92 (SR 600) from Ivy Mist Lane to Avenue A in Osceola County. The proposed improvements consist of reconstructing the existing two-lane roadway to a four-lane divided roadway.

Project Actions: This notice applies to the Type 2 Categorical Exclusion and all other Federal agency licenses, permits, or approvals for the listed project as of the issuance date of this notice including but not limited to the Section 4(f) Evaluation approval 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 *et seq.*]; Federal-Aid Highway Act (FAHA) [23 U.S.C. 109 and 23 U.S.C. 128]; 23 CFR part 771.

2. *Air:* Clean Air Act (CAA) [42 U.S.C. 7401–7671(q)], with the exception of project level conformity determinations [42 U.S.C. 7506].

3. *Noise:* Noise Control Act of 1972 [42 U.S.C. 4901–4918]; 23 CFR part 772.

4. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; 23 CFR part 774; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200302–200310].

5. *Wildlife:* Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and 1536]; Marine Mammal Protection Act [16 U.S.C. 1361–1423h], Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(f)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act (MBTA) [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801–1891d], with Essential Fish Habitat requirements [16 U.S.C. 1855(b)(2)].

6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 3006101 *et seq.*]; Archaeological Resources Protection Act of 1979 (ARPA) [16 U.S.C. 470(aa)–470(ii)]; Preservation of Historical and Archaeological Data [54 U.S.C. 312501–312508]; Native American Grave Protection and Repatriation Act

(NAGPRA) [25 U.S.C. 3001–3013; 18 U.S.C. 1170].

7. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000–2000d–1]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

8. *Wetlands and Water Resources:* Clean Water Act (Section 319, Section 401, Section 404) [33 U.S.C. 1251–1387]; Coastal Barriers Resources Act (CBRA) [16 U.S.C. 3501–3510]; Coastal Zone Management Act (CZMA) [16 U.S.C. 1451–1466]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300f–300j–26]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; Wetlands Mitigation, [23 U.S.C. 119(g) and 133(b)(3)]; Flood Disaster Protection Act [42 U.S.C. 4001–4130].

9. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

(Authority: 23 U.S.C. 139(l)(1)).

Issued on: December 2, 2025.

James Cons Christian,
Division Administrator, Federal Highway Administration.

[FR Doc. 2025–22508 Filed 12–10–25; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****Notice of Final Federal Agency Actions on Proposed Transportation Project in Florida**

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review.

SUMMARY: The FHWA, on behalf of the State Department of Transportation (FDOT), is issuing this notice to announce actions taken by FDOT and other Federal agencies that are final agency actions. These actions relate to the proposed Broad Causeway Bridge Replacement Project Development and Environment (PD&E) Study (Financial Management Number 452428–1–21–01). The project involves the replacement of the existing bascule bridge with a 65-foot High-Level Fixed Bridge connecting the Town of Bay Harbor Islands with the City of North Miami in Miami-Dade County.

DATES: By this notice, the FHWA, on behalf of FDOT, 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 listed highway project will be barred unless the claim is filed on or before May 11, 2026. 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.

ADDRESSES: The Type 2 Categorical Exclusion and additional project documents can be viewed and downloaded from the project website at: <https://www.bayharborislands-fl.gov/444/Broad-Causeway-Bridge-Replacement-PDE-St> or by contacting FDOT Office of Environmental Management, 605 Suwannee Street, MS 37, Tallahassee, Florida 32399, during normal business hours are 8 a.m. to 5 p.m. (Eastern Standard Time), Monday through Friday, except State holidays.

FOR FURTHER INFORMATION CONTACT: Katasha Gruver, Interim Director, Office of Environmental Management, FDOT; telephone (850) 414–5260; email: Katasha.Gruver@dot.state.fl.us.

SUPPLEMENTARY INFORMATION: Effective December 14, 2016, and as subsequently renewed on May 26, 2022, the FHWA assigned, and the FDOT assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that FDOT and other Federal Agencies have taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, or approvals for the proposed improvement highway project. The actions by FDOT and other Federal Agencies on the project, and the laws under which such actions were taken are described in the Type 2 Categorical Exclusion approved on October 10, 2025, and in other project records for the listed project. The Type 2 Categorical Exclusion and other documents for the listed project are

available by contacting FDOT at the address provided above.

The project subject to this notice is:

Project Location: The project limits include Miami-Dade County, Florida, and includes portions of the Town of Bay Harbor Islands. The project limits extend from the Broad Causeway Island on the west side to east of West Broadview Drive, a distance of approximately 0.77 miles.

Project Actions: This notice applies to the Type 2 Categorical Exclusion and all other Federal agency licenses, permits, or approvals for the listed project as of the issuance date of this notice including, but not limited to the Section 4(f) Resource Programmatic Approval and laws under which such actions were taken, including but not limited to:

1. **General:** National Environmental Policy Act (NEPA) [42 U.S.C. 4321 *et seq.*]; Federal-Aid Highway Act (FAHA) [23 U.S.C. 109 and 23 U.S.C. 128]; 23 CFR part 771.

2. **Air:** Clean Air Act (CAA) [42 U.S.C. 7401–7671(q)], with the exception of project level conformity determinations [42 U.S.C. 7506].

3. **Noise:** Noise Control Act of 1972 [42 U.S.C. 4901–4918]; 23 CFR 772.

4. **Land:** Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; 23 CFR part 774; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200302–200310].

5. **Wildlife:** Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and 1536]; Marine Mammal Protection Act [16 U.S.C. 1361–1423h]; Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(f)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act (MBTA) [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801–1891d], with Essential Fish Habitat requirements [16 U.S.C. 1855(b)(2)].

6. **Historic and Cultural Resources:** Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 3006101 *et seq.*]; Archaeological Resources Protection Act of 1979 (ARPA) [16 U.S.C. 470(aa)–470(II)]; Preservation of Historical and Archaeological Data [54 U.S.C. 312501–312508]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013; 18 U.S.C. 1170].

7. **Social and Economic:** Civil Rights Act of 1964 [42 U.S.C. 2000d–1]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

8. **Wetlands and Water Resources:** Clean Water Act (Section 319, Section 401, Section 404) [33 U.S.C. 1251–1387]; Coastal Barriers Resources Act (CBRA) [16 U.S.C. 3501–3510]; Coastal Zone Management Act (CZMA) [16 U.S.C. 1451–1466]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300f–300j–26]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; Wetlands Mitigation, [23 U.S.C. 119(g) and 133(b)(3)]; Flood Disaster Protection Act [42 U.S.C. 4001–4130].

9. **Hazardous Materials:** Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. **Executive Orders:** E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

(Authority: 23 U.S.C. 139(l)(1)).

Issued on: December 2, 2025.

James Cons Christian,
Division Administrator, Federal Highway Administration.

[FR Doc. 2025–22509 Filed 12–10–25; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Nos. FRA–2015–0062 and FRA–2022–0098]

Brightline Trains Florida's and Florida East Coast Railway's Requests To Operate During a Temporary Outage of Their Positive Train Control Systems

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability, request for comments, and notice of decision.

SUMMARY: This document provides the public with notice that, on December 5, 2025, Brightline Trains Florida

(Brightline) and Florida East Coast Railway (FECR) each submitted a request for amendment (RFA) to their FRA-certified positive train control (PTC) systems. On December 5, 2025, Brightline and FECR experienced an outage of their PTC back office servers and a short-term loss of PTC functionality, temporarily impacting the operations of Brightline, FECR, and FECR's tenant railroad. On December 5, 2025, Brightline and FECR sought and obtained FRA's authorization under FRA's PTC regulations to continue rail operations, with certain conditions and restrictions, while their PTC systems were temporarily disabled.

DATES: FRA will review any comments received by December 19, 2025. FRA may consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket numbers for Brightline and FECR are Docket Nos. FRA-2022-0098 and FRA-2015-0062, respectively. For convenience, all active PTC dockets are hyperlinked on FRA's website at <https://railroads.dot.gov/research-development/program-areas/train-control/ptc/railroads-ptc-dockets>. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information.

FOR FURTHER INFORMATION CONTACT:

Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816-516-7168, email: Gabe.Neal@dot.gov.

SUPPLEMENTARY INFORMATION: In general, title 49 of the United States Code (U.S.C.) section 20157(h) requires FRA to certify that a host railroad's PTC system complies with title 49 of the Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or temporarily disabling the PTC system, a host railroad must submit, and obtain FRA's approval of, an RFA under 49 CFR 236.1021(m).

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification or

discontinuance of a signal or train control system. Accordingly, this notice informs the public that, on December 5, 2025, Brightline and FECR each submitted an RFA to their PTC systems, the Interoperable Electronic Train Management System (I-ETMS), under 49 CFR 236.1021(m). Those RFAs are available in Docket Nos. FRA-2015-0062 and FRA-2022-0098. Interested parties are invited to comment on Brightline's and FECR's RFAs by submitting written comments or data.

FRA typically invites the public to comment on such RFAs for a period of 20 days, as FRA must issue a decision to the railroad within 45 days of receipt of the RFA. 49 CFR 236.1021(e), (m)(3)(i). However, FRA's PTC regulations, at § 236.1021(m)(3)(ii), recognize that FRA may issue a decision before the standard 45-day decision deadline in emergencies or under other circumstances necessitating immediate approval. Given the specific, unique circumstances and the impact to Brightline's and FECR's PTC-governed networks, FRA issued a decision on December 5, 2025 (the date of receipt of the RFAs), conditionally approving Brightline's and FECR's RFAs to enable them to continue operating without I-ETMS until 11:59pm EST on December 8, 2025, subject to speed limitations and other restrictions to help ensure rail safety. FRA's decision letter is available in both railroads' PTC dockets. FRA will review and consider any comments received during the comment period, even after issuing its decision.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to <https://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov. To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2025-22585 Filed 12-10-25; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2024-0124]

Notice of Petition for Extension of Waiver of Compliance

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This document provides the public notice that the City of North Salt Lake and Salt Lake City (the Cities) jointly petitioned FRA for an extension of relief from certain regulations concerning grade crossing warning devices at crossings within a quiet zone.

DATES: FRA must receive comments on the petition by January 12, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Brian Gilleran, Railroad Safety Specialist, FRA Grade Crossing & Trespasser Outreach, telephone: 202-493-6276, email: brian.gilleran@dot.gov.

SUPPLEMENTARY INFORMATION: Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter dated September 15, 2025 the Cities petitioned FRA for an extension of a waiver of compliance from certain

provisions of the Federal railroad safety regulations contained at 49 CFR part 222 (Use of Locomotive Horns at Public Highway-Rail Grade Crossings). FRA assigned the petition Docket Number FRA-2024-0124.

The Cities request extended relief from 49 CFR 222.35(b)(1), *What are the minimum requirements for quiet zones?*, which requires that each public highway-rail grade crossing in a quiet zone “must be equipped, no later than the quiet zone implementation date, with active grade crossing warning devices comprising both flashing lights and gates which control traffic over the crossing.” The Cities were previously granted a one-year waiver to bring the crossings within the Woods Cross Quiet Zone (crossing numbers 805664P and 805836V) into compliance by completing the design and construction of a new signal mast and gate arms. In their petition, the Cities request one additional year of relief to complete the construction of these devices, as involved railroad companies must still finalize the agreements to perform the work and then order the equipment, which has a long lead time.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by January 12, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can

be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety,
Chief Safety Officer.

[FR Doc. 2025-22541 Filed 12-10-25; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2025-0960]

Request for Comments on the Renewal of a Previously Approved Information Collection: Application for Conveyance of Port Facility Property

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request approval from the Office of Management and Budget (OMB) to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed information collection 2133-0524 (Application for Conveyance of Port Facility Property) is used to determine if an applicant is committed to a port redevelopment plan, the plan is in the best interests of the public, and the property for development will be used in accordance with the terms of port conveyance and applicable statutes and regulations. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before February 9, 2026.

ADDRESSES: You may submit comments identified by Docket No. MARAD-2025-0960 through one of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. Search using the above DOT docket number and follow the online instructions for submitting comments.

- **Mail or Hand Delivery:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to www.regulations.gov including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is reasonable for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be lessened without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Dr. Linden Houston, 202-366-4839, Maritime Administration, Office of Deepwater Ports and Port Conveyance, 1200 New Jersey Avenue SE, (MAR-530), Washington, DC 20590, Email: Linden.Houston@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Application for Conveyance of Port Facility Property.

OMB Control Number: 2133-0524.

Type of Request: Extension without change of a previously approved information collection.

Abstract: Public Law 103-160, as applied by 40 U.S.C. 554, authorizes the Department of Transportation to convey to public entities surplus Federal property needed for the development or operation of a port facility. This information collection allows MARAD to approve the conveyance of property and administer the port facility conveyance program.

Respondents: Eligible state and local public entities.

Affected Public: State, Local or Tribal Government and Not-for-profit institutions.

Estimated Number of Respondents: 13.

Estimated Number of Responses: 13.

Estimated Hours per Response: 44.

Annual Estimated Total Annual Burden Hours: 572.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administration.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2025-22465 Filed 12-10-25; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF THE TREASURY**Office of the Comptroller of the Currency****FEDERAL RESERVE SYSTEM****FEDERAL DEPOSIT INSURANCE CORPORATION****Proposed Agency Information Collection Activities; Comment Request**

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the OCC, the Board, and the FDIC (the agencies) 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. On July 10, 2025, the agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), requested public comment for 60 days on a proposal to revise and extend for three years the Consolidated Reports of Condition and Income (Call Report) (FFIEC 031, FFIEC 041, and FFIEC 051), which are currently approved collections of information (Call Report proposal). The revisions described in the Call Report proposal related to proposed revisions to the enhanced supplementary leverage ratio standards applicable to global systemically important bank holding companies and their depository institution subsidiaries under the agencies' regulatory capital rules. The comment period for the Call Report proposal ended on September 8, 2025. As described in the **SUPPLEMENTARY INFORMATION** of this document, the agencies are proceeding with the proposed revisions to the FFIEC 031 report form and instructions, but with certain modifications. These revisions to reporting requirements would take effect as of the June 30, 2026, report date. The agencies are giving notice they are sending the collections to OMB for review.

DATES: Comments must be submitted on or before January 12, 2026.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments will be shared among the agencies.

OCC: You may submit comments by any of the following methods:

- *Email:* prainfo@occ.treas.gov.
- *Mail:* Chief Counsel's Office, Office of the Comptroller of the Currency, Attention: 1557-0081, 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E-218, Washington, DC 20219.

Instructions: You must include "OCC" as the agency name and "1557-0081" 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.

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 following method:

- *Viewing Comments Electronically:* Go to www.reginfo.gov. Hover over the "Information Collection Review" drop down menu and select "Information Collection Review." Underneath the "Currently under Review" section heading, from the drop-down menu select "Department of Treasury" and then click "submit." This information collection can be located by searching by OMB control number "1557-0081." 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.

Board: You may submit comments, which should refer to "Call Report Revisions," by any of the following methods:

- *Agency website:* <http://www.federalreserve.gov>. Follow the instructions for submitting comments at: <http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm>.

- *Email:* regs.comments@federalreserve.gov. Include "Call Report Revisions" in the subject line of the message.

- *Fax:* (202) 395-6974.

- *Mail:* Benjamin W. McDonough, Deputy Secretary and Ombuds of the Board, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available on the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons.

Accordingly, your comments will not be edited to remove any identifying or contact information.

FDIC: You may submit comments, which should refer to "Call Report Revisions—eSLR" by any of the following methods:

- *Agency website:* <https://www.fdic.gov/federal-register-publications>. Follow the instructions for submitting comments on the FDIC's website.

- *Email:* comments@FDIC.gov.

Include "Call Report Revisions—eSLR" in the subject line of the message.

- *Mail:* Jennifer Jones, Deputy Executive Secretary, Attn: Comments: Call Report Revisions—eSLR, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street NW building (located on F Street NW) on business days between 7 a.m. and 5 p.m.

- *Public Inspection:* Comments received, including any personal information provided, may be posted without change to <https://www.fdic.gov/federal-register-publications>.

Commenters should submit only information that the commenter wishes to make available publicly. The FDIC may review, redact, or refrain from posting all or any portion of any comment that it may deem to be inappropriate for publication, such as irrelevant or obscene material. The FDIC may post only a single representative example of identical or substantially identical comments, and in such cases will generally identify the number of identical or substantially identical comments represented by the posted example. All comments that have been redacted, as well as those that have not been posted, that contain comments on the merits of this document will be retained in the public comment file and will be considered as required under all applicable laws. All comments may be accessible under the Freedom of Information Act.

Written comments and recommendations for this information collection also should be sent within 30 days of publication of this document 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: For further information about the proposed revisions to the information collections discussed in this notice, please contact any of the agency staff whose names appear below. In addition, copies of the report forms for the Call Report can be obtained at the FFIEC’s website (<https://www.ffiec.gov/resources/reporting-forms>).

OCC: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel’s Office, Office of the Comptroller of the Currency, 400 7th Street SW, 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.

Board: Nuha Elmaghrabi, Federal Reserve Board Clearance Officer, (202) 452–3884, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Kimberly Yeh, Senior Attorney, (202) 898–6514, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

I. Call Report

The agencies propose to extend for three years, with revision, their information collections associated with the FFIEC 031, FFIEC 041, and FFIEC 051 Call Report.

Report Title: Consolidated Reports of Condition and Income (Call Report).

Form Number: FFIEC 031 (Consolidated Reports of Condition and Income for a Bank with Domestic and Foreign Offices), FFIEC 041 (Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only), and FFIEC 051 (Consolidated Reports of Condition and Income for a Bank with Domestic Offices Only and Total Assets Less Than \$5 Billion).

Frequency of Response: Quarterly.

Affected Public: Business or other for-profit.

OCC:

OMB Control No.: 1557–0081.

Estimated Number of Respondents: 971 national banks and Federal savings associations.

Estimated Average Burden per Response: 41.29 burden hours per quarter to file.

Estimated Total Annual Burden: 160,370 burden hours to file.

Board:

OMB Control No.: 7100–0036.

Estimated Number of Respondents: 707 State member banks.

Estimated Average Burden per Response: 45.32 burden hours per quarter to file.

Estimated Total Annual Burden: 128,165 burden hours to file.

FDIC:

OMB Control No.: 3064–0052.

Estimated Number of Respondents: 2,798 insured State nonmember banks and State savings associations.

Estimated Average Burden per Response: 39.12 burden hours per quarter to file.

Estimated Total Annual Burden: 437,831 burden hours to file.

The estimated average burden hours collectively reflect the estimates for the FFIEC 031, the FFIEC 041, and the FFIEC 051 reports for each agency. When the estimates are calculated by type of report across the agencies, the estimated average burden hours per quarter are 86.25 (FFIEC 031), 55.56 (FFIEC 041), and 34.99 (FFIEC 051). The changes to the Call Report forms and instructions proposed in this notice would result in an estimated increase in burden hours per quarter for the FFIEC 031 of 0.13 hours. There would be no burden change for the FFIEC 041 or FFIEC 051. The estimated burden per response for the quarterly filings of the Call Report is an average that varies by agency because of differences in the composition of the institutions under each agency’s supervision (for example, size distribution of institutions, types of activities in which they are engaged, and existence of foreign offices).

Type of Review: Extension and revision of currently approved collections. In addition to the proposed revisions discussed below, the Call Report is periodically updated to clarify instructional guidance and correct grammatical and typographical errors on the forms and instructions which are published on the FFIEC website.¹ These non-substantive updates may also be commented upon.

Legal Basis and Need for Collections

The Call Report information collections are mandatory: 12 U.S.C. 161 (national banks), 12 U.S.C. 324 (State member banks), 12 U.S.C. 1817 (insured State nonmember commercial and savings banks), and 12 U.S.C. 1464 (Federal and State savings associations). At present, except for selected data items and text, these information

collections are not given confidential treatment.

Banks and savings associations submit Call Report data to the agencies each quarter for the agencies’ use in monitoring the condition, performance, and risk profile of individual institutions and the industry as a whole. Call Report data serve a regulatory or public policy purpose by assisting the agencies in fulfilling their shared missions of ensuring the safety and soundness of financial institutions and the financial system and protecting consumer financial rights, as well as agency-specific missions affecting Federal and State-chartered institutions, such as conducting monetary policy, ensuring financial stability, and administering Federal deposit insurance. Call Reports are the source of the most current statistical data available for identifying areas of focus for on-site and off-site examinations. Among other purposes, the agencies use Call Report data in evaluating institutions’ corporate applications, including interstate merger and acquisition applications for which the agencies are required by law to determine whether the resulting institution would control more than 10 percent of the total amount of deposits of insured depository institutions in the United States. Call Report data also are used to calculate the risk-based assessments for insured depository institutions.

II. Current Actions

A. Background

On July 10, 2025, the agencies requested comment on a notice of proposed rulemaking titled “Regulatory Capital Rule: Modifications to the Enhanced Supplementary Leverage Ratio Standards for U.S. Global Systemically Important Bank Holding Companies and Their Subsidiary Depository Institutions; Total Loss-Absorbing Capacity and Long-Term Debt Requirements for U.S. Global Systemically Important Bank Holding Companies” (capital proposal).² The capital proposal would have, among other things, modified the enhanced supplementary leverage ratio (eSLR) standard for depository institution subsidiaries of U.S. top-tier bank holding companies identified as global systemically important bank holding companies (GSIBs) from the current six percent “well capitalized” threshold under the prompt corrective action framework to an eSLR buffer standard

¹ <https://www.ffiec.gov/resources/reporting-forms>.

² 90 FR 30780 (July 10, 2025).

equal to 50 percent of the GSIB's most recent method 1 surcharge.

On December 1, 2025, the agencies published a final rule amending their regulatory capital rule that, among other things, modifies the eSLR standard applicable to depository institution subsidiaries of GSIBs to an eSLR buffer standard equal to 50 percent of a covered depository institution's parent GSIB's method 1 surcharge, capped at one percent (capital final rule).³ The changes in the capital final rule are effective as of April 1, 2026, with the option to early adopt starting on January 1, 2026.

B. Proposed Revisions to Call Report Schedule RC-R

In the July 2025 Call Report proposal,⁴ the agencies proposed revisions to the FFIEC 031 report form and instructions, consistent with the capital proposal. The agencies proposed adding two new line items to Schedule RC-R, Regulatory Capital, Part I, Regulatory Capital Components and Ratios (Schedule RC-R, Part I), to reflect leverage buffer requirements, as applicable, under the capital proposal. Specifically, the agencies proposed to add new line items 56.a, "Leverage buffer standard," and 56.b, "Leverage buffer." These line items would be reported only by respondents that are depository institution subsidiaries of GSIBs. Additionally, the agencies proposed revisions to the Call Report instructions consistent with the capital proposal.

C. Comments Received and Final eSLR Rule Reporting Revisions

No comments were received on the July 2025 Call Report proposal that were specifically related to the proposed revisions to the FFIEC 031 report form and instructions. Therefore, the agencies will proceed with adding two new line items to Schedule RC-R, Part I, to reflect leverage buffer requirements. The Call Report instructions for Schedule RC-R, Part I, will also be revised to be consistent with the capital final rule including incorporation of the eSLR buffer standard applicable to depository institution subsidiaries of GSIBs equal to 50 percent of a covered depository institution's parent GSIB's method 1 surcharge, capped at one percent.

III. Timing

As stated in the July 2025 notice, the agencies plan to make these revisions to the Call Report forms and instructions effective with the first report date

following the effective date of the capital final rule. Thus, the reporting revisions to the Call Report would take effect as of the June 30, 2026, report date. For institutions that early adopt the final rule prior to April 1, 2026, the agencies plan to provide supplemental instructions to facilitate reporting in the March 31, 2026, Call Report.

IV. Request for Comment

Public comment is requested on all aspects of this joint notice. Comment is specifically invited on:

(a) Whether the proposed revisions to the collections of information that are the subject of this notice are necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

(b) The accuracy of the agencies' estimates of the burden of the information collections as they are proposed to be revised, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections 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.

Comments submitted in response to this joint notice will be shared among the agencies.

Carl Kaminski,

Assistant Director, Office of the Comptroller of the Currency.

Benjamin W. McDonough,

Deputy Secretary of the Board, Board of Governors of the Federal Reserve System. Federal Deposit Insurance Corporation.

Dated at Washington, DC on December 8, 2025.

Jennifer M. Jones,

Deputy Executive Secretary.

[FR Doc. 2025-22481 Filed 12-10-25; 8:45 am]

BILLING CODE 4810-33-P; 6210-01-P; 6714-01-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names

of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on December 9, 2025. See **SUPPLEMENTARY INFORMATION** for relevant dates.

FOR FURTHER INFORMATION CONTACT:

OFAC: Associate Director for Global Targeting, 202-622-2420; the Assistant Director for Sanctions Compliance, 202-622-2490 or <https://ofac.treasury.gov/contact-ofac>.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: <https://ofac.treasury.gov>.

Notice of OFAC Action

On December 9, 2025, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. DUQUE BOTERO, Mateo Andres, Calle 77 9 76 APT 302, Bogota, Colombia; DOB 07 Apr 1975; POB Bogota, Colombia; nationality Colombia; alt. nationality Spain; Gender Male; Cedula No. 79782423 (Colombia); Passport AS272175 (Colombia) expires 31 Mar 2026; alt. Passport XDD789846 (Spain); alt. Passport BF868819 (Colombia) expires 01 Mar 2035 (individual) [SUDAN-EO14098] (Linked To: MAINE GLOBAL CORP S.A.S.).

Designated pursuant to section 1(a)(ii)(B) of Executive Order 14098 of May 4, 2023, "Imposing Sanctions on Certain Persons Destabilizing Sudan and Undermining the Goal of a Democratic Transition," (E.O. 14098), for being a foreign person who is or has been a leader, official, senior executive officer, or member of the board of directors of the Maine Global Corp S.A.S., an entity whose property and interests in property are blocked pursuant to E.O. 14098 relating to the tenure of such leader, official, senior executive officer, or member of the board of directors.

2. MUNOZ UCROS, Monica (Latin: MUÑOZ UCROS, Monica), Calle 77 9 76 APT 302, Bogota, Colombia; DOB 14 Jun 1976; POB Bogota, Colombia; nationality Colombia; Gender Female; Cedula No. 52413003 (Colombia); Passport AX032470 (Colombia) expires 11 Mar 2031 (individual) [SUDAN-EO14098] (Linked To: MAINE GLOBAL CORP S.A.S.).

Designated pursuant to section 1(a)(ii)(B) of E.O. 14098, for being a foreign person who

³ 90 FR 55248 (December 1, 2025).

⁴ 90 FR 30641 (July 10, 2025).

is or has been a leader, official, senior executive officer, or member of the board of directors of the Maine Global Corp S.A.S., an entity whose property and interests in property are blocked pursuant to E.O. 14098 relating to the tenure of such leader, official, senior executive officer, or member of the board of directors.

3. OLIVEROS FORERO, Claudia Viviana, Bogota, Colombia; DOB 02 Jan 1973; POB Bogota, Colombia; nationality Colombia; Gender Female; Cedula No. 52252815 (Colombia); Passport AZ321704 (Colombia) expires 20 Jul 2032 (individual) [SUDAN–EO14098] (Linked To: INTERNATIONAL SERVICES AGENCY S.A.S.).

Designated pursuant to section 1(a)(ii)(B) of E.O. 14098, for being a foreign person who is or has been a leader, official, senior executive officer, or member of the board of directors of the International Services Agency S.A.S., an entity whose property and interests in property are blocked pursuant to E.O. 14098 relating to the tenure of such leader, official, senior executive officer, or member of the board of directors.

4. QUIJANO BECERRA, Alvaro Andres, Bogota, Colombia; United Arab Emirates; DOB 18 Jul 1967; POB Bogota, Colombia; nationality Colombia; alt. nationality Italy; Gender Male; Cedula No. 80413253 (Colombia); Passport AP628498 (Colombia); alt. Passport YB7731256 (Italy) expires 01 Mar 2031 (individual) [SUDAN–EO14098].

Designated pursuant to section 1(a)(i)(A) of E.O. 14098, for being a foreign person who is responsible for, or complicit in, or who has directly or indirectly engaged or attempted to engage in, actions or policies that threaten the peace, security, or stability of Sudan.

Entities

1. COMERCIALIZADORA SAN BENDITO S.A.S., Bogota, Colombia; NIT # 9011008200 (Colombia); Matricula Mercantil No 02846256 (Colombia) [SUDAN–EO14098] (Linked To: MUÑOZ UCROS, Monica).

Designated pursuant to section 1(a)(v) of E.O. 14098, for being a foreign person who is owned or controlled by, or has acted or purported to act for or on behalf of, directly or indirectly, Monica Munoz Ucros, a person whose property and interests in property are blocked pursuant to E.O. 14098.

2. TALENT BRIDGE, S.A. (a.k.a. GLOBAL STAFFING S.A.), Calle 54 Barrio PH Twist Tower, 28th Floor, Office F, Panama City, Panama; website <https://globalstaffingsa.com/>; RUC # 155722003–2–2022 (Panama) [SUDAN–EO14098] (Linked To: INTERNATIONAL SERVICES AGENCY S.A.S.).

Designated pursuant to section 1(a)(v) of E.O. 14098, for being a foreign person who is owned or controlled by, or has acted or purported to act for or on behalf of, directly or indirectly, International Services Agency S.A.S., a person whose property and interests in property are blocked pursuant to E.O. 14098.

3. INTERNATIONAL SERVICES AGENCY S.A.S. (a.k.a. “A4SI”; a.k.a. “ACADEMY FOR SECURITY INSTRUCTION S.A.S.”), Avenida Carrera 19 No. 97–31 Of. 603, Bogota, Colombia; website <https://a4si.com.co>; NIT # 9010625922 (Colombia); Matricula Mercantil No 02792522 (Colombia) [SUDAN–EO14098].

Designated pursuant to section 1(a)(i)(A) of E.O. 14098, for being a foreign person who is responsible for, or complicit in, or who has directly or indirectly engaged or attempted to engage in, actions or policies that threaten the peace, security, or stability of Sudan.

4. MAINE GLOBAL CORP S.A.S., Bogota, Colombia; website <https://maineglobal.net>; NIT # 9018645322 (Colombia); Matricula Mercantil No 03863364 (Colombia) [SUDAN–EO14098] (Linked To: TALENT BRIDGE, S.A.).

Designated pursuant to section 1(a)(iv) of E.O. 14098, for being a foreign person who has materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Global Staffing S.A., an entity whose property and interests in property are blocked pursuant to E.O. 14098.

(Authority: E.O. 14098.)

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2025–22554 Filed 12–10–25; 8:45 am]

BILLING CODE 4810–AL–P



FEDERAL REGISTER

Vol. 90

Thursday,

No. 236

December 11, 2025

Part II

Department of Justice

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Placement of CUMYL-PEGACLONE in Schedule I; Proposed Rule; Schedules of Controlled Substances: Extension of Temporary Placement of CUMYL-PEGACLONE in Schedule I of the Controlled Substances Act; Rule

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308****[Docket No. DEA-1511]****Schedules of Controlled Substances: Placement of CUMYL-PEGACLONE in Schedule I****AGENCY:** Drug Enforcement Administration, Department of Justice.**ACTION:** Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing the substance CUMYL-PEGACLONE (SGT-151; 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one), including its salts, isomers (including optical, positional, and geometric isomers), and salts of isomers, in schedule I of the Controlled Substances Act. CUMYL-PEGACLONE was temporarily scheduled in an order dated December 12, 2023. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle CUMYL-PEGACLONE.

DATES: Comments must be submitted electronically or postmarked on or before January 12, 2026. The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for a hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.47 and/or 1316.49, as applicable. Requests for a hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received or postmarked on or before January 12, 2026.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). To ensure proper handling of comments, please reference "Docket No. DEA1356" on all electronic and written correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit comments 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 www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper comments:* Paper comments that duplicate the electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

• *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

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

As required by 5 U.S.C. 553(b)(4), a summary of this proposed rule may be found in the docket for this rulemaking at www.regulations.gov.

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) proposes to permanently schedule CUMYL-PEGACLONE (SGT-151; 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one) in schedule I of the Controlled Substances Act (CSA), including its salts, isomers (including optical, positional, and geometric isomers), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at <http://www.regulations.gov>, unless reasonable cause is given. Such information includes personal or business identifiers (such as name, address, state of federal identifiers, etc.) voluntarily submitted by the commenter.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want to be made publicly available should submit two copies of the comment. One copy must be marked "CONTAINS CONFIDENTIAL INFORMATION" and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked "TO BE PUBLICLY POSTED" and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on <http://www.regulations.gov> for public inspection. DEA generally will not redact additional information contained in the comment marked "TO BE PUBLICLY POSTED." The Freedom of Information Act applies to all comments received.

For easy reference, an electronic copy of this document and supplemental information to this proposed scheduling action are available at <http://www.regulations.gov>.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the

Administrative Procedure Act (APA).¹ Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

- (1) state with particularity the interest of the person in the proceeding;
- (2) state with particularity the objections or issues concerning which the person desires to be heard; and
- (3) state briefly the position of the person regarding the objections or issues.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing.²

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**.³ Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, he will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether CUMYL-PEGACLONE meets the statutory criteria for placement in schedule I, as proposed in this rulemaking.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on her own motion, at the request of the Secretary of Health and Human Services (HHS), or on the petition of an interested party.⁴ This proposed action is initiated on the Administrator's own motion and supported by, *inter alia*, a

recommendation from the then-Assistant Secretary for Health of the HHS (Assistant Secretary) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle CUMYL-PEGACLONE.

In addition, the United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are set forth in 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of HHS (Secretary),⁵ after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the CSA and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.⁶ In the event that the Secretary did not consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General (as delegated to the Administrator of DEA) may, by rule, and upon the recommendation of the Secretary, add to such a schedule or transfer between such schedules any drug or other substance, if she finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

On June 10, 2021, the Secretary-General of the United Nations advised the Secretary of State of the United

States that the Commission on Narcotic Drugs (CND), during its 64th Session on April 14, 2021, voted to place CUMYL-PEGACLONE in Schedule II of the 1971 Convention (CND Decision 64/2). As a signatory to the 1971 Convention, the United States is required, by scheduling under the CSA, to place appropriate controls on CUMYL-PEGACLONE to meet the minimum requirements of the treaty. The relevant treaty provisions and domestic statutes executing those provisions are below.

To begin, Article 2, paragraph 7(b), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule II of the 1971 Convention. Pursuant to the 1971 Convention, the United States must require licenses for the manufacture, export and import, and distribution of CUMYL-PEGACLONE. The CSA's registration requirement as set forth in 21 U.S.C. 822, 823, 957, and 958, as well as implementing regulations in 21 CFR parts 1301 and 1312, set forth this licensing requirement.

In addition, the United States must adhere to specific export and import provisions set forth in the 1971 Convention. The CSA's export and import provisions established in 21 U.S.C. 952, 953, 957, and 958, and implemented in 21 CFR part 1312, execute these requirements.

Likewise, under Article 13, paragraphs 1 and 2 of the 1971 Convention, a party to the 1971 Convention may notify through the U.N. Secretary-General that it prohibits the importation of a substance in Schedule II, III, or IV of the 1971 Convention. If such notice is presented to the United States, the United States shall take measures to ensure that the named substance is not exported to the notifying country. The CSA's above-mentioned export provisions set forth these procedures.

Further, under Article 16, paragraph 4, of the 1971 Convention, the United States is required to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) In regard to each substance in Schedule I and II of the 1971 Convention, quantities manufactured, exported to, and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule III and IV of the 1971 Convention, quantities manufactured, as well as quantities exported and imported; (3) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in

¹ 5 U.S.C. 551–559; 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D.

² 21 CFR 1316.49.

³ 21 CFR 1308.44(b), 1316.53.

⁴ 21 U.S.C. 811(a).

⁵ As discussed in a memorandum of understanding entered into by the FDA and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (Mar. 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

⁶ 21 U.S.C. 811(d)(3).

the manufacture of exempt preparations; and (4) in regard to each substance in Schedule II–IV of the 1971 Convention, quantities used for the manufacture of non-psychoactive substances or products.

Lastly, under Article 2 of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. Persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action.

DEA notes that there are differences between the schedules of substances in the 1971 Convention and the CSA. The CSA has five schedules (schedules I–V) with specific criteria set forth for each schedule. Schedule I is the only possible schedule in which a drug or other substance may be placed if it has high potential for abuse and no currently accepted medical use in treatment in the United States.⁷ In contrast, the 1971 Convention has four schedules (Schedules I–IV) but does not have specific criteria for each schedule. The 1971 Convention simply defines its four schedules, in Article 1, to mean the correspondingly numbered lists of psychoactive substances annexed to the Convention and altered in accordance with Article 2.

Proposed Determination To Schedule CUMYL-PEGACLONE

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on CUMYL-PEGACLONE and, on June 12, 2023, submitted it to the then-Assistant Secretary for Health of HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for CUMYL-PEGACLONE.

On December 12, 2023, the previous Administrator published a temporary scheduling order in the **Federal Register** temporarily placing six synthetic cannabinoids (SCs) in schedule I of the CSA based on the finding that these substances pose an imminent threat to public safety.⁸ The six SCs temporarily controlled under the CSA were (1) MDMB-4en-PINACA; (2) methyl 2-[[1-(4-fluorobutyl)indole-3-carboxyl]amino]-3,3-dimethyl-butanoate (other name: 4F-MDMB-BUTICA); (3) 4F-MDMB-BICA; N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-

1-yl)-1H-indazole-3-carboxamide (other name: ADB-4en-PINACA); (4) 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one (other names: CUMYL-PEGACLONE; SGT-151); (5) ethyl 2-[[1-(5-fluoropentyl)indole-3-carboxyl]amino]-3,3-dimethyl-butanoate (other names: 5F-EDMB-PICA; 5F-EDMB-2201); and (6) methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate (other name: MMB-FUBICA). These six SCs have not been investigated for medical use. Nor are they intended for human use.

On December 11, 2024, HHS provided DEA a scientific and medical evaluation entitled, “Basis for the Recommendation to Place CUMYL-PEGACLONE and its salts in Schedule I of the Controlled Substances Act,” and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b), following consideration of the eight factors and findings related to the substance’s abuse potential, legitimate medical use, and dependence liability, HHS recommended that CUMYL-PEGACLONE be controlled in schedule I of the CSA under 21 U.S.C. 812(b). HHS noted that CUMYL-PEGACLONE is a full agonist at the cannabinoid type 1 (CB1) receptor, has no known medical use in the United States, has no approved new drug applications, and is not known to be marketed anywhere in the world as an approved drug product. HHS also noted that health care practitioners and medical examiners have reported cases of severe clinical adverse events and even death when CUMYL-PEGACLONE was ingested.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, and all other relevant data, and conducted its own eight-factor analysis in accordance with 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA in their respective eight-factor analyses, and as considered by DEA in this proposed scheduling determination. Please note that both the DEA and HHS analyses, including the evaluation of the eight factors determinative of control along with their supporting data and citations, are available in their entirety under the tab “Supporting Documents” of the public docket of this proposed rule at <https://www.regulations.gov>, under docket number “DEA1356.”

1. The Drug’s Actual or Relative Potential for Abuse

In addition to considering the information HHS provided in its scientific and medical evaluation document for CUMYL-PEGACLONE, DEA also considered all other relevant

data regarding actual or relative potential for abuse of CUMYL-PEGACLONE. The term “abuse” is not defined in the CSA; however, the legislative history of the CSA suggests the following four prongs in determining whether a particular drug or substances has a potential for abuse:⁹

a. There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or

b. There is a significant diversion of the drug or substance from legitimate drug channels; or

c. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

d. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Both DEA and HHS eight-factor analyses found that CUMYL-PEGACLONE produces pharmacological effects that are similar to those produced by schedule I SCs, such as JWH-018 and AM2201. CUMYL-PEGACLONE has been associated with numerous reports of severe health effects and intoxications including seizures followed by collapse, and deaths. CUMYL-PEGACLONE does not have an approved medical use in the United States, but evidence indicates that CUMYL-PEGACLONE is being abused and trafficked in the United States. Because this substance is not an approved drug product, a practitioner may not legally prescribe it, and it cannot be dispensed to an individual. However, case reports, coroner/medical examiner reports, and law enforcement data¹⁰ demonstrate that CUMYL-PEGACLONE is being used without medical advice. CUMYL-PEGACLONE has been identified during the toxicological screening in both fatal and non-fatal overdoses. Law enforcement

⁹ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.A.N. 4566, 4603.

¹⁰ While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See *Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV*, 76 FR 77330, 77332 (Dec. 12, 2011).

⁷ See 21 U.S.C. 812(b).

⁸ *Schedules of Controlled Substances: Temporary Placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I*, 88 FR 86040 (Dec. 12, 2023).

data show that CUMYL-PEGACLONE has been encountered in the United States illicit drug market.

Overall, these data demonstrate that CUMYL-PEGACLONE has a high potential for abuse. Thus, based on these data, it is reasonable to conclude that CUMYL-PEGACLONE, having no medical use, and thus no therapeutic value, presents a hazard to the health and safety of individuals and the community.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

As explained in the 8-factor analyses by HHS and by DEA, the available pharmacology data indicate that CUMYL-PEGACLONE produces pharmacological effects that are similar to those produced by schedule I substances, such as JWH-018 and AM2201. *In vitro* results indicate that CUMYL-PEGACLONE, similar to other schedule I SCs, binds to CB1 receptors and acts as an agonist at CB1 receptors. Data also demonstrates that CUMYL-PEGACLONE produces discriminative stimulus effects that are similar to those of the schedule I JWH-018 and AM2201. These pharmacological characteristics of CUMYL-PEGACLONE are predictive of substances that have a high potential for abuse. Overall, these data indicate that CUMYL-PEGACLONE produces pharmacological effects and hallucinogen-like behaviors that are similar to those of the JWH-018 and AM2201.

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

CUMYL-PEGACLONE is a CB1 receptor agonist that is pharmacologically similar to JWH-018 and AM2201 that is often smoked for recreational purposes. Neither DEA nor HHS are aware of any currently accepted medical use for CUMYL-PEGACLONE. There are no well-controlled clinical studies showing safety or efficacy for this substance. In addition, there is no evidence by qualified experts that CUMYL-PEGACLONE is accepted as having therapeutic uses. In the HHS report, the Food and Drug Administration (FDA) concluded that CUMYL-PEGACLONE has no currently accepted medical use in the United States. Similarly, DEA concludes CUMYL-PEGACLONE has no currently accepted medical use according to established DEA procedure and case law.

4. History and Current Pattern of Abuse

In their review, HHS described how the history and current pattern of abuse

of CUMYL-PEGACLONE was evidenced by law enforcement data from DEA regarding drug seizures and poison control center reports, indicating the substance is used for abuse purposes. HHS noted that while law enforcement data is not direct evidence of abuse, it can be inferred that CUMYL-PEGACLONE has been consumed for its psychoactive and intoxicating effects as with other SCs. CUMYL-PEGACLONE was described in a patent from 2014. In addition, CUMYL-PEGACLONE was first reported as an adulterated plant material in Germany in December 2016 and appeared in the United States in September 2018.

5. Scope, Duration and Significance of Abuse

Evidence shows that CUMYL-PEGACLONE is a recreational drug of abuse. HHS noted in their recommendation that SCs continue to be encountered on the illicit market despite scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel substances continue to be encountered that differ only by small chemical structural modifications intended to avoid prosecution, while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products. These encounters of CUMYL-PEGACLONE by law enforcement indicate that this substance is being trafficked and abused in the United States. Furthermore, evidence also indicates that CUMYL-PEGACLONE is abused internationally.

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

Available evidence on the overall public health risks associated with the use of CUMYL-PEGACLONE suggests that CUMYL-PEGACLONE can cause acute health problems leading to emergency department admissions and death. Case reports detailing serious adverse effects have been reported in the literature (*see* additional details at www.regulations.gov contained within DEA's 8-factor analysis at docket DEA-1356). Following the ingestion of products containing CUMYL-PEGACLONE, individuals have experienced seizures followed by collapse and death. Serious adverse effects and previously discussed data showing that CUMYL-PEGACLONE shares pharmacological similarities with schedule I substances, including JWH-018 and AM2201, demonstrate that

CUMYL-PEGACLONE is a serious public health threat.

7. Its Psychic or Physiological Dependence Liability

In their recommendation, HHS noted that there are no clinical studies evaluating dependence liabilities specific for CUMYL-PEGACLONE. However, scientific data indicate that CUMYL-PEGACLONE has a pharmacological profile that is similar to other schedule I SCs. It is reasonable to assume that CUMYL-PEGACLONE would retain a physiological and psychological dependence liability that is similar to that of other schedule I SCs such as JWH-018 and AM2201. Thus, it is reasonable to conclude that the cannabinoid-like properties of CUMYL-PEGACLONE may produce a psychic and/or physiological dependence liability that is similar to other SCs already controlled in schedule I under the CSA.

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

CUMYL-PEGACLONE is not an immediate precursor of any substance controlled under the CSA, as defined in 21 U.S.C. 802(23).

Conclusion

After considering the scientific and medical evaluation conducted and accompanying recommendation of HHS, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of CUMYL-PEGACLONE. As such, DEA hereby proposes to permanently schedule CUMYL-PEGACLONE as a schedule I controlled substance under the CSA. This action would also enable the United States to meet its obligations under the 1971 Convention.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule.¹¹ After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

¹¹ 21 U.S.C. 812(b).

1. CUMYL-PEGACLONE Has a High Potential for Abuse

CUMYL-PEGACLONE has a high potential for abuse, evidenced in part by data from *in vitro* binding affinity and functional activity studies, as well as by data from *in vivo* drug discrimination tests in animals. In these studies, CUMYL-PEGACLONE is demonstrated to be an agonist at CB1 receptors, which is a mechanism of action shared with other SCs, substances with a high potential for abuse and controlled in schedule I under the CSA. This finding is also consistent with the drug abuse patterns of CUMYL-PEGACLONE and adverse outcomes evident from epidemiological data sources. In summary, CUMYL-PEGACLONE has similar patterns of drug abuse, as well as similar adverse outcomes from its use, as have been observed with other SCs currently controlled in schedule I of the CSA.

2. CUMYL-PEGACLONE Has No Currently Accepted Medical Use in Treatment in the United States

CUMYL-PEGACLONE is not legally marketed in the United States, as FDA has not approved a marketing application for a drug product containing CUMYL-PEGACLONE for any indication. There are no known medically approved uses worldwide at this time. Moreover, there are no clinical studies or petitioners, of which FDA is aware, that claim an accepted medical use in the United States. There is no evidence that CUMYL-PEGACLONE has a currently accepted medical use in treatment in the United States.¹²

¹² Pursuant to 21 U.S.C. 812(b)(1)(B), when placing a drug or other substance in schedule I of the CSA, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. First, DEA looks to whether the drug or substance has FDA approval. When no FDA approval exists, DEA has traditionally applied a five-part test to determine whether a drug or substances has a currently accepted medical use: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available. *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 FR 10499 (Mar. 26, 1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in

3. There is a Lack of Accepted Safety for Use of CUMYL-PEGACLONE Under Medical Supervision

Because CUMYL-PEGACLONE has no approved medical use and has not been thoroughly investigated as new drugs, its safety for use under medical supervision is not determined. Thus, there is a lack of accepted safety for use of these substances under medical supervision.

Based on these findings, the Administrator concludes that CUMYL-PEGACLONE (SGT-151; 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one), including its salts, isomers (including optical, positional, and geometric isomers), and salts of isomers, warrants control in schedule I of the CSA. More precisely, because of its hallucinogenic-like effects, DEA is proposing to place CUMYL-PEGACLONE in 21 CFR 1308.11(d) (the hallucinogens category of schedule I).

Requirements for Handling CUMYL-PEGACLONE

If this rule is finalized as proposed, CUMYL-PEGACLONE would continue¹³ to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, import, export, engagement in research, conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *1. Registration.* Any person who handles (manufactures, distributes,

accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which the part 1 is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (Apr. 11, 2024). In its eight-factor assessment, HHS determined that CUMYL-PEGACLONE does not satisfy this two-part test. Therefore, since both DEA and HHS have determined that this substance does not satisfy the five-part test, and HHS has determined that this substance does not satisfy the additional two-part test, DEA concludes that CUMYL-PEGACLONE does not have a currently accepted medical use.

¹³ CUMYL-PEGACLONE is currently subject to schedule 1 controls on a temporary basis, pursuant to 21 U.S.C. 811(h). *See Schedule of Controlled Substances: Temporary Placement of MDMB-4en PINACA, 4f-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA and MMB-FUBICA into Schedule I*, 88 FR 86040 (Dec. 12, 2023).

dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) CUMYL-PEGACLONE must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* CUMYL-PEGACLONE is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling these three substances also must comply with the screening requirements of 21 CFR 1301.90–1301.93.

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

4. *Quota.* Only registered manufacturers would be permitted to manufacture CUMYL-PEGACLONE in accordance with a quota assigned, pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle CUMYL-PEGACLONE must have an initial inventory of all stocks of controlled substances (including this substance) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including CUMYL-PEGACLONE) on hand every two years pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to CUMYL-PEGACLONE, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74 and 1301.76, and parts 1304, 1312, and 1317. Manufacturers and distributors would be required to submit reports regarding CUMYL-PEGACLONE to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes CUMYL-PEGACLONE must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of CUMYL-PEGACLONE must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving CUMYL-PEGACLONE not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. DEA scheduling actions are not subject to either E.O. 14192, *Unleashing Prosperity Through Deregulation*, or E.O. 14294, *Fighting Overcriminalization in Federal Regulations*.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected

conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this proposed rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

On December 12, 2023, DEA published an order to temporarily place CUMYL-PEGACLONE, including its salts, isomers (including optical, positional, and geometric isomers), and salts of isomers, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle CUMYL-PEGACLONE have already established

and implemented systems and processes required to handle these substances. This action was taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, dispense, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle CUMYL-PEGACLONE.

According to HHS, CUMYL-PEGACLONE has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. There appear to be no legitimate sources for CUMYL-PEGACLONE as a marketed drug in the United States, but DEA notes that this substance is available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of CUMYL-PEGACLONE from legitimate suppliers. Therefore, DEA has concluded that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

The entities affected by this proposed rule include the manufacturers, distributors, importers, exporters, and researchers of CUMYL-PEGACLONE. DEA determines the North American Industry Classification System (NAICS) industries that best represent these business activities. Table 1 lists the business activities and corresponding NAICS industries.¹⁴

TABLE 1—BUSINESS ACTIVITY AND CORRESPONDING NAICS INDUSTRIES

Business activity	NAICS code	NAICS industry description
Manufacturer	325412	Pharmaceutical Preparation Manufacturing.
Distributor, Importer, Exporter	424210	Drugs and Druggists' Sundries Merchant Wholesalers.
	424690	Other Chemical and Allied Products Merchant Wholesalers.
Researcher	541715	Research and Development in Physical, Engineering, and Life Sciences (except
	611310	Nanotechnology and Biotechnology).
		Colleges, Universities and Professional Schools.

¹⁴ Executive Office of the President Office of Management and Budget, North American Industry

Classification System, United States, 2022, [https://](https://www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf)

www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf.

From Statistics of U.S. Businesses (SUSB) data, DEA determined the number of firms and small firms for each of the affected industries, and by

comparing the number of affected small entities to the number of small entities for each industry, DEA determined whether a substantial number of small

entities are affected in any of the industries. Table 2 lists the number of firms, small firms, and percent small firms in each affected industry.

TABLE 2—PERCENT AFFECTED SMALL ENTITIES BY INDUSTRY

NAICS industry	Firms ¹⁵	SBA size standard ¹⁶	Small firms ¹⁷	Percent of small entities (%)
325412—Pharmaceutical Preparation Manufacturing	1,179	1,300 employees ...	1,099	93.2
424210—Drugs and Druggists' Sundries Merchant Wholesalers	7,012	250 employees	6,760	96.4
424690—Other Chemical and Allied Products Merchant Wholesalers	5,487	175 employees	5,197	94.7
541715—Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).	10,042	1,000 employees ...	9,599	95.6
611310—Colleges, Universities and Professional Schools	2,494	\$34.5 million	1,515	60.8

Based on the American Chemical Society's SciFinder database,¹⁸ DEA identified three entities supplying CUMYL-PEGACLONE across the industries 325412, 424210, and 424690. However, one entity has already registered with DEA to handle controlled substances. Hence, DEA expects only two of the entities in the 325412, 424210, and 424690 industries will be affected by this rule. Assuming that all affected suppliers were small entities and concentrated in the smallest NAICS industry, 325412—Pharmaceutical Preparation Manufacturing, they would account for insubstantial number of small entities in that industry, 0.18 percent.¹⁹

Additionally, DEA expects that the number of researchers working with CUMYL-PEGACLONE is small, because CUMYL-PEGACLONE is not approved for medical use and has a substantial capability to be a hazard to the health of the user and to the safety of the community. Also, DEA believes that the researchers working with CUMYL-PEGACLONE may also work with other controlled substances; hence, these

researchers are likely already registered with DEA and are qualified to handle controlled substances. For these reasons, DEA believes the number of affected researchers that are small entities is not a substantial number of small entities in 541715 and 611310 industries.

In summary, the small entities affected by this proposed rule are those in 325412—Pharmaceutical Preparation Manufacturing, 424210—Drugs and Druggists' Sundries Merchant Wholesalers, and 424690—Other Chemical and Allied Products Merchant Wholesalers. The affected small entities account for less than 0.18 percent of the small businesses and are not likely to manufacture or carry inventory of CUMYL-PEGACLONE. As such, the proposed rule, if finalized, is not expected to result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined and certifies that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This proposed rule would not impose a new collection or modify an existing collection of information under the

Paperwork Reduction Act of 1995.²⁰ Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this proposed rule would require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–00010, 1117–00012, 1117–00014, 1117–00021, 1117–00023, 1117–00029, 1117–00056. 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.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. In § 1308.11:

■ a. Add a new paragraph (d)(107) to read as follows:

§ 1308.11 Schedule I.

* * * * *

²⁰ 44 U.S.C. 3501–3521.

¹⁵ Statistics of U.S. Businesses, 2022 SUSB Annual Data Tables by Establishment Industry, <https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html> (Accessed 6/24/2025).

¹⁶ U.S. Small Business Administration, Table of size standards, Version March 2023, Effective: March 17, 2023, https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%20C%202023%20%282%29.pdf (Accessed 6/24/2025).

¹⁷ Based on the estimated number of firms below the SBA size standard for each industry.

¹⁸ SciFinder; Chemical Abstracts Service: Columbus, OH; CAS 2504100–70–1; <https://scifinder.cas.org> (accessed May 14, 2024).

¹⁹ 2/1,099 = 0.18%.

(d) * * *

	*	*	*	*	*	*	*
(106) 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one (other names: CUMYL-PEGACLONE; SGT-151)							7093
	*	*	*	*	*	*	*

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on December 8, 2025, by Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative

purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this

document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–22495 Filed 12–10–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1511]

Schedules of Controlled Substances: Extension of Temporary Placement of CUMYL-PEGACLONE in Schedule I of the Controlled Substances Act**AGENCY:** Drug Enforcement Administration, Department of Justice.**ACTION:** Temporary scheduling order; extension.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this temporary scheduling order to extend the temporary schedule I status of CUMYL-PEGACLONE. In an order dated December 12, 2023, DEA temporarily placed CUMYL-PEGACLONE in schedule I of the Controlled Substances Act. This temporary order will extend the temporary scheduling of CUMYL-PEGACLONE for one year, or until the permanent scheduling action for this substance is completed, whichever occurs first. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will continue to be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle CUMYL-PEGACLONE.

DATES: This temporary scheduling order, which extends schedule I control of CUMYL-PEGACLONE covered by an order (88 FR 86040, December 12, 2023), is effective December 12, 2025, and expires on December 12, 2026. If DEA publishes a final rule making this scheduling action permanent, this order will expire on the effective date of that rule, if the effective date is earlier than December 12, 2026.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: In this order, the Drug Enforcement Administration (DEA) extends the temporary scheduling of CUMYL-PEGACLONE in schedule I of the Controlled Substances Act (CSA), including its salts, isomers, and salts of isomers, whenever the existence of such

salts, isomers, and salts of isomers is possible within the specific chemical designation:

- CUMYL-PEGACLONE (SGT-151; 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one).

Background and Legal Authority

On December 12, 2023, pursuant to 21 U.S.C. 811(h)(1), DEA published an order in the **Federal Register** temporarily placing CUMYL-PEGACLONE in schedule I of the CSA based upon a finding that this substance poses an imminent hazard to the public safety.¹ That temporary order was effective upon the date of publication. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of a substance expires at the end of two years from the date of issuance of the scheduling order, except that DEA may extend temporary scheduling of that substance for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1) with the respect to the temporarily controlled substance. In this instance, the temporary scheduling of CUMYL-PEGACLONE expires on December 12, 2025, unless extended.

Proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on her own motion, at the request of the Secretary of the Department of Health and Human Services (HHS), or on the petition of any interested party.² The Administrator of DEA, on his own motion pursuant to 21 U.S.C. 811(a), has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule CUMYL-PEGACLONE. DEA is publishing a notice of proposed rulemaking elsewhere in this issue of the **Federal Register** for the permanent placement of

¹ *Schedules of Controlled Substances: Temporary Placement of MDMA-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I*, 88 FR 86040 (December 12, 2023).

² 21 U.S.C. 811(a). As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. *Memorandum of Understanding with the National Institute on Drug Abuse*, 50 FR 9518 (Mar. 8, 1985). Because the Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations, see *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91–513, As Amended; Delegation of Authority*, 58 FR 35460 (July 1, 1993), for purposes of this temporary order, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.”

CUMYL-PEGACLONE in schedule I. If that proposed rule is finalized, DEA will publish a final rule in the **Federal Register** to make permanent the schedule I status of this substance.

Pursuant to 21 U.S.C. 811(h)(2), the Administrator orders that the temporary scheduling of CUMYL-PEGACLONE and its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, be extended for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety.³ This provision of the CSA allows the Attorney General, by order, to temporarily place substances in schedule I.⁴ The same subsection also provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings to permanently schedule the substance under 21 U.S.C. 811(a)(1), extend the temporary scheduling for up to one year.

To the extent that 21 U.S.C. 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended, the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this extension of the temporary scheduling action. The APA expressly differentiates between orders and rules, as it defines an “order” to mean a “final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making*.”⁵ This contrasts with permanent scheduling actions, which are subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” and final decisions that conclude the scheduling process and are subject to judicial review.⁶ The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an order instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney General to follow rulemaking

³ 21 U.S.C. 811(h).

⁴ *Id.*

⁵ 5 U.S.C. 551(6) (emphasis added).

⁶ 21 U.S.C. 811(a) and 877.

procedures for other kinds of scheduling actions,⁷ it is noteworthy that, in subsection 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even if this action were subject to 5 U.S.C. 553, the Administrator finds that there is good cause under 5 U.S.C. 553(b)(B) and (d)(3) to forgo the notice-and-comment requirements and the delayed effective date requirements of such section, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety that this substance would present if scheduling expired, for the reasons expressed in the temporary scheduling order.⁸

Further, DEA believes that this order extending the temporary scheduling action is not a “rule” as defined by 5 U.S.C. 601(2) and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by the APA at 5 U.S.C. 553 or any other law to publish a general notice of proposed rulemaking. Therefore, in this instance, since DEA believes this temporary scheduling action is not a “rule,” it is not subject to the requirements of the RFA when issuing this temporary action.

In addition, in accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and

equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866, sec. 3(f), provides the definition of a “significant regulatory action,” requiring review by the Office of Management and Budget. Because this is not a rulemaking action, this is not a significant regulatory action as defined in subsection 3(f) of E.O. 12866. DEA scheduling actions are not subject to either E.O. 14192, *Unleashing Prosperity Through Deregulation*, or E.O. 14294, *Fighting Overcriminalization in Federal Regulations*.

This action will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, “any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.”⁹

It is in the public interest to maintain the temporary placement of CUMYL-PEGACLONE, including its salts, isomers, and salts of isomers, in schedule I because it poses a public health risk. The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. For the same reasons that underlie 21 U.S.C. 811(h),

that is, the need to keep this substance in schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Further, public notice and comment is impracticable in the amount of time remaining before expiration of the temporary scheduling order and considering the manifest urgency to avoid an imminent hazard to the public safety that this substance would present if scheduling expired, for the reasons expressed in the temporary scheduling order. Therefore, in accordance with subsection 808(2) of the CRA, this order extending the temporary scheduling order, for CUMYL-PEGACLONE currently covered under the temporary order, shall take effect immediately upon its publication.

Nonetheless, DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 8, 2025, by Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,
Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–22496 Filed 12–10–25; 8:45 am]

BILLING CODE 4410–09–P

⁷ See 21 U.S.C. 811(a).

⁸ See *Schedules of Controlled Substances: Temporary Placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I*, 88 FR 86040 (December 12, 2023).

⁹ 5 U.S.C. 808(2).



FEDERAL REGISTER

Vol. 90

Thursday,

No. 236

December 11, 2025

Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 217

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Alaska LNG Project in Cook Inlet; Final Rule

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 217**

[Docket No. 251205–0179]

RIN 0648–BN50

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Alaska LNG Project in Cook Inlet

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

ACTION: Final rule; notification of issuance of Letter of Authorization.

SUMMARY: NMFS, upon request from 8 Star Alaska, LLC (8 Star Alaska), which is jointly owned by Glenfarne and Alaska Gasline Development Corporation (AGDC), is promulgating regulations to govern the taking of marine mammals incidental to the Alaska Liquefied Natural Gas (LNG) project in Cook Inlet, Alaska, over the course of 5 years. These regulations, which allow for the issuance of a Letter of Authorization (LOA) for the incidental take of marine mammals during the specified activities in the specified geographical region during the effective dates of the regulations, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, as well as requirements pertaining to the monitoring and reporting of such taking.

DATES: Effective from January 1, 2026, through December 31, 2030.

ADDRESSES: Electronic copies of the application and supporting documents, the proposed rule and associated public comments, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-oil-and-gas>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Kristy Jacobus, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:**Purpose of Regulatory Action**

These regulations, promulgated under the authority of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*), establish a framework for NMFS to authorize the take of marine

mammals incidental to activities associated with the Alaska LNG Project in Cook Inlet, Alaska.

Legal Authority for the Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs 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 for up to 5 years if, after notice and public comment, the agency makes certain findings and promulgates regulations that set forth permissible methods of taking pursuant to that activity and other means of effecting the “least practicable adverse impact” on the affected species or stocks and their habitat (see Mitigation section), as well as monitoring and reporting requirements.

Summary of Major Provisions Within the Rule

Following is a summary of the major provisions of this rule regarding 8 Star Alaska’s activities:

- NMFS may authorize, through a LOA, the take of small numbers of marine mammals, by harassment only;
- Mitigation measures are required during certain activities should a marine mammal be detected within identified zones; and
- Restrictions related to beluga whales are required during summer months in the western portion of Cook Inlet.

Through adaptive management, the regulations will allow NMFS to modify (*e.g.*, remove, revise, or add to) the existing mitigation, monitoring, or reporting measures summarized above and required by the LOA, as appropriate.

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. 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 promulgated or an incidental harassment authorization is issued.

The MMPA provides that authorization for incidental takings shall be granted if NMFS finds that the

taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance and on the availability of the species or stocks for taking for certain subsistence uses (collectively referred to as “mitigation”); and requirements pertaining to the monitoring and reporting of the takings. The definitions of all applicable MMPA statutory terms used above are included in the relevant sections below and can be found in section 3 of the MMPA (16 U.S.C. 1362) and NMFS regulations at 50 CFR 216.103.

Fixing America’s Surface Transportation Act

This project is covered under Title 41 of the Fixing America’s Surface Transportation Act, or “FAST–41.” FAST–41 includes a suite of provisions designed to expedite the environmental review for covered infrastructure projects, including enhanced interagency coordination as well as milestone tracking on the public-facing Permitting Dashboard.

8 Star Alaska’s project is listed on the Permitting Dashboard. Milestones and schedules related to the environmental review and permitting for the Alaska LNG Project can be found at <https://www.permits.performance.gov/permitting-project/fast-41-covered-projects/alaska-lng-project>.

Summary of Request

On December 5, 2024, NMFS received a request from 8 Star Alaska for regulations and a LOA to take marine mammals incidental to construction of LNG facilities in Cook Inlet, Alaska. Following NMFS’ review of the application, 8 Star Alaska submitted a revised version on April 3, 2025, which was deemed adequate and complete. On April 8, 2025, NMFS published a notice of receipt (NOR) of application in the **Federal Register** (90 FR 15137), requesting comments and information during a 30-day public comment period related to 8 Star Alaska’s request. NMFS received one letter from the Center for Biological Diversity and Cook Inletkeeper providing substantive comments and approximately 14,000 comments from members of the public expressing general opposition to 8 Star Alaska’s proposed project but providing

no specific concerns relevant to the information contained within 8 Star Alaska's application or to NMFS' determination that the application was adequate and complete. The comment letters from members of the public followed a generic template format in which respondents provided comments that were identical or substantively the same. NMFS has reviewed the submitted material and considered it for promulgation of these regulations. NMFS published a proposed rulemaking and request for public comments in the **Federal Register** for 8 Star Alaska's project on July 29, 2025 (90 FR 35762, July 29, 2025). All comments were considered in development of this final rule (see Comments and Responses section).

Except with respect to certain activities not pertinent here, section 3(18) of 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). NMFS is authorizing take of 12 species of marine mammals by Level B harassment and Level A harassment for a subset of 3 of these species. Neither 8 Star Alaska nor NMFS expect serious injury or mortality to result from the specified activities and neither may be authorized. However, since 8 Star Alaska's LNG facility construction activities are expected to last for 5 years, authorization under section 101(a)(5)(A) is appropriate.

NMFS previously promulgated regulations and issued an LOA to AGDC for the same work on September 15, 2020 (85 FR 59291, September 21, 2020), effective from January 1, 2021, through December 31, 2025. However, no work has been conducted during the effective period of that LOA, and none is planned prior to its expiration.

Description of the Specified Activity

8 Star Alaska will construct facilities to transport and offload LNG in Cook Inlet, Alaska, for export. Project activities include the construction of a Marine Terminal comprised of a temporary Marine Terminal Material Offloading Facility (MOF) and a permanent Product Loading Facility (PLF) on the east side of Cook Inlet, near Nikiski; construction of a pipeline (referred to as the Mainline) across Cook Inlet; and construction of a Mainline

MOF on the west side of Cook Inlet, north of Tyonek. The components of the construction activities that have the potential to expose marine mammals to sound levels that could result in take include vibratory and impact pile driving of steel sheet piles and 24-, 48-, 60-, and 66-inch (61-, 122-, 152.4-, and 167.6-centimeter [cm]) steel pipe piles, as well as the use of anchor handling tugs (AHTs). The in-water work will occur over 5 years between January 1, 2026, and December 31, 2030. The construction window is based on the ice-free working window, which is from approximately April 1 through October 31 of each year. Pile driving will occur during daylight hours and is estimated to occur 6 days per week. Work for pipelaying will occur 24 hours per day, 7 days per week, and could occur during periods of low visibility. In-water pile-driving is expected to occur over an estimated 323 nonconsecutive days over the 5-year period, and use of AHTs used for pipelaying in construction of the Mainline is expected to occur over an estimated 55 nonconsecutive days during Years 3 and 4 of the project, for a total of 378 construction days over the 5 year period.

A detailed description of the planned construction project is provided in the **Federal Register** notice for the proposed rule (90 FR 35762, July 29, 2025). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

NMFS published the proposed rule in the **Federal Register** on July 28, 2025 (90 FR 35762), beginning a 30-day comment period. It described, in detail, 8 Star Alaska's specified activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. In that document, we requested public input on the request for authorization described therein as well as our analyses, preliminary determinations, and the proposed regulations, and requested that interested persons submit relevant information, suggestions, and comments.

During the 30-day public comment period, NMFS received letters from the Marine Mammal Commission (the Commission), Alaska Department of Fish & Game (ADF&G), Chickaloon Village Traditional Council (Chickaloon Village), and Defenders of Wildlife; a joint comment letter from the Center for Biological Diversity, Alaska

Wildlife Alliance, Cook Inletkeeper, Fairbanks Climate Action Coalition, Pacific Environment, the Alaska Center, and 350 Juneau (herein referred to as CBD *et al.*); and multiple comments from private citizens. CBD *et al.* gathered comments from their supporters and submitted a spreadsheet with over 11,000 comments from the general public expressing general opposition to the rule. All relevant substantive comments and NMFS' responses are summarized below. We organize our comment responses by major categories. The comments and recommendations are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-oil-and-gas>. Please see the comment submissions for full details regarding the recommendations and supporting rationale.

The Commission submitted comments on the 2020 Proposed Rule for the Taking of Marine Mammals Incidental to Alaska LNG Project in Cook Inlet and referenced this letter in their submittal for this rule. A summary of their comments and NMFS' responses can be found in the notice of the 2020 final rule (85 FR 50720, August 17, 2020).

Impact Analysis

Comment 1: The Commission reviewed the datasets that NMFS used to determine its proposed source levels of 213 decibels (dB) peak sound pressure level (SPL_{peak}), 192 dB root-mean-square sound pressure level (SPL_{rms}), and 179 dB single strike sound exposure level (SELs-s) (see Estimated Take of Marine Mammals section in the proposed rule; 90 FR 35762, July 29, 2025) for impact installation of 48-inch (122 cm) steel pipe piles and recommended instead that NMFS use the median source levels of 209 dB SPL_{peak}, 195 dB SPL_{rms}, and 181 dB SELs-s from Caltrans (2020; Alameda, Vallejo, and Kitsap) and Austin *et al.* (2016), while omitting certain datasets that the Commission stated are inappropriate for use in informing appropriate proxy source levels. The Commission also recommended that these source levels be used to re-estimate Level A and Level B harassment zones for impact driving of 48-inch steel pipe piles and associated take numbers and that these source levels should be used for all future projects until NMFS finalizes recommendations related to proxy source levels.

Response: NMFS has reviewed the aforementioned data sets and partially concurs with the Commission's recommendation. NMFS agrees with the

Commission that data from Antioch, Avon Wharf, and Navy Kitsap (Caltrans, 2020) should be excluded from consideration and that data from Austin *et al.* (2016) should be included. NMFS also agrees that certain incorrect source levels from Illingworth and Rodkin (2017) should not be used. However, NMFS disagrees that the source levels from Illingworth and Rodkin (2017) should be entirely disregarded. Therefore, for this final rule, NMFS has determined it appropriate to use median values of 208 dB SPLpeak, 195 dB SPLrms, and 180 dB SELs-s (Caltrans, 2020; Illingworth and Rodkin, 2017; Austin *et al.*, 2016) as source levels for impact installation of 48-inch steel pipe piles. Level A and Level B harassment zones, take numbers, and relevant shutdown zones were re-estimated for this final rule. See Estimated Take of Marine Mammals and Mitigation sections below for these changes. In general, NMFS plans to use these source levels as interim proxy values for impact installation of 48-inch steel pipe piles for future projects that do not have sound source level verification data available until recommendations regarding proxy source levels are finalized. However, final determinations regarding appropriate proxy source levels will be made by NMFS, in coordination with applicants, on a case-by-case basis for each project.

Comment 2: CBD *et al.* asserted that NMFS failed to consider whether Cook Inlet beluga whales (CIBWs) or other marine mammals would be taken incidental to geophysical surveys to be conducted using echosounders or side-scan sonar before pipe-laying activities.

Response: NMFS considered these possible impacts to CIBWs and other marine mammals. As described in the notice of the proposed rule (90 FR 35762, July 29, 2025), the planned acoustic survey equipment includes a single-beam echosounder, a multi-beam echosounder, and a side-scan sonar system, all of which operate at or above 200 kilohertz (kHz), which is outside the general hearing range of marine mammals. Therefore, take of marine mammals is not expected to result from the use of these sources.

Comment 3: CBD *et al.* questioned the efficacy of a soft start as mitigation, asserting that there is little information as to whether animals move away from the source and that “more harmful” take may occur despite the soft start requirement. CBD *et al.* stated both that the “efficacy of such measures is questionable,” as well as that “such measures may prevent injury or other more harmful impacts.” CBD *et al.* also stated that “the efficacy of [soft starts]

as mitigation is questionable” and therefore additional mitigation is needed. CBD *et al.* further stated that NMFS failed to analyze potential take by Level B harassment from the use of soft starts for impact pile driving.

Response: As pointed out by CBD *et al.*, animal response to soft starts is not completely understood. However, soft-start procedures are reasonably expected to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. Soft starts are required, among other reasons, to minimize the instances of Level A harassment during exposure to impulsive sounds. NMFS agrees with the comment that soft starts may prevent injury or other more harmful impacts and is including soft start requirements for this project.

With regard to the commenters’ assertion that additional mitigation beyond soft start is needed, soft start is not the only mitigation measure required for impact pile driving. The rule also includes a requirement for 8 Star Alaska to implement shutdown zones as well as a seasonal pile driving restriction for CIBW. If an animal were to elect not to move away from the pile driving site during a soft start, protected species observers (PSOs) would record the observation, and if the animal were to enter the shutdown zone, the pile driving activity would be shut down.

NMFS disagrees with the commenter that the agency did not analyze potential take of marine mammals incidental to noise produced during soft starts. Potential take is evaluated per 24-hour pile driving period based on the most impactful activity occurring during that 24-hour period. Therefore, because full-power pile driving necessarily follows soft start, the likelihood of take is appropriately evaluated based on the more impactful full-power pile driving period that began with and includes the period of soft start, and take estimates are not discounted based on the relatively lesser impact that occurs during soft start.

Comment 4: CBD *et al.* asserted that NMFS failed to consider whether dredging activities would result in take of CIBW or other marine mammals and failed to account for the potential effects of dredging on marine mammal habitat. They stated that dredging degrades water quality which can harm prey and can stir up contaminants from the sea floor, exposing CIBWs and their prey to toxins.

Response: As stated in the proposed rule, dredging activity would occur during the construction of the Marine

Terminal MOF using either a hydraulic (cutter head) dredger or a mechanical dredger, and pipeline trenching would occur during pipeline laying operations. These activities typically have low noise levels (120-dB isopleths are typically within 150 meters (m)). For example, URS (2007) measured underwater sound level of 141 dB referenced to 1 micropascal (re 1 μ Pa) root-mean squared (rms) (at 12 m) associated with U.S. Army Corps of Engineers (USACE) dredging activities at the Port of Alaska, resulting in an estimated 120-dB RMS isopleth of 135 m. In addition, these activities are typically associated with slow, predictable vessel movements. As a result, regardless of source level, it is unlikely that these activities would result in harassment of marine mammals, as defined by the MMPA, and CBD *et al.* provide no evidence to the contrary. While marine mammals may behaviorally respond in some small degree to the noise generated by dredging operations, given the slow, predictable movements of these vessels, and low source levels, NMFS does not expect 8 Star Alaska’s dredging to result in the take of marine mammals.

Regarding potential impacts to water quality, approximately 42 hectares (103 acres) would be disturbed directly by dredging of the Marine Terminal MOF and trenching for the Mainline crossing, and another 486 hectares (1,200 acres) would be disturbed by the disposal of dredged material. Approximately 26 hectares (64 acres) of seafloor would be disturbed by installation of the Marine Terminal MOF, Mainline MOF, and Mainline Crossing. Additional area would be indirectly affected by the re-deposition of sediments suspended in the water column by the dredging/trenching and dredge disposal. Existing benthic communities would be temporarily lost during dredging in Cook Inlet, but this temporary loss is not expected to be significant due to the availability of additional benthic habitat in Cook Inlet. The physical effects on the benthic habitat from dredging would likely be of short duration due to the high energy and dynamic nature of the Cook Inlet seafloor and water column in these open water areas. Dredging would also temporarily increase turbidity in a localized area in Cook Inlet, but turbidity modeling suggests that the turbidity would return to baseline levels within 100 minutes (Federal Energy Regulatory Commission, 2020). Therefore, disturbance from dredging is expected to be temporary and mild.

Regarding contaminants, while the Recovery Plan for the Cook Inlet Beluga Whale cited by CBD *et al.* identifies pollution as a threat, the Recovery Plan

also notes that available information indicates that the magnitude of the pollution threat to CIBW appears low, though not all pollutants to which CIBW are exposed have been studied in that environment. For example, chemical analyses of water and dredging sediments from Cook Inlet found that contaminants analyzed were below management levels, and some were below detection limits (Frenzel, 2002 and U.S. Army Corp of Engineers, 2003 as cited in NMFS 2016). In addition, for the contaminants that have been studied, CIBWs generally had lower contaminant loads than did beluga whales from other populations (Becker *et al.*, 2000, Lebeuf *et al.*, 2004, NMFS 2008b, Becker 2009, DFO 2012, Reiner *et al.*, 2011, Wetzel *et al.*, 2010, Hoguet *et al.*, 2013 as cited in NMFS 2016).

Comment 5: Defenders of Wildlife and CBD *et al.* asserted that NMFS failed to account for take of marine mammals due to vessel noise, aside from tugs engaged in anchor handling. CBD *et al.* described what it characterizes as “behavioral responses to vessel noises” and described vessel noise as a stressor relevant to CIBW.

Response: NMFS disagrees that exposure to vessel noise would generally be expected to result in responses that qualify as take as defined under the MMPA. Vessel noise is generally transient, and NMFS considers it to be part of the baseline soundscape. There are also multiple contextual factors (including the signal characteristics (*i.e.*, impulsivity, intensity, frequency, and duration) and the spatio-temporal (*i.e.*, space and time) acoustic footprint of vessels as well as bearing and distance, predictability of source movement, and likelihood of habituation to routine vessel traffic) that minimize the likelihood of behavioral disturbance even if a marine mammal is exposed to elevated sound levels relative to background sound levels. As such, take from vessel noise, with the exception of AHTs under load, is not expected and was neither proposed nor will be authorized.

As explained in the proposed rule, given the slow, predictable, and generally straight path (or stationary nature) of vessels associated with the specified activity, the likelihood of these activities causing responses that would qualify as harassment under the MMPA is considered relatively low. Nevertheless, we have quantified the potential exposures from tugs engaged in anchor handling activities, assumed that these exposures would equate to take, and analyzed the impacts of the assumed takes, which we authorize here. While CBD *et al.*'s comment

described behavior responses to vessel noise, allegedly a stressor, the comment did not adequately support its contention that these effects reasonably likely to result in take as defined under the MMPA.

Comment 6: CBD *et al.* recommended that NMFS consider using a dose-response function to calculate take by Level B harassment, rather than the single-threshold approach.

Response: NMFS acknowledges that the dose-dependent approach to calculating estimated take by Level B harassment may be more reflective of the complexity of real-world behavioral disturbance (Ellison *et al.*, 2012). As described in the proposed rule, based on the available science and the practical need to use a threshold based on a metric that is predictable, measurable, and simple to implement for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment via a single received level (*i.e.*, a step function), rather than employing a more complicated dose-response function. Indeed, CBD *et al.* made no specific recommendations regarding the details of any dose-response function, and there is no scientific consensus regarding what criteria might be more appropriate. Defining sound levels that disrupt behavioral patterns is difficult because responses depend on the context in which the animal receives the sound, including an animal's behavioral mode when it hears sounds (*e.g.*, feeding, resting, or migrating), prior experience, and biological factors (*e.g.*, age and sex). Other contextual factors, such as signal characteristics, distance from the source, and signal to noise ratio, may also help determine response to a given received level of sound. Therefore, levels at which responses occur are not necessarily consistent and can be difficult to predict. The relatively simple step function criteria adequately account for the potential for Level B harassment to occur.

NMFS recognizes the potential for Level B harassment at exposures to received levels below 160 dB rms, in addition to the potential that animals exposed to received levels above 160 dB rms will not respond in ways constituting behavioral harassment. While in practice this threshold works as a step-function, *i.e.*, animals exposed to received levels above the threshold are considered to be “taken” and those exposed to levels below the threshold are not, it in fact represents a mid-point of likely behavioral responses (which are extremely complex depending on many factors including species, noise

source, individual experience, and behavioral context). The function recognizes that some animals exposed to levels below the threshold will react in ways that are appropriately considered take, while others that are exposed to levels above the threshold will not. Use of the 160-dB threshold allows for a workable quantitative estimate of take, while we qualitatively address the variation in responses across different received levels in our discussion and analysis.

Overall, while there may be methods of assessing likely behavioral response to acoustic stimuli that better capture the variation and context-dependency of those responses than the step-function used here, there is no scientific consensus on what that method should be. For future marine mammal behavioral criteria, NMFS will be exploring various factors including the use of a dose-response function in helping better predict behavioral disturbance and, as recommended by CBD *et al.*, will consider using a dose-response function in the future, as available information allows.

Comment 7: Chickaloon Village and several members of the public asserted that NMFS should not issue the incidental take regulations without a scientific understanding of risks to the CIBW.

Response: NMFS shares the commenters' concern regarding the impacts of human activities on CIBWs and is committed to supporting the conservation and recovery of the species to the extent appropriate under the MMPA. Under section 101(a)(5)(A) of the MMPA, NMFS considers the at-risk status of CIBWs (and other species) in both the negligible impact analysis and through consideration of impact minimization measures that result in the least practicable adverse impact on those species. For example, the mitigation measures include time-area restrictions on pile driving and AHT activity to protect CIBWs, vessel transit restrictions in the Susitna Delta area, and shutdown zones equivalent to the Level B harassment zones for CIBWs. Section 101(a)(5)(A) also mandates that NMFS “shall issue” an Incidental Take Authorization (ITA), provided the necessary findings are made for the specified activity for which incidental take is requested.

In accordance with our implementing regulations at 50 CFR 216.104(c), we use the best available scientific evidence to determine whether the taking by the specified activity within the specified geographic region will have a negligible impact on the species or stock and will not have an unmitigable adverse impact

on the availability of such species or stock for subsistence uses. Based on the scientific evidence available, NMFS determined that the impacts of the 8 Star Alaska facility construction activities would meet these standards, and 8 Star Alaska has developed a suite of rigorous monitoring and mitigation measures to reduce impacts to CIBWs and other marine mammals to the lowest level practicable.

Our analysis indicates that issuance of these regulations will not adversely affect annual rates of recruitment or survival of the CIBW. Additionally, the Endangered Species Act (ESA) Biological Opinion determined that the issuance of regulations is not likely to jeopardize the continued existence of the CIBW or destroy or adversely modify CIBW critical habitat. The Biological Opinion also outlined Terms and Conditions and Reasonable and Prudent Measures to reduce impacts, which have been incorporated into the rule. Therefore, based on the analysis of potential effects, the parameters of the activity, and the rigorous mitigation and monitoring program, NMFS determined that the activity would have a negligible impact on CIBW.

As described in this notice, NMFS has made the necessary findings, as required by Section 101(a)(5)(A) of the MMPA and NMFS' implementing regulations, and therefore, the MMPA requires issuance of incidental take regulations.

Monitoring and Reporting

Comment 8: The Commission recommended that NMFS specify in the regulatory text that for all pile-driving activities, a minimum of two PSOs must be on duty (1) at each specified pile-driving location at all times when a single hammer is used and (2) to monitor the area around each active hammer, totaling four PSOs at all times during concurrent pile driving.

Response: NMFS partially concurs with the Commission's recommendations. NMFS agrees that the location should be specified and has edited the regulatory text to include location of pile driving activities (*i.e.*, on either the east or west side of Cook Inlet). Although NMFS agrees with the Commission that the number of PSOs should be increased for concurrent pile driving, NMFS has determined that a minimum of three PSOs should be required for concurrent pile driving. One PSO should be present for the near field for each active hammer. Concurrent pile driving will occur at the same site, and the far field will be virtually the same for both hammers. Therefore, NMFS has determined that a minimum of one PSO should be

sufficient to monitor the far field. NMFS has therefore revised in the regulatory text of this final rule that a minimum of three PSOs must be present for all concurrent pile driving (See § 217.45(b)(i)).

Comment 9: The Commission recommended that NMFS clarify in the regulatory text that 8 Star Alaska conduct sound source verification (SSV) measurements at the beginning of pile driving activities and clarify that SSV measurements must be conducted at each location, given that pile driving will occur on both the west side and east side of Cook Inlet. The Commission also suggested that, in the regulatory text, NMFS require 8 Star Alaska to monitor a minimum of two piles of each size, type, and installation method with and without the sound attenuation device at each location.

Response: NMFS concurs with the Commission that SSV should be conducted at the beginning of pile driving activities at each location and has made these corrections to the regulatory text in §§ 217.44(n) and 217.45(b)(1) of this final rule.

NMFS agrees that in addition to the requirement to measure a minimum of two piles of each type and size, installation method should also be added to the regulatory text in § 217.45(b)(1)(ii) of this final rule. Pursuant to this change, 8 Star Alaska must monitor a minimum of two piles of each size, type, and installation method with and without the sound attenuation device at each location. 8 Star Alaska will coordinate with NMFS to determine the appropriate methods, such as conducting SSV on two piles with and two piles without the sound attenuation device, or two piles total with the sound attenuation device turned on and off and, as such, NMFS has not specified a method in the regulatory text. NMFS will work with 8 Star Alaska during development of the SSV plan to ensure that it will employ appropriate methods to assess the effectiveness of the sound attenuation device.

Comment 10: The Commission recommended that SSV measurements must be made on an appropriate number of each concurrent pile driving scenario in consultation with NMFS and as specified in the final SSV plan.

Response: NMFS has determined that SSV specific to concurrent pile driving scenarios is not necessary, as Level A and Level B harassment isopleths for concurrent pile driving may be estimated on the basis of the SSV results for the single hammer pile driving scenarios and methods as described in the Estimated Take of Marine Mammals

in this notice to estimate isopleths. Therefore, NMFS has not required SSV for concurrent pile driving in the regulatory text.

If 8 Star Alaska decides to conduct SSV for concurrent pile driving, NMFS will work with 8 Star Alaska during development of the detailed SSV plan regarding the details of that effort.

Comment 11: The Commission recommended that NMFS provide the detailed SSV plan to the Commission for review.

Response: NMFS declines to provide the Commission with the detailed SSV plan for review. The objectives of the proposed acoustic monitoring were explained in the proposed rule, the basic methodological details will follow widely accepted practices, and NMFS believes that the appropriate details regarding the SSV plans were noticed and believes appropriate details of the SSV were provided during the rulemaking process.

Comment 12: The Commission recommended that NMFS include in the regulatory text the requirement that 8 Star Alaska report the extent of the Level A and Level B harassment zones and transmission loss values for attenuated and unattenuated impact and vibratory installation of each pile size and type, including the concurrent pile driving scenarios.

Response: NMFS agrees that 8 Star Alaska must report the results of the SSV and has added a requirement to report transmission loss values in § 217.45(b)(1)(iv)(F). However, NMFS disagrees that a requirement to report the exact numeric extent of the Level A and Level B harassment zones for attenuated and unattenuated impact and vibratory installation of each pile size/type needs to be reflected in the regulatory text because the required data, including sound source levels and transmission loss values, will allow for calculation of these zones. As described in the preamble of the proposed rule, 8 Star Alaska may propose revised estimated Level A and Level B harassment zones (for the purpose of monitoring and reporting) and adjusted shutdown zones for NMFS review and approval following the analysis of SSV results. It is up to 8 Star Alaska if they would like to request adjustments of Level A and Level B harassment zones, and, therefore, it is not necessary to require that they report these zone sizes in the regulatory text. When reviewing the detailed SSV plan, NMFS will ensure that 8 Star Alaska provides the correct reporting elements in order to request adjustment of the Level A and Level B harassment zones if they so choose.

Mitigation and Least Practicable Adverse Impact

Comment 13: CBD *et al.* stated that NMFS previously stated that the use of bubble curtains during vibratory pile driving is an effective and important mitigation measure for CIBW (89 FR 85686, October 29, 2024) but failed to require bubble curtains as well as other noise reduction technologies such as pile caps, dewatered cofferdams, and other physical barrier mitigations.

Response: NMFS fully considered whether requiring the use of bubble curtains or other sound attenuation methods was appropriate for this rulemaking and included a requirement to use such methods if proven effective in the project environment in both the proposed rule and this final rule.

Where conditions are appropriate, bubble curtains and cofferdams are generally the most common noise attenuation methods used in construction projects. Pile caps are generally used, regardless of regulatory requirements, to protect piles and equipment during impact pile driving. While NMFS expects that pile caps will likely be used during this project due to their common usage for the aforementioned purposes, we do not typically consider pile caps to be an effective noise mitigation method. They are typically made of wood or plastic and are designed to compress and fracture during use, limiting their consistency with respect to noise mitigation and potentially leading to safety issues if replaced during hammer operations (Caltrans, 2020).

As described in the proposed rule and finalized here, 8 Star Alaska will use a noise attenuation device, such as a bubble curtain, and test it for effectiveness through SSV at the beginning of pile driving. If the results show the device to be effective, *i.e.*, at least a 2 dB source reduction is achieved, the LOA will require 8 Star Alaska to use the device throughout construction. If the device is not found to be effective, 8 Star Alaska will not be required to use it. The use of bubble curtains and other sound attenuation devices can be time consuming and costly and, therefore, if not effective, the incidental take regulations do not require their use.

NMFS acknowledges describing bubble curtains as effective and important mitigation measures for CIBW, but that assertion was made in regards to construction at the Port of Alaska in Anchorage. For the Port of Alaska project, bubble curtains during vibratory pile driving were expected to minimize the potential for impacts to

CIBWs transiting through the relatively narrow Knik Arm to critical foraging areas. Further, outside this context, NMFS does not typically agree that use of a sound attenuation device is warranted for vibratory pile driving due to the lower potential for more harmful impact from vibratory pile driving. Finally, a bubble curtain may not be effective at mitigating impacts in the construction area at the Alaska LNG project sites given the locations and the strong currents in Cook Inlet. Bubble curtains create a “wall” of bubbles around the pile, allowing for attenuation of sound. Strong currents, such as those in Cook Inlet, can disrupt the barrier of bubbles, reducing or negating the expected sound attenuation from the bubble curtain. 8 Star Alaska is required to test the effectiveness of a bubble curtain or other sound attenuation device, and the device will be used if it provides at least 2 dB reduction in sound.

As described in the response to comment 17, when considering the least practicable adverse impact, NMFS takes into consideration the degree to which the implementation of the measure is expected to reduce impacts and considers the practicability of the measures for applicant implementation. 8 Star Alaska must complete construction during the ice-free period. While certain additional sound attenuation devices, such as dewatered cofferdams, are typically considered effective, use of these devices would likely result in delays and extension of the project, due to the time needed to construct them, rendering them impracticable.

Comment 14: The Commission recommended that NMFS include in the regulatory text the requirements that, if an unconfined or confined bubble curtain is used, specific standard performance measures must be met.

Response: NMFS agrees that any sound attenuation device must meet minimum requirements to ensure that the sound attenuation device is being used properly. Therefore NMFS has included a measure in § 217.44(n)(1) of this final rule requiring that any sound attenuation device used by 8 Star Alaska must meet minimum requirements as determined by NMFS in the SSV plan.

Comment 15: The Commission noted that NMFS did not specify whether the 2-dB attenuation from the sound attenuation device must be verified in the near-field (at the 10 m distance), the far-field (1 kilometer [km] or near the extent of the Level B harassment zone), or in both. The Commission recommended that in the regulatory text NMFS require 8 Star Alaska to use the

sound attenuation device if a reduction of at least 2 dB is achieved in both the near and the far field.

Response: NMFS agrees that sound measurements should be conducted in both the near field and the far field. When 8 Star Alaska is developing its detailed SSV plan, NMFS will work with them to ensure that these measurements adhere to available best practices and are properly designed to evaluate the efficacy of the sound attenuation device. However, NMFS disagrees that 8 Star Alaska should only be required to use the sound attenuation device if at least 2 dB of sound reduction is achieved in both the near-field and far-field. Effectiveness of noise attenuation systems is traditionally measured in the near field (*e.g.*, 10 m) due to the complexity of sound propagation, and in this case prevents noise contamination from other sources at distance. NMFS additionally notes that the conservation value of a bubble curtain is not quantified simply by the broadband sound reduction, but by reduction of sound at specific frequencies to which marine mammals are more sensitive. Therefore, NMFS finds that if at least a 2-dB reduction of sound is measured in either the near- or far-field, the selected bubble curtain or other sound attenuation device would provide sufficient conservation benefit to warrant inclusion in the suite of measures necessary to effect the least practicable adverse impact on marine mammal species or stocks and should be employed for the duration of impact pile driving.

Comment 16: CBD *et al.* stated that NMFS must include in the regulatory text a prohibition on pile driving associated with the Mainline MOF from June 1 to September 7 and a requirement that in-water pile driving must only occur during daylight hours. CBD *et al.* also recommended that NMFS prohibit all activities at night, in bad weather, or other conditions when visibility is low.

Response: NMFS agrees with the commenter that it is appropriate to include the requirement that 8 Star Alaska must not conduct pile driving associated with the Mainline MOF from June 1 to September 7 in the regulatory text, and has made that addition under § 217.44(f) of this final rule.

NMFS disagrees with the recommendation to prohibit all activities at night, in bad weather, or other conditions when visibility is low, and has not adopted it. Some activities, such as dredging, are not expected to result in take of marine mammals, and therefore prohibitions related to these actions are not relevant. For other

activities for which take is expected, 8 Star Alaska needs to complete work during the ice free season and therefore plans to conduct some work at night, including dredging and pipelaying, as necessary to meet that objective. 8 Star Alaska plans to conduct pile driving during daylight hours, though it is unnecessary to preclude activity outside of daylight hours should the need arise (e.g., on an emergency basis or to complete driving of a pile begun during daylight hours, should the construction operator deem it necessary to do so). If visibility degrades such that the entirety of a corresponding shutdown zone is not visible during impact pile driving, or at least 2 km during vibratory pile driving, pile driving may continue only until the current segment of the pile is driven, and no further sections or additional piles may be driven until conditions improve such that the zones can be effectively monitored. We note that NMFS' Biological Opinion, issued pursuant to section 7 of the ESA, requires that pile driving only be conducted during daylight hours, and 8 Star Alaska must abide by the reasonable and prudent measures and terms and conditions of the Biological Opinion and Incidental Take Statement issued by NMFS pursuant to section 7 of the ESA.

Comment 17: CBD et al., citing *Natural Resources Defense Council (NRDC) v. Pritzker*, 828 F.3d 1125, 1134 (9th Cir. 2016), and members of the public asserted that NMFS failed to require mitigation measures sufficient to ensure the least practicable adverse impact on marine mammals including the CIBW. *CBD et al.* asserted that NMFS has conflated the negligible impact determination and the separate least practicable adverse impact requirement. *CBD et al.* also contended that the required mitigation measures fail to ensure the least practicable adverse impact as required by the MMPA. As part of its rationale, *CBD et al.* stated that NMFS "failed to include several mitigation measures required" in the 2020 rule. In a related comment, Defenders of Wildlife stated that it generally supports the recommendations made by the Commission in its comment letter on the proposed rule and that absent the recommended changes to regulatory language regarding the use of sound attenuation devices; the performance, reporting and use of SSV; and the number and placement of PSOs, NMFS will have failed to include measures to ensure the least practicable adverse impact as required by the MMPA.

Response: NMFS disagrees with *CBD et al.*'s unexplained assertion that we

have inappropriately conflated the negligible impact determination with the separate least practicable adverse impact requirement. NMFS concurs with *CBD* regarding the holding in *NRDC v. Pritzker* that "[c]ompliance with the 'negligible impact' requirement does not mean there [is] compliance with the 'least practicable adverse impact' standard." 828 F.3d at 1134. The "negligible impact" and "least practicable adverse impact" requirements are distinct, even though both statutory standards refer to species and stocks.

The MMPA focuses on reducing impacts from human activities at the species or stock (*i.e.*, population) level. See 16 U.S.C. 1361 (finding that species and population stocks are or may be in danger of extinction or depletion; that species and population stocks should not diminish beyond being significant functioning elements of their ecosystems; and that species and population stocks should not be permitted to diminish below their optimum sustainable population level). Annual rates of recruitment (*i.e.*, reproduction) and survival are the key biological metrics used in the evaluation of population-level impacts, and in practice these same metrics are also used in the evaluation of population-level impacts for the least practicable adverse impact standard. Recognizing this common focus of the least practicable adverse impact and negligible impact provisions on the "species or stock" does not mean that NMFS conflates the two standards; despite some common statutory language, we recognize the two provisions are different and have different functions.

In *NRDC v. Pritzker*, the Ninth Circuit stated, "[t]he statute is properly read to mean that even if population levels are not threatened *significantly*, still the agency must adopt mitigation measures aimed at protecting *marine mammals* to the greatest extent practicable in light of military readiness needs." *Pritzker*, 828 F.3d at 1134 (emphases added). This statement is consistent with our understanding that even when the effects of an action satisfy the negligible impact standard (*i.e.*, in the court's words, "population levels are not threatened significantly"), the agency must still prescribe mitigation under the least practicable adverse impact standard. However, as the statute indicates, the focus of both standards is ultimately the impact on the affected "species or stock"; the standards are not solely focused on or directed at the impact on individual marine mammals.

While the Ninth Circuit's reference to "marine mammals" rather than "marine mammal species or stocks" in the italicized language above might be construed as a holding that the least practicable adverse impact standard applies at the individual "marine mammal" level, *i.e.*, that NMFS must require mitigation to minimize impacts to each individual marine mammal unless impracticable, such an interpretation does not accurately reflect the court's decision, which turned on the court's determination that the agency had not given separate and independent meaning to the least practicable adverse impact standard apart from the negligible impact standard and its conclusion that the agency had failed to meet the latter standard. Moreover, the court's use of the term "marine mammals" was not addressing the question of whether the standard applies to individual animals as opposed to the species or stock as a whole.

We recognize that while consideration of mitigation can play a role in a negligible impact determination, consideration of mitigation measures extends beyond that analysis. In evaluating what mitigation measures are appropriate, as required by the statute and implementing case law NMFS considers the potential impacts of the specified activity, the availability of measures to minimize those potential impacts, and the practicability of implementing those measures.

Although some mitigation measures from the 2020 rule are not included in the final rule, the final rule's mitigation measures ensure the least practicable adverse impact on marine mammals as required by the MMPA. As described in response to comment 18, shutdown zones have been modified from that of the 2020 rule to reflect updated source levels and changes to Level A and Level B harassment isopleths. Additionally, NMFS did not carry forward a requirement that in-water pile driving must occur only during daylight hours. As described in response to comment 16, NMFS determined that it was not necessary to preclude 8 Star Alaska from pile driving outside of daylight hours. If visibility degrades such that the entirety of a corresponding shutdown zone is not visible during impact pile driving, or at least 2 km during vibratory pile driving, pile driving may continue only until the current segment of the pile is driven, and no further sections or additional piles may be driven until conditions improve such that the zones can be effectively monitored. Finally, NMFS did not carry forward a mitigation

measure that stated that, “Other than in-water sheet pile driving and pile removal, anchor handling, trenching, pipe laying, and vessel transits related to these activities [8 Star Alaska] may not engage in in-water sound producing activities within 10 miles (16 km) of the mean higher high water (MHHW) line of the Susitna Delta (Beluga River to the Little Susitna River) between April 15 and October 15 which produce sound levels in excess of 120 dB rms re 1µPa @ 1 m.” This mitigation measure was replaced with a measure that prohibits pile driving or AHT activities with Level B harassment isopleths that would extend shoreward of the mean lower low water (MLLW) line in the Susitna River Delta. The intent of this change was to enhance clarity and protective value.

NMFS worked with 8 Star Alaska to develop a suite of rigorous mitigation measures that NMFS has determined provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat (see Mitigation section for a full description of all mitigation measures).

As described in this notice and the proposed rule, NMFS considers two primary factors when evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable. These factors are:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This evaluation considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost and impact on operations.

Taking these factors into consideration, NMFS has determined that the mitigation measures provide the means of effecting the least practicable adverse impact on the affected species and stocks, including the CIBW. Please see NMFS responses to comments 13–15 regarding use of sound attenuation devices, comments 9–12 regarding SSV,

and comment 8 regarding number and placement of PSOs. Responses to additional mitigation recommendations are included in responses to comments 18–23.

Comment 18: CBD *et al.* stated that NMFS does not ensure the least practicable adverse impact because it is requiring smaller shutdown zones for this rule than that of the final rule for the Taking of Marine Mammals Incidental to Alaska Liquefied Natural Gas Project in Cook Inlet published on August 17, 2020 (85 FR 50720) (herein referred to as the 2020 rule).

Response: Although the shutdown zones in this final rule differ from those adopted in the 2020 rule, they meet the statutory standard of ensuring the least practicable adverse impact. In this final rule, for all species aside from CIBW, shutdown zones were prescribed to avoid or minimize Level A harassment through consideration of the estimated Level A harassment zone sizes in context of the expected distance at which species are expected to be observable by PSOs. For example, the record reflects that low frequency cetaceans could be visible to PSOs up to 2,000 m away and high and very high frequency cetaceans, phocids, and otariids could be visible up to 400 m away. Therefore, when the Level A harassment zone was smaller than these visible zones, the shutdown zone was set at approximately the estimated Level A harassment zone distance. If the Level A harassment zone was larger than the distance within which we expect these species to be detectable under typical conditions, the shutdown zone was reduced to that expected detection distance. There is thus no functional distinction between these shutdown zone sizes. This approach is consistent with CBD *et al.*'s statement that use of zones larger than what can be observed is “meaningless.”

For CIBW, shutdown zones were prescribed to avoid or minimize take by Level A and Level B harassment, and therefore, shutdown zones were aligned with the Level B harassment zones. Recognizing that some CIBW shutdown zones are larger than what PSOs can reliably observe, these zones are functionally equivalent to a requirement to shut down upon detection at any distance (within the estimated harassment zones), which is warranted based on the status of this stock (note that take by Level B harassment of CIBW is authorized).

Some of the CIBW shutdown zones are smaller in this final rule than in the 2020 rule as a result of our incorporation of updated scientific information to our analysis. For

example, for impact installation of 24-inch and 48-inch steel pipe piles, NMFS updated the sound source levels used for pile driving in this rule from those used in the 2020 rule.

Furthermore, the 2020 final rule prescribed shutdown zones by grouping piles based on location and installation method. For example, in the 2020 final rule the Level B harassment zones for impact installation of 48-inch and 60-inch pipe piles at the PLF were determined to be 3,593 m and 2,254 m, respectively. The shutdown zones were prescribed inclusive of both of these pile types, requiring a 3,600 m shutdown for CIBWs for impact installation of both 48- and 60-inch steel pipe piles at the PLF, even though the Level B harassment zone for impact installation of the 60-inch pipe pile is over 1,000 m smaller than the shutdown zone. This larger shutdown zone does not provide any further protective value for the CIBW, but was a simpler way of prescribing a shutdown zone. Therefore, the Level B harassment isopleths vary between the 2020 rule and this final rule. Nonetheless, in both the 2020 final rule (85 FR 50720, August 17, 2020) and this final rule, the CIBW shutdown zones were prescribed to avoid Level A harassment and minimize Level B harassment for CIBW.

Comment 19: CBD *et al.* asserted that NMFS should restrict construction and/or vessel traffic in areas of Cook Inlet other than the Susitna River Delta, such as near the mouth of the Kenai River, Trading Bay, or Tyonek. Further, NMFS included a mitigation measure that prohibits pile driving or AHT activities with Level B harassment isopleths that would extend shoreward of the MLLW line in the Susitna Delta (Beluga River to the Little Susitna River) from April 15 through October 15, and CBD *et al.* asserted that NMFS failed to ensure the least practicable adverse impact because it did not prohibit these activities throughout the project area Cook Inlet from April 15 through October 15. Defenders of Wildlife recommended that NMFS consider mitigation measures in other locations such as the Kenai River.

Response: Additional measures to restrict construction and/or vessel traffic in other areas of Cook Inlet, as recommended by CBD *et al.*, do not provide sufficient mitigation benefit to warrant the additional operational costs associated with implementation of the measures, and so do not meet the least practicable adverse impact requirement under the MMPA. The Susitna River Delta is a known hotspot for CIBWs, particularly in the summer and fall months. Groups of 200 to 300

individuals, including adults, juveniles, and neonates, have been observed in the Susitna River Delta area in recent years (McGuire *et al.*, 2014; McGuire *et al.*, 2020). Acoustic recorders at the Little Susitna River detected a peak concentration of CIBWs from late May to early June, and a large peak from July through August (Castellote *et al.*, 2015). At the Beluga River, acoustic recorders detected three peaks of occurrence: mid-February to early April, June to mid-July (the strongest peak), and mid-November and December (Castellote *et al.*, 2016). The peaks in May and June appear to coincide with eulachon runs (Vincent-Lang and Queral 1984), and the peaks from June and July coincide with salmon runs (particularly silver and chinook salmon; Brenner, *et al.*, 2019). Given the high numbers of beluga whales and the critical foraging in this area as well as the proximity of 8 Star Alaska's project to the Susitna River Delta, NMFS deemed it appropriate to require time/area restrictions and vessel speed restrictions for the Susitna River Delta.

CIBWs were historically seen in and around the Kenai River during June aerial surveys conducted by ADF&G in the late 1970s and early 1980s and by NMFS starting in 1993 (Shelden *et al.*, 2015b). Despite the historic sightings (1970s–1990s) of CIBWs throughout the summer (June–August) in the area, recent visual and acoustic detections suggest the presence of CIBWs in the fall and winter (late August through March) (Kumar *et al.*, 2024). Evaluation of photo-identification studies from 2005 to 2017 suggest that the presence of beluga whales in the Kenai River Delta is much more sporadic than other areas (McGuire *et al.*, 2020), with beluga whales present one day and absent the next, and the numbers present on any given day are not expected to rise to that of other areas of Cook Inlet, such as the Susitna River Delta. NMFS further notes that although Level B harassment isopleths from vibratory pile driving could reach Kenai River Delta, no construction is planned in this area. Because of the expected low numbers of CIBWs and the distance of construction to the Kenai River Delta (approximately 15 km [9.3 mi]) additional mitigation measures in this area are not warranted. In the 1970s and 1980s, CIBWs were seen in Trading Bay during June aerial surveys, but from the early 1990s on, CIBWs were not seen in this region during the June aerial surveys (Shelden *et al.*, 2015a). Acoustic monitoring conducted by Castellote *et al.* (2020) detected the presence of CIBWs in the Trading Bay area in the winter with a

few detections in August–October. 8 Star Alaska's construction is not expected to occur in Trading Bay, although it is possible that some Level B harassment isopleths from vibratory pile driving at the Marine Terminal near Nikiski may extend into parts of Trading Bay. Furthermore, the numbers of CIBWs are not expected to be near that of the Susitna River Delta and construction is expected to occur from April to October, times in which CIBWs are not known to frequent Trading Bay.

NMFS is aware that CIBWs may be seen near Tyonek. From December 2015 through January 2016, Tyonek Platform personnel observed 200 to 300 CIBWs regularly, in the open water areas between ice sheets, although this was not previously a known area of occurrence (NMFS, 2019b). However, NMFS is not aware of such an occurrence near Tyonek platform since 2016, and notes these observations of large numbers of CIBWs occurred during a time of the year (winter) when 8 Star Alaska does not plan to conduct construction. Movement data from 14 CIBWs between May 1999 and March 2003 showed that CIBWs concentrated in areas near Tyonek during the fall (NMFS, 2016). However, the CIBW concentrations observed near Tyonek did not approach the levels that have been observed in other areas of Cook Inlet, such as Susitna River Delta, and subsequent studies have not shown substantial densities of CIBWs at Tyonek. In their comment letter, CBD *et al.* asserted that CIBWs are regularly seen feeding in the Tyonek area from June to September. NMFS, however, is not aware of any data to support this assertion, and citations provided by CBD ostensibly in support of this assertion do not provide any such information. Further, given the proximity of Tyonek to construction of the Mainline MOF and AHT activity, the mitigation measures prohibiting pile driving associated with the Mainline MOF from June 1 to September 7 and restricting pile driving and AHT activities near the Susitna River Delta from April 15 to October 15 should also be protective of the Tyonek area.

NMFS acknowledges that CIBWs occur in areas of Cook Inlet aside from the Susitna River Delta, including 8 Star Alaska's project area. However, their occurrence is expected to be much more sporadic, and there are no known areas in the project area with densities suggesting that the importance of other areas is similar to that of the Susitna River Delta. Restricting activities in other areas would thus provide little benefit to marine mammals and the

commenters do not provide persuasive evidence to the contrary.

Furthermore, 8 Star Alaska's construction activities are based on the ice-free working window, which extends approximately from April 1 through October 31. Imposing the limitations sought by the commenters would restrict construction throughout 8 Star Alaska's project area and would therefore not allow for the completion of 8 Star Alaska's project. In context of the limited benefit of such a requirement, NMFS has determined that these operational costs render such a requirement impracticable.

Comment 20: CBD *et al.* asserted that NMFS failed to ensure the least practicable adverse impact because it did not include measures that would require vessels to travel at reduced speeds at all times and in all areas of Cook Inlet. In a related comment, Chickaloon Village recommended that stricter vessel speed limits be required, although the comment did not provide specific recommendations as to what those requirements should be. Similar to their comment described in Comment 15, Defenders of Wildlife suggested that NMFS include a speed limit for vessels operating near the mouth of the Kenai River.

Response: NMFS disagrees. As described in response to comment 13 and in the Mitigation section, NMFS takes into account (1) the manner and degree to which the implementation is expected to reduce impacts to marine mammals and (2) the practicability of the measures for applicant implementation. The expected transiting speeds of the vessels used for 8 Star Alaska's planned construction range from less than 10 knots (for vessels such as barges) to 26 knots, depending on the vessel (Federal Energy Regulatory Commission, 2020). Reduction to a speed over ground below 4 knots in the Susitna River Delta was determined to be an important mitigation measure as this area is known to have high densities of beluga whales. Speed reduction in other areas to 10 knots or less during low visibility and to less than 5 knots when in proximity to whales were required as these would be considered high risk scenarios. Requiring speed reductions for the entirety of the project area and at all times would not be expected to significantly reduce the risk to marine mammals and would not be a practicable measure.

8 Star Alaska will not have any vessels in or around the mouth of the Kenai River, and therefore speed restrictions in this area are not necessary.

Comment 21: CBD *et al.* asserted that NMFS failed to consider the use of drones to detect the presence of marine mammals.

Response: NMFS agrees that drones can be an effective tool for monitoring for marine mammals during certain projects. As CBD *et al.* pointed out in their letter, NMFS uses drones in some marine mammal surveys, and this technology could “significantly reduce cost, risk, and disturbance in marine mammal surveys” (Alaska Fisheries Science Center, 2019). However, the use of drones discussed in the above-referenced article refers specifically to abundance and population monitoring, rather than real time monitoring for purposes of mitigation during construction. Visual monitoring and the related protocols required by this final rule will effectively monitor the presence or absence of marine mammals in the project area. The use of drones would not substantially increase the effectiveness of the mitigation measures or affect the least practicable adverse impact determination. The use of drones is also not practicable for 8 Star Alaska to implement due to operational constraints including line-of-sight limits for operating drones, battery range/duration, the need for FAA licensed and trained staff, and the distance limitations of some drones would render them unusable for observing for long periods. Thus visual monitoring and related protocols satisfy the MMPA’s least practicable adverse impact standard.

Comment 22: CBD *et al.* asserted that NMFS failed to consider the use of passive acoustic monitoring (PAM) as a mitigation strategy, and Chickaloon Village suggested that PAM should be required.

Response: PAM for real-time mitigation purposes has been used in Cook Inlet for some studies. These efforts have generally not resulted in successful deployment of PAM or useful detections of marine mammals to inform mitigation and monitoring during the activities due to the environmental conditions of the region (Austin and Zeddies, 2012; Kendall *et al.*, 2015). For example, background acoustic conditions, including flow noise from strong currents, large tidal changes, and weather along with additional noise from the project (e.g., vessel noise, noise from project equipment) made it difficult to detect marine mammals from a real-time PAM system implemented as part of the 2012 Apache 3D seismic survey program in lower- and mid-Cook Inlet (Austin and Zeddies, 2012; Lomac-MacNair *et al.*, 2013) and during the 2015 SAExploration Cook Inlet 3D

seismic survey program (Kendall *et al.*, 2015). Further, environmental conditions restricted the type of PAM systems that could be deployed during these programs to a single omnidirectional hydrophone lowered from the side of a vessel, which restricted the possible range of detections. These factors suggest that effective PAM monitoring in Cook Inlet can be challenging (Austin and Zeddies, 2012).

As CBD *et al.* noted, academic researchers have begun to implement more effective passive acoustic monitors for research purposes at several places in Cook Inlet (e.g., Lammers *et al.*, 2013; Castellote *et al.*, 2020; Castellote *et al.*, 2024). However, the framework used by those researchers is not practicable for 8 Star Alaska’s planned activity. An article on NOAA’s website (<https://www.fisheries.noaa.gov/science-blog/beluga-whale-acoustic-monitoring-survey-post-3>) illustrates the level of customization, expertise, and difficulty required to assemble a passive acoustic mooring to then deploy in the Inlet. Additionally, these instruments are stationary, which means to effectively use these monitors as a means of avoiding harassment of marine mammals during 8 Star Alaska’s activities, 8 Star Alaska would need to build and successfully deploy dozens (or more) stationary monitors along a route of travel that is subject to change depending upon weather or other environmental and shipping restrictions. Additionally, the data stored on these types of moorings is not accessible until they are retrieved by the researcher who deployed them. In the future, if an established network of passive acoustic monitors with shared access to the data is available, PAM could be a useful tool for implementing mitigation measures, but it is currently not practicable due to the feasibility issues described above as well as the significant cost associated with the development of such a system.

Comment 23: CBD *et al.* asserted that NMFS failed to separately consider mitigation aimed at reducing impacts to the habitat of marine mammals in Cook Inlet, citing particular concern for CIBW habitat.

Response: In order to promulgate a rulemaking under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity and other means of effecting the least practicable adverse impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance. Marine mammal habitat value is informed by marine mammal presence and use and, in some

cases, there may be overlap in mitigation measures for the species or stock directly and for use of habitat. As described in the proposed rule, with the exception of CIBW habitat, there are no known habitats of particular importance to marine mammals in the project area. Further, as described in the Marine Mammal Habitat Effects section of the proposed rule, impacts to marine mammal habitat would be localized and temporary. As such, for species other than CIBW, additional mitigation aimed at reducing habitat impacts is not warranted.

In this rule, NMFS has identified time/area restrictions and vessel speed restrictions in the Susitna River Delta based on a combination of factors that include higher densities and observations of specific important behaviors of marine mammals themselves, but also that clearly reflect preferred habitat. In addition to being delineated based on physical features that drive habitat function (e.g., bathymetric features, among others for some Biologically Important Areas (BIAs)), the high densities and concentration of certain important behaviors (e.g., feeding) in these particular areas indicate the presence of preferred habitat. As described in response to Comment 15, the Susitna River Delta is an area of high importance for the CIBW, particularly in the summer to fall months. Therefore, as discussed in the Mitigation section in the proposed rule and in this final rule, 8 Star Alaska must implement time/area restrictions and vessel transit restrictions in the area of the Susitna River Delta. Please see the Mitigation section of this final rule for additional detail. The MMPA does not specify that effects to habitat must be mitigated using separate measures, and NMFS has identified measures that provide significant reduction of impacts to both marine mammal species and stocks and their habitat, as required by the statute.

Small Numbers and Negligible Impact

Comment 24: CBD *et al.* asserted that NMFS’ interpretation of small numbers is unlawful, that a number may be considered small only if it is “little or close to zero” or “limited in degree,” and that NMFS’ small numbers determinations are arbitrary. Multiple members of the public similarly asserted that NMFS’ small numbers determinations are improper and that NMFS is relying on an arbitrary threshold. Separately, CBD *et al.* suggested that NMFS must consider the “highly imperiled status of the species” in making a small numbers determination specifically for CIBW.

Response: The proposed rule referenced an earlier rulemaking in which we provided a full explanation of the agency's interpretation of "small numbers" (86 FR 5322, January 19, 2021). NMFS makes its small numbers findings based on an analysis of whether the number of individuals authorized to be taken annually from a specified activity is small relative to the stock or population size. This relative approach is consistent with the statement from the legislative history that "[small numbers] is not capable of being expressed in absolute numerical limits" (H.R. Rep. No. 97–228, at 19 (September 16, 1981)), and relevant case law (*Center for Biological Diversity v. Salazar*, 695 F.3d 893, 907 (9th Cir. 2012) (holding that the U.S. Fish and Wildlife Service reasonably interpreted "small numbers" by analyzing take in relative or proportional terms)). Using a simple approach that establishes equal bins corresponding to small, medium, and large proportions of the population abundance, when the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers (86 FR at 5438).

Federal courts have upheld this proportional approach, which is used by both NMFS and U.S. Fish and Wildlife Service for all ITAs issued under the MMPA. See, e.g., *Center for Biological Diversity*, 695 F.3d at 906–907. NMFS has defended the approach successfully in court where the issue has been raised in litigation for various authorizations. See *Melone v. Coit*, 100 F.4th 21, 30–32 (1st Cir. 2024) (upholding NMFS application of the proportional approach); *Save Long Beach Island v. U.S. Department of Commerce*, 2025 WL 1829543, at *26 (D.N.J. 2025) (same); see also *Native Village of Chickaloon v. NMFS*, 947 F. Supp. 2d 1031, 1052–1053 (D. Alaska 2013) (upholding NMFS finding that the non-lethal take of 30 beluga whales during seismic surveys in Cook Inlet, Alaska, which amounted to 10 percent of the total whale population, constitutes a small number).

Contrary to the commenters' definition-based argument, NMFS' small numbers determination approach comports with dictionary definitions. For example, the definition of "small" in Webster's New Collegiate Dictionary (1981) included "having little size, especially as compared with other similar things." See also <https://www.merriam-webster.com/dictionary/small> (defining "small" as "having comparatively little size"). These definitions are consistent with the small numbers interpretation developed by

NMFS, which utilizes a proportionality approach.

Regarding CIBW, establishing a small numbers threshold on the basis of stock-specific context is unnecessarily duplicative of the required negligible impact finding, in which relevant biological and contextual factors are considered in conjunction with the amount of take. See *Center for Biological Diversity*, 695 F.3d at 907 (cautioning the U.S. Fish and Wildlife Service to "keep [] the standards distinct"). This suggestion is not founded in any relevant requirement of statute or regulation, discussed in relevant legislative history, or supported by relevant case law.

Comment 25: ADF&G suggested that NMFS consider the likelihood of repeat takes of harbor seals. ADF&G suggested that the large number of estimated Level B harassment takes of harbor seals is misleading given that only a few hundred harbor seals occur in middle and upper Cook Inlet where activities will take place, and during the breeding season, late spring and summer (when construction will occur) seals have strong site fidelity. ADF&G stated that incidental take was calculated based on daily impacts, which assumes that new seals will be present in the affected areas each day, instead of taking into consideration site fidelity (and thus likely repeat exposure) of individual seals.

Response: NMFS acknowledges that the number of total takes that was estimated and authorized is significantly greater than the number of individual seals that are likely to be impacted. As ADF&G points out, harbor seals are generally non-migratory (Lowry *et al.*, 2001; Small *et al.*, 2003; Boveng *et al.*, 2012) and strong fidelity of individuals for haulout sites during the breeding season has been documented for harbor seals in Cook Inlet (Small *et al.*, 2005; Pitcher and McAllister, 1981; Boveng *et al.*, 2012; Womble, 2012; Womble and Gende, 2013). Therefore, some individual harbor seals will likely be taken by Level B harassment more than once. However, NMFS must authorize the total number of takes anticipated regardless of the number of anticipated individuals affected. If some harbor seals were to incur multiple instances of Level B harassment, we expect those instances to be of low intensity, consisting of, at worst, temporary modification in behavior, and we would not expect these instances to result in impacts on reproduction or survival. We account for the fact that relatively few individuals are expected to be impacted in comparison with the total number of

estimated takes in the negligible impact analysis for this stock.

Comment 26: Members of the public asserted that NMFS has not considered cumulative effects to CIBWs and that NMFS should consider all threats to CIBWs. Similarly, CBD *et al.* asserted that NMFS' negligible impact determination is improper because it fails to take into account impacts from the other ITAs NMFS has recently issued in Cook Inlet (e.g., 90 FR 31756, July 15, 2025; 89 FR 77836, September 24, 2024; 89 FR 79529, September 30, 2024) and the cumulative impacts of vessel noise already in Cook Inlet.

Response: Neither the MMPA nor NMFS' implementing regulations call for consideration of the take resulting from other activities in the negligible impact analysis. The preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989) states, in response to comments, that the impacts from other past and ongoing anthropogenic activities are to be incorporated into the negligible impact analysis via their impacts on the baseline. Consistent with that direction, NMFS has factored into its negligible impact analysis the impacts of other past and ongoing anthropogenic activities via their impacts on the baseline, e.g., as reflected in the density/distribution and status of the species, population size and growth rate, and other relevant stressors (such as incidental mortality in commercial fisheries, Unusual Mortality Events (UMEs), and subsistence hunting); see the Negligible Impact Analyses and Determinations section of this notice). The 1989 final rule for the MMPA implementing regulations also addressed public comments regarding cumulative effects from future, unrelated activities. There, NMFS stated that such effects are not considered in making findings under section 101(a)(5) concerning negligible impact. In this case, this rule as well as other ITAs currently in effect or proposed within the specified geographic region are appropriately considered as authorizing activities unrelated to the others in the sense that they are discrete actions under sections 101(a)(5)(A) or (D) issued to discrete applicants.

The Federal Energy Regulatory Commission (FERC) prepared an Environmental Impact Statement (EIS) for the Alaska LNG Project that considered cumulative effects of construction of the Alaska LNG Project in Cook Inlet on marine mammals and concluded that cumulative impacts would be unlikely or minor. Additionally, under the ESA, NMFS' Biological Opinion independently

considered the reasonably foreseeable cumulative effects of activities on ESA-listed species and determined that 8 Star Alaska's proposed action is not likely to jeopardize the continued existence of ESA-listed species in the action area.

As described in the Negligible Impact Analysis and Determination section of this notice, our analysis indicates that issuance of these regulations will not adversely affect marine mammals through effects on annual rates or recruitment or survival and will have a negligible impact on all marine mammal stocks, including CIBWs.

Comment 27: Members of the public asserted that NMFS is underestimating the effects of noise and chronic stress from 8 Star Alaska's activities over the course of 5 years and asserted that the pile driving, vessel traffic, and anchor handling will drive the CIBWs from prime habitat, disrupting feeding cycles, and threatening calf survival.

Response: As discussed in the Negligible Impact Analysis and Determination section of this notice, monitoring data from similar regional activities suggest that the presence of tugs under load and pile driving do not discourage CIBWs from transiting throughout Cook Inlet and between critical habitat areas and that the whales do not abandon critical habitat areas (e.g., Horsley and Larson, 2023, 2024, 61N Environmental, 2021, 2022a, 2022b; Easley-Appleyard and Leonard, 2022). In addition, large numbers of CIBWs have continued to use Cook Inlet and pass through the area, likely traveling to critical foraging grounds in upper Cook Inlet, while noise-producing anthropogenic activities, including vessel use, have taken place during the past 2 decades (e.g., Shelden *et al.*, 2013, 2015b, 2017, 2022; Shelden and Wade, 2019; Goetz *et al.*, 2023). Further, 8 Star Alaska will implement time/area restrictions around the Susitna River Delta during critical periods during the summer and fall for CIBWs (see the Mitigation section for a full description). For these reasons, and the reasons outlined in the Negligible Impact Analysis and Determination section, NMFS disagrees that CIBWs will be driven from prime habitat or that calf survival will be threatened.

Comment 28: CBD *et al.* asserted that NMFS' negligible impact determination is unreasonable. For CIBW, CBD *et al.* stated that NMFS overlooks that CIBWs are highly endangered, fails to properly recognize the unique threat that noise pollution poses to CIBWs, and has no rational basis for concluding that additional harassment by noise has a negligible impact on the species. CBD *et*

al. further stated that NMFS ignores science that indicates that the CIBW population is declining and that NMFS discounts the best available science for CIBWs. CBD *et al.* asserted that NMFS' negligible impact conclusion is particularly arbitrary because the project will occur within a year-round BIA for CIBWs and in CIBW critical habitat. CBD *et al.* asserted that NMFS incorrectly stated that the project area is not known "to be of particular importance for feeding or reproduction."

Response: The Description of Marine Mammals in the Area of Specified Activities section of the proposed rule thoroughly described the baseline conditions for marine mammals in the project area including past (e.g., whaling) and ongoing stressors (e.g., noise, subsistence use for some species) for all marine mammal species and stocks, discussed where these stressors are most prevalent (e.g., ports, where subsistence hunting occurs, *etc.*), and described the status of the species and stocks. The Potential Effects of Specified Activities on Marine Mammals and Their Habitat section of the proposed rule described, based on the best available science, the anticipated effects of the specified activities on marine mammals, including a discussion about habituation and sensitization of marine mammals to their environment and the importance of context when predicting impacts.

Between 1994 and 1998, the CIBW stock declined by approximately 50 percent due largely to unsustainable subsistence harvesting (NMFS, 2016). Since their listing as endangered under the ESA in October 2008, there have been 95 confirmed dead stranded Cook Inlet beluga whales (NMFS, 2022a). Live stranding effects were the leading cause of death (23 percent, n=9) among belugas necropsied between 1998 and 2013 (n=38), though 29 percent (n=11) had unknown cause of death (Burek-Huntington *et al.*, 2015). Burek-Huntington *et al.* (2015) also noted that disease may have contributed to cause of death in some events. Other causes of death included trauma, malnutrition, and perinatal mortality (fetus or neonatal calf mortality of unspecified cause). NMFS recognizes that the CIBW population has not recovered from subsistence harvest and that noise, among many other stressors such as disease, contaminants, and natural live strandings, could be a contributing factor impeding recovery. However, in the Negligible Impact Analysis and Determination sections of the proposed rule and this final rule, NMFS describes the various factors considered in our

determination that the specified activities, in combination with 8 Star Alaska's proposed mitigation measures, would not appreciably contribute to existing noise stressors such that they would affect the population through effects to recruitment or survival.

The Negligible Impact Analysis and Determination section of the proposed rule and this final rule describe the basis of NMFS' finding that the total marine mammal take from the specified activity will have a negligible impact on all affected marine mammal species or stocks. These sections discuss the basis for this determination is based upon, including the expected low intensity and duration of takes by Level B harassment for all stocks consisting, of, at worst, temporary modifications in behavior; that impacts are not expected to affect reproduction or survival; that the project area represents a very small portion of any stock's home range and available foraging area; and the likelihood that required mitigation measures further lessen the likelihood, magnitude, or severity of exposures. NMFS also considered the status of each stock in its analysis.

NMFS' negligible impact finding considers a number of parameters including, but not limited to, the nature of the activities (e.g., duration, sound source), effects/intensity of the taking, the context of takes, and mitigation. For CIBWs, NMFS considered data from previous similar activities. Monitoring data from similar regional activities suggest that the presence of tugs under load does not discourage CIBWs from transiting throughout Cook Inlet and between critical habitat areas and that the whales do not abandon critical habitat areas (e.g., Horsley and Larson, 2023, 2024). Any disturbance that may occur is anticipated to be limited to behavioral changes such as increased swim speeds, changes in diving and surfacing behaviors, and alterations to communication signals, not the loss of foraging capabilities or the abandonment of critical habitat. Given these anticipated impacts, none of which would be expected to impact the fitness or reproduction of any individual marine mammal, much less adversely impact annual rates of recruitment or survival of CIBWs, NMFS' independent evaluation of the best scientific evidence in this case supports our negligible impact determination.

Modeling by Warlick *et al.* (2024) projects that the CIBW population will decline at an average rate of 1.6 percent per year in the coming decades and modeling from Jacobson *et al.* (2020) suggests that low survival may be

impeding recovery of the CIBW. Results of recent studies provide evidence that the CIBW population increased between 2004 and 2010, declined after 2010, and increased again from 2016 to 2022 (Shelden and Wade, 2019; Goetz *et al.*, 2023). Further, as discussed in the proposed rule, findings from NMFS' aerial survey data from June 2021 and 2022, which NMFS considers the best scientific information available, indicate that the population may be increasing (Goetz *et al.*, 2023). Contrary to the commenter's assertions, NMFS acknowledges the earlier studies described in its comment while also noting that more recent science offers a more hopeful note. Additional data in the coming years will help to inform whether the recent positive trend in the CIBW population will continue.

NMFS acknowledges observation of two potential but unconfirmed incidences of mating behavior in the Trading Bay area in 2014 (Lomac-Macnair *et al.*, 2015) and notes that no construction is planned to occur in Trading Bay. Such behaviors have not been reported since 2014. Surveys by NMFS or McGuire *et al.* (2020) have not yielded a comparable sighting. Other key behaviors, such as calving and feeding, are described in more detail below but are thought to occur primarily in areas outside of 8 Star Alaska's action area.

We are unaware of any information regarding areas where CIBWs are more likely to engage in mating behavior; however, what is known about calving suggests that it is most concentrated in the upper Inlet, north of 8 Star Alaska's project area. McGuire *et al.* (2020) characterized habitat use by age class in northern Cook Inlet and documented the majority of calves in the northernmost parts of Cook Inlet (*e.g.*, Susitna Delta, Knik Arm, and Susitna Delta).

While feeding behaviors may occur in 8 Star Alaska's project area, there are no known foraging hot spots in or near the project area. CIBWs are expected to be transiting through the project area, headed to or from the concentrated foraging areas farther north near the Beluga River, Susitna Delta, and Knik and Turnagain Arms. Therefore, any exposures are likely to be limited in duration and would take place in a small portion of available foraging habitat. Any impacts on feeding are expected to be minimal.

As described above, we have no reason to expect CIBWs to be concentrated in the area of 8 Star Alaska's pile driving activities or in the path of 8 Star Alaska's AHTs for the purposes of reproductive or feeding

behaviors, but if an instance occurs in which noise from pile driving or AHTs briefly intersects with an individual CIBW engaged in these behaviors, the anticipated short duration and low level disturbance of any such encounter would not be likely to impact reproductive or foraging success of any individuals.

While exposure to elevated noise levels associated with 8 Star Alaska's activities may result in low-level behavioral changes in marine mammals, NMFS' review of the best available scientific evidence, as summarized and cited herein and including information included with public comments, demonstrates that these responses do not rise to the level of having adverse effects on the reproduction or survival of any marine mammals, much less on rates of recruitment or survival of any species or stock. 8 Star Alaska's project area is within the CIBW critical habitat Area 2 which is largely based on dispersed fall and winter feeding and transit areas in waters where whales typically occur in smaller densities or deeper waters. Breeding and feeding were not primary considerations in designation of this critical habitat area. While 8 Star Alaska's project area does overlap ESA-designated critical habitat for CIBWs and the CIBW small and resident BIA (Wild *et al.*, 2023), the impacts from the project are not expected to occur in areas that are specifically important for feeding or reproduction for any species, including CIBWs, nor are they anticipated to result in a loss of prey or habitat.

NMFS has made, based on the best available science, the findings required to promulgate this final rule. Further, the Biological Opinion associated with this action concluded that 8 Star Alaska's activities would not jeopardize the continued existence of ESA-listed species, including CIBWs, or adversely modify critical habitat.

Comment 29: CBD *et al.* asserted that NMFS' negligible impact determination for all species is improper because it relies, in large part, on the presumed effectiveness of required mitigation measures. CBD *et al.* suggested that the mitigation measures rely nearly exclusively on the ability of PSOs to observe marine mammals and that NMFS fails to acknowledge the difficulty of actually observing marine mammals. Chickaloon Village similarly asserted that the mitigation plan's reliance on PSOs is inadequate.

Response: NMFS disagrees with the comment. As NMFS stated in its negligible impact analysis, consideration of the implementation of prescribed mitigation is one factor but is

not determinative in any case. In certain circumstances, mitigation is more important in reaching the negligible impact determination, *e.g.*, when mitigation helps to alleviate the likely significance of taking by avoiding or reducing impacts in important areas. Our discussion in the Negligible Impact Analysis and Determination section below contains the factors NMFS considered in reaching its negligible impact determinations. Although NMFS' implementing regulations at 50 CFR 216.104(c) state that NMFS may incorporate successful implementation of mitigation measures to arrive at a negligible impact determination, for promulgation of regulations for 8 Star Alaska's pile driving and tugging activities, NMFS did not rely upon an assumption of set level of effectiveness in mitigation to make our negligible impact determinations. While NMFS acknowledges that visual observations can be difficult in Cook Inlet due to the extreme tidal range, harsh weather, turbid waters, and seasonal ice presence (*e.g.*, Castellote *et al.*, 2020; Lammers *et al.*, 2013), prior monitoring efforts in Cook Inlet have shown that it is possible to detect and identify marine mammals, including CIBWs, to the species level several km away from the source, acknowledging that visibility depends on several factors such as visual acuity, sea state, glare, light, animal behavior/body type, speed of travel for vessel and animal, *etc.* (Horsley and Larson, 2023). NMFS does not assume total effectiveness of monitoring, but the demonstrated record of PSO sightings for activities in Cook Inlet illustrates that visual monitoring is appropriate for implementing mitigation in this case.

Other Comments

Comment 30: ADF&G provided comments indicating that it supports issuance of the rule, concurring with NMFS' analyses and determinations in the proposed rule. ADF&G identified that the proposed rule includes numerous mitigation measures to avoid incidental serious injury or mortality to marine mammals, which it stated helps ensure the conservation of marine mammal stocks. Lastly, ADF&G stated that it does not consider ongoing or proposed oil and gas activities, with appropriate mitigation measures, to threaten the conservation or sustainability of marine mammals in Cook Inlet.

Response: NMFS appreciates ADF&G's comments. All mitigation measures that were discussed by ADF&G and contained within the proposed rule have been carried over to this final rule.

Comment 31: CBD *et al.* asserted that NMFS' unmitigable adverse impact determination is arbitrary and that the specified activity may have an adverse impact on the availability of beluga whales, harbor seals, Steller sea lions, and sea otters for subsistence harvest. They assert that (1) any take of beluga whales has an adverse impact on their availability for subsistence use; (2) the determination relies on the mitigation measures in the proposed ITRs, but those measures are inadequate; and (3) the determination relies on 8 Star Alaska's stakeholder engagement plan that improperly delegates to the applicant NMFS' statutory obligation to prescribe regulations setting forth means of effecting the least practicable adverse impact on the availability for subsistence uses. CBD *et al.* asserted that "the [stakeholder engagement] plan contains no information on how 8 Star Alaska will respond to issues regarding how its activity may be impeding subsistence activities."

Response: As described in the proposed rule and this final rule, in order to promulgate regulations, NMFS must find that the specified activity will not have an "unmitigable adverse impact" on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined "unmitigable adverse impact" in 50 CFR 216.103 as an impact resulting from the specified activity: (1) that is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) causing the marine mammals to abandon or avoid hunting areas; (ii) directly displacing subsistence users; or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

Subsistence hunting of whales is not known to currently occur in Cook Inlet. Specific to CIBW, in 2008, NMFS issued regulations (73 FR 60976; October 15, 2008) establishing long-term limits on the maximum number of CIBWs that may be taken for subsistence by Alaska Natives. These long-term harvest limits, developed for 5-year intervals, require that the abundance estimates reach a minimum 5-year average of 350 belugas before hunting can take place (50 CFR 216.23(f)(2)(v)). No hunt has been authorized since 2006. Therefore, given the current moratorium on subsistence hunting of CIBWs, 8 Star Alaska's activities will not reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by:

(i) causing the marine mammals to abandon or avoid hunting areas; (ii) directly displacing subsistence users; or (iii) placing physical barriers between the marine mammals and the subsistence hunters.

Given the nature of the activity and the required mitigation measures, serious injury and mortality of marine mammals is not expected to occur. For most species, impacts to marine mammals will include limited, temporary behavioral disturbance. Small numbers of humpback whales, harbor porpoise, and harbor seals may incur slight auditory injury. As described above, the required mitigation measures, such as implementation of shutdown zones, are expected to reduce the frequency and severity of takes of marine mammals.

The commenters did not provide support for the assertion that the specified activity may have an adverse impact on the availability of harbor seals, Steller sea lions, and sea otters for subsistence harvest (of note, sea otters are managed by the U.S. Fish and Wildlife Service, rather than NMFS, and as such, are not discussed in this rulemaking). As noted in the Unmitigable Adverse Impact Analysis and Determination section of the proposed rule and this final rule, subsistence hunting in Cook Inlet consists mostly of opportunistic hunting of seals, which may overlap 8 Star Alaska's pile driving and anchor handling activities. Subsistence hunting occurs mostly nearshore and near river mouths. The majority of anchor handling activities are expected to occur offshore and are therefore expected to have little overlap with subsistence hunting. Any harassment to harbor seals due to pile driving is anticipated to be short-term, mild, and not result in any abandonment or behaviors that would make the animals unavailable for harvest, nor are the activities expected to directly displace subsistence users or place physical barriers between the marine mammals and the subsistence hunters.

Regarding stakeholder engagement, as described in the Unmitigable Adverse Impact Analysis and Determination section of the proposed rule and this final rule, 8 Star Alaska must coordinate with local subsistence communities as described in their stakeholder engagement plan, notify the communities of any changes in operation, and work with communities to avoid or mitigate impacts to subsistence harvest through pre-construction planning, communication, or other actions. This measure ensures that impacts to subsistence harvest will

be avoided or entirely mitigated, while providing flexibility in how those impacts, when identified, are avoided or mitigated.

As such, and as stated in the Unmitigable Adverse Impact Analysis and Determination section of this final rule, NMFS has determined that there would not be an unmitigable adverse impact on subsistence uses from 8 Star Alaska's planned activities.

Comment 32: The Commission recommended that NMFS require 8 Star Alaska to include in its stakeholder engagement plan which stakeholders have been or will be contacted, a summary of input received, a schedule for ongoing community engagement, and measures that would be implemented to mitigate any potential conflicts with subsistence hunting.

Response: NMFS generally concurs that the stakeholder engagement plan should include elements identified by the Commission, though as stated below, some specifics are not currently available given that 8 Star Alaska has not yet identified its construction schedule. 8 Star Alaska initially submitted a draft stakeholder engagement plan dated July 25, 2025. 8 Star Alaska expressed concerns about divulging information publicly for the Tribes and subsistence groups that it had contacted or engaged with and, therefore, did not include such information in the stakeholder engagement plan. Following input from NMFS, 8 Star Alaska submitted a revised stakeholder engagement plan dated August 22, 2025. The revised stakeholder engagement plan includes reference to the assessment of potential impacts to subsistence communities in the 2020 Alaska LNG Final EIS (FEIS). This assessment includes a description of the subsistence communities in the project area, a list of stakeholders that have been contacted, including Tribes and members of the subsistence community, dates of interaction and input received. As stated in the stakeholder engagement plan, specific future meetings have not yet been scheduled, but 8 Star Alaska plans to continue engagement with stakeholders. Meetings will be scheduled once the dates of construction have been identified and will include meetings with communities prior to construction that will provide schedule and contact information. Consistent with the Commission's recommendations, and as described in the proposed and final regulations, 8 Star Alaska must work with communities to avoid or mitigate impacts to subsistence harvest through pre-construction planning, communication, or other actions. The

stakeholder engagement plan describes such plans as well.

Comment 33: CBD *et al.* and a member of the public asserted that NMFS cannot rely on the 2020 Alaska LNG FEIS because it fails to consider a reasonable range of alternatives, including alternative mitigation measures, and because it fails to consider new information. CBD *et al.* therefore suggested that NMFS must conduct a supplemental analysis for the EIS.

Response: NMFS disagrees with the commenters that a supplemental EIS is warranted. Regarding the range of alternatives considered, NMFS worked with the FERC and required a suite of monitoring and mitigation measures that are the most protective to ensure the least practicable adverse impact. While a range of alternatives concerning the scope of the project was presented in the EIS, many of these project-related alternatives were eliminated either because they provided no environmental advantage or were impracticable for the project.

Regarding new information, NMFS prepared a supplemental information report (SIR) which documents NMFS' decision regarding whether a supplemental FEIS for its action (*i.e.*, promulgation of regulations and issuance of a 5-year LOA) is needed. The SIR considered new scientific information since the publication of the 2020 Alaska LNG Project FEIS, including relevant literature cited in CBD *et al.*'s public comment letter, as well as minor changes to the project and analyses. As described in the SIR, the minor changes to the project and new scientific information do not amount to a substantial change relevant to environmental concerns, and the new information does not alter the significance of adverse effects that were identified in the 2020 Alaska LNG FEIS.

Comment 34: CBD *et al.* asserted that NMFS cannot promulgate regulations and issue an LOA to 8 Star Alaska for the taking of marine mammals incidental to construction of the Alaska LNG Project in Cook Inlet, AK until NMFS conducts a consultation under section 7 of the ESA.

Response: As stated in the proposed rule, Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the promulgation of regulations, NMFS consults internally

whenever we propose to authorize take for endangered or threatened species. In this case NMFS Office of Protected Resources (OPR) consulted with the Alaska Regional Office (AKRO).

NMFS issued a Biological Opinion on June 3, 2020, concluding that the issuance of an LOA for the same project activities in Cook Inlet was not likely to jeopardize the continued existence of the threatened and endangered species under NMFS' jurisdiction and was not likely to destroy or adversely modify CIBW critical habitat. On July 14, 2025, NMFS OPR reinitiated consultation with NMFS AKRO pursuant to Section 7 of the ESA on the promulgation of regulations and issuance of a subsequent LOA to 8 Star Alaska. As described in this final rule, AKRO issued a Biological Opinion on October 31, 2025, which found that the Alaska LNG project is not likely to jeopardize the continued existence of fin whales, humpback whales (Mexico and Western North Pacific Distinct Population Segments (DPS)), beluga whales (Cook Inlet DPS), and Steller sea lions (Western DPS).

Comment 35: Defenders of Wildlife suggested that these regulations require significant revisions and therefore request that NMFS publish a revised proposed rule before publishing a final rule.

Response: NMFS has considered the revisions suggested by the commenter (as described in response to comments 5, 17, 19, and 20) and disagrees that they are necessary. NMFS has made the necessary revisions to the proposed rule, which are not significant enough to warrant publishing a revised proposed rule.

Comment 36: NMFS received multiple comments from the public expressing opposition to the killing of marine mammals.

Response: As described in this notice and the proposed rule, no serious injury or mortality to marine mammals is anticipated or authorized.

Changes From the Proposed Rule

Following a comment from the Commission, NMFS has determined it appropriate to change the source levels for the impact installation of 48-inch (122 cm) steel pipe piles from 213 SPLpeak, 192 SPLrms, and 181 dB SELs-s included in the proposed rule to 209 dB SPLpeak, 195 dB SPLrms, and 181 dB SELs-s (see comment 1 in Comments and Responses section). These source levels have been used to recalculate the estimated Level A and Level B harassment isopleths. Based on these changes, estimated take numbers have changed for harbor seals only (See

Estimated Take of Marine Mammals section). Shutdown zones for impact installation of 48-inch (122 cm) steel pipe piles have been changed as appropriate based on the updated Level A and Level B harassment isopleths (see Mitigation section).

The density for killer whale was inadvertently written as 0.0061 animals/km² in the proposed rule, and it has been corrected to accurately reflect the correct density used in the analysis of 0.00061 animals/km².

NMFS has updated the regulatory text in several places.

NMFS has updated § 217.44(f) to include a requirement that 8 Star Alaska must not pile drive in association with the Mainline MOF from June 1 to September 7. Although this mitigation measure had been discussed in the preamble to the proposed rule and proposed by 8 Star Alaska in its application, it was inadvertently omitted from the regulatory text in the proposed rule (See response to comment 16 in Comments and Responses section).

NMFS has clarified in § 217.44(n) that 8 Star Alaska must conduct sound source verification measurements at the beginning of pile driving, rather than prior to pile driving (see response to comment 9 in Comments and Responses section).

NMFS has added a requirement in § 217.44(n)(1) that any sound attenuation device used by 8 Star Alaska must meet minimum requirements as determined by NMFS in the SSV plan (see response to comment 14 Comments and Responses section).

NMFS has clarified in § 217.45(a)(6)(i) that for all single hammer pile driving activities a minimum of two PSOs must be on duty and has also specified locations of pile driving (see response to comment 8 in Comments and Responses section).

NMFS has added a requirement in § 217.45(a)(6)(ii) that for all concurrent pile driving activities at the Marine Terminal near Nikiski a minimum of three PSOs must be on duty at all times (see response to comment 8 in Comments and Responses section).

NMFS has clarified in § 217.45(b)(1) that SSV must be conducted at each location and in § 217.45(b)(1)(ii) that 8 Star Alaska must measure a minimum of each type, size, and installation method for single pile driving scenarios (see response to comment 9 in Comments and Responses section).

NMFS has added a requirement in § 217.45(b)(1)(iv)(F) that transmission loss values for attenuated and unattenuated impact and vibratory installation of each pile size and type

must be included in the SSV report (see response to comment 12 in Comments and Responses section).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about these species (e.g., physical and

behavioral descriptions) may be found on NMFS' website (<https://www.fisheries.noaa.gov/find-species>).

Table 1 lists all species or stocks for which take is expected and authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or authorized here, PBR and annual serious injury and mortality (M/SI) from anthropogenic sources are included here as gross

indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Alaska and Pacific SARs. All values presented in table 1 are the most recent available at the time of publication (including from the draft 2024 SARs) and are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>.

TABLE 1—SPECIES ¹ WITH ESTIMATED TAKE FROM THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ²	Stock abundance (CV, N _{min} , most recent abundance survey) ³	PBR	Annual M/SI ⁴
Order Artiodactyla—Cetacea—Mysticeti (baleen whales)						
<i>Family Eschrichtiidae:</i> Gray Whale	<i>Eschrichtius robustus</i>	Eastern North Pacific	-, -, N	26,960 (0.05, 25,849, 2016).	801	131
<i>Family Balaenopteridae</i> (rorquals):						
Fin Whale	<i>Balaenoptera physalus</i>	Northeast Pacific	E, D, Y	11,065 (0.405 7,970, 2013) ⁵ .	UND	0.6
Humpback Whale	<i>Megaptera novaeangliae</i>	Hawai'i	-, -, N	11,278 (0.56, 7,265, 2020).	127	27.09
Humpback Whale	<i>Megaptera novaeangliae</i>	Mexico-North Pacific	T, D, Y	N/A ⁶ (N/A, N/A, 2006)	UND	0.57
Humpback Whale	<i>Megaptera novaeangliae</i>	Western North Pacific	E, D, Y	1,084 (0.088, 1,007, 2006).	3.4	5.82
Minke Whale	<i>Balaenoptera acutorostrata</i>	Alaska	-, -, N	N/A ⁷ (N/A, N/A, N/A)	UND	0
Odontoceti (toothed whales, dolphins, and porpoises)						
<i>Family Delphinidae:</i> Killer Whale	<i>Orcinus orca</i>	Eastern North Pacific Alaska Resident.	-, -, N	1,920 (N/A, 1,920, 2019)	19	1.3
Killer Whale	<i>Orcinus orca</i>	Eastern North Pacific Gulf of Alaska, Aleutian Islands and Bering Sea Transient.	-, -, N	587 (N/A, 587, 2012)	5.9	0.8
Pacific White-Sided Dolphin	<i>Aethalodelphis obliquidens</i>	North Pacific	-, -, N	26,880 (N/A, N/A, 1990)	UND	0
<i>Family Monodontidae (white whales):</i> Beluga Whale	<i>Delphinapterus leucas</i>	Cook Inlet	E, D, Y	331 (0.076, 311, 2022) ...		0
<i>Family Phocoenidae (por- poises):</i> Dall's Porpoise	<i>Phocoenoides dalli</i>	Alaska	-, -, N	UND ⁸ (UND, UND, 2015).	UND	37
Harbor Porpoise	<i>Phocoena phocoena</i>	Gulf of Alaska	-, -, Y	31,046 (0.21, N/A, 1998)	UND	72
Order Carnivora—Pinnipedia						
<i>Family Otariidae (eared seals and sea lions):</i> California Sea Lion	<i>Zalophus californianus</i>	U.S.	-, -, N	257,606 (N/A, 233,515, 2014).	14,011	>321
Steller Sea Lion	<i>Eumetopias jubatus</i>	Western	E, D, Y	49,837 ⁹ (N/A, 49,837, 2022).	299	267
<i>Family Phocidae (earless seals):</i> Harbor Seal	<i>Phoca vitulina</i>	Cook Inlet/Shelikof Strait	-, -, N	28,411 (N/A, 26,907, 2018).	807	107

¹ Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/>).

²Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

³NMFS marine mammal stock assessment reports online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region>. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

⁴These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range.

⁵The best available abundance estimate for this stock is not considered representative of the entire stock as surveys were limited to a small portion of the stock's range.

⁶NMFS's abundance estimate for this stock is greater than 8 years old and not considered current. PBR is therefore considered undetermined for this stock, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimate as the best available information.

⁷Reliable population estimates are not available for this stock.

⁸The best available abundance estimate is likely an underestimate for the entire stock because it is based upon a survey that covered only a small portion of the stock's range.

⁹Nest is best estimate of counts, which have not been corrected for animals at sea during abundance surveys. Estimates provided are for the U.S. only. The overall N_{min} is 73,211 and overall PBR is 439.

A detailed description of the species likely to be affected by the Alaska LNG project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the proposed rule. Since publication of the proposed rule, the Society for Marine Mammalogy Committee on Taxonomy (2025) updated the genus for the Pacific white-sided dolphin from *Lagenorhynchus* to *Aethalodelphis*, based on the work of Galatius *et al.* (2025) and Vollmer *et al.* (2019). Therefore, the scientific name for the Pacific white-sided dolphin will be referred to as *Aethalodelphis obliquidens* in this notice. Aside from this change in scientific name, we are not aware of any changes in the status

of these species and stocks since publication of the proposed rule; therefore, detailed descriptions are not provided here. Please refer to the proposed rule for detailed descriptions. Please also refer to NMFS' website (<https://www.fisheries.noaa.gov/find-species>) for generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities

(e.g., Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Generalized hearing ranges were chosen based on the ~65 dB threshold from composite audiograms, previous analyses in NMFS (2018), and/or data from Southall *et al.* (2007) and Southall *et al.* (2019). We note that the names of two hearing groups and the generalized hearing ranges of all marine mammal hearing groups have been recently updated (NMFS 2024) as reflected below in table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS
(NMFS, 2024)

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 hertz (Hz) to 36 kHz.
High-frequency (HF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency (VHF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>)	200 Hz to 165 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	40 Hz to 90 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 68 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges may not be as broad. Generalized hearing range chosen based on ~65 dB threshold from composite audiogram, previous analysis in NMFS 2018, and/or data from Southall *et al.* (2007) and Southall *et al.* (2019). Additionally, animals are able to detect very loud sounds above and below that "generalized" hearing range.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2024) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from 8 Star Alaska's construction activities have the potential to result in harassment of marine mammals in the vicinity of the project area. The proposed rule included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from 8 Star

Alaska's construction activities on marine mammals and their habitat. That information and analysis is not repeated here.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes that may be authorized through issuance of a LOA, which will inform NMFS' consideration of "small numbers," the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities

not pertinent here, section 3(18) of 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).

Authorized takes will primarily be by Level B harassment, as exposure to sound resulting from use of the acoustic

sources (*i.e.*, pile driving and AHT activities) has the potential to result in disruption of behavioral patterns for individual marine mammals. We note here that given the slow, predictable, and generally straight path of tugs towing and positioning, the likelihood of a resulting disruption of marine mammal behavioral patterns that would qualify as harassment is considered relatively low. However, in consideration of the relatively louder sound produced by these tugs and the sensitive context present in Cook Inlet, NMFS cannot consider the likelihood of take to be discountable and considers it to be sufficiently likely to justify an assumption that quantified exposures above the generalized harassment threshold equate to take. Therefore, we have quantified the potential exposures from this activity, assumed that these exposures would equate to take, and analyzed the impacts of the assumed takes. There is also some potential for auditory injury (AUD INJ) (Level A harassment) to result due to impact pile driving, primarily for mysticetes, very high frequency species, and phocids because predicted AUD INJ zones are larger than for high-frequency species and otariids. AUD INJ is unlikely to occur for high-frequency species. The mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or authorized for this activity. Below we describe how the take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic criteria above which NMFS believes the best available science indicates marine mammals will likely be behaviorally harassed or incur some degree of AUD INJ; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can

qualitatively inform take estimates is also sometimes available (*e.g.*, previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the take estimates.

Acoustic Criteria

NMFS recommends the use of acoustic criteria that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur AUD INJ of some degree (equated to Level A harassment). We note that the criteria for AUD INJ, as well as the names of two hearing groups, have been recently updated (NMFS, 2024) as reflected below in the Level A harassment section.

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.*, frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.*, bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.*, Southall *et al.*, 2007, 2021, Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB re 1 μ Pa for continuous (*e.g.*, vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (*e.g.*, seismic

airguns) or intermittent (*e.g.*, scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by temporary threshold shift (TTS) as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

8 Star Alaska's activity includes the use of continuous (vibratory pile driving and AHTs engaged in anchor handling) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μ Pa are applicable.

Level A Harassment—NMFS' Updated Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 3.0) (Updated Technical Guidance, 2024) identifies dual criteria to assess AUD INJ (Level A harassment) to five different underwater marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). 8 Star Alaska's activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving and use of AHTs) sources.

The 2024 Updated Technical Guidance criteria include both updated thresholds and updated weighting functions for each hearing group. The thresholds are provided in the table below. The references, analysis, and methodology used in the development of the criteria are described in NMFS' 2024 Updated Technical Guidance, which may be accessed at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools>.

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY

Hearing group	AUD INJ onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 222 dB; $L_{E,LF,24h}$: 183 dB	Cell 2: $L_{E,LF,24h}$: 197 dB.
High-Frequency (HF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_{E,HF,24h}$: 193 dB	Cell 4: $L_{E,HF,24h}$: 201 dB.
Very High-Frequency (VHF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_{E,VHF,24h}$: 159 dB	Cell 6: $L_{E,VHF,24h}$: 181 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{pk,flat}$: 223 dB; $L_{E,PW,24h}$: 183 dB	Cell 8: $L_{E,PW,24h}$: 195 dB.

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY—Continued

Hearing group	AUD INJ onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{pk,flat}$: 230 dB; $L_{E,OW,24h}$: 185 dB	Cell 10: $L_{E,OW,24h}$: 199 dB.

* Dual metric criteria for impulsive sounds: Use whichever criteria results in the larger isopleth for calculating AUD INJ onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level criteria associated with impulsive sounds, the PK SPL criteria are recommended for consideration for non-impulsive sources.

Note: Peak sound pressure level ($L_{p,0-pk}$) has a reference value of 1 μ Pa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 μ Pa²s. In this table, criteria are abbreviated to be more reflective of International Organization for Standardization standards (ISO 2017). The subscript “flat” is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals underwater (*i.e.*, 7 Hz to 165 kHz). The subscript associated with cumulative sound exposure level criteria indicates the designated marine mammal auditory weighting function (LF, HF, and VHF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level criteria could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these criteria will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional noise from pile driving and AHTs engaging in anchor handling from the project.

Pile Driving

8 Star Alaska will conduct vibratory pile installation and removal and impact pile installation. Source levels for these activities are based on reviews

of measurements of sound source levels from the same or similar types and dimension of piles available in the literature. Source levels for each pile size and activity are presented in table 4. Source levels for vibratory installation and removal of piles of the same diameter are assumed to be the same.

8 Star Alaska will conduct concurrent pile driving during construction of the combi-wall and coffer cells in the Marine Terminal MOF. When two noise sources have overlapping sound fields, the sources are considered additive and combined using the rules of dB addition. For addition of two concurrent sources, the difference between the two

sound source levels is calculated, and if that difference is between 0 and 1 dB, 3 dB are added to the higher sound source levels; if the difference is between 2 and 3 dB, 2 dB are added to the highest sound source levels; if the difference is between 4 and 9 dB, 1 dB is added to the highest sound source levels; and with differences of 10 or more dB, there is no addition. For two concurrent sources of different type (*i.e.*, impact and vibratory driving), there is no sound source addition. Combinations of concurrent pile driving and the predicted source values are shown in table 5. All concurrent pile driving will consist of two vibratory hammers.

TABLE 4—SOUND SOURCE LEVELS FOR SINGLE HAMMER PILE DRIVING

Pile type	Source level (at 10 m)			Proxy	Source
	Peak (dB re 1 μPa)	SEL (dB re 1 μPa2 sec)	RMS (dB re 1 μPa)		
Impact					
Sheet Pile	205	180	190	24-inch (61-cm) AZ Sheet Pile	Caltrans (2015).
24-inch Steel Pipe Pile	203	177	190	24-inch (61-cm) Steel Pipe Pile	Caltrans (2015).
48-inch Steel Pipe Pile *	208	180	195	48-inch (121.9-cm) Steel Pipe Pile	Caltrans (2020); Austin, <i>et al.</i> (2016); Illingworth & Rodkin (2017).
60-inch Steel Pipe Pile	210	185	195	60-inch (152.4 cm) Steel Pipe Pile	Caltrans (2020).
Vibratory					
Sheet Pile	N/A	N/A	160	24-inch (61-cm) AZ Sheet Pile	Caltrans (2015).
24-inch Steel Pipe Pile)	N/A	N/A	163	20- to 24-inch (50.8- to 61-cm) Steel Pipe Pile.	U.S. Navy (2012, 2013), (Miner, 2020).
66-inch Steel Pipe Pile	N/A	N/A	170	49- to 72-inch (124.5–182.9-cm) to Steel Pipe Piles (average).	Caltrans (2020), Illingworth & Rodkin (2021).

* Source levels for impact installation of 48-inch steel pipe piles have change since publication of the proposed rule due to comments received from the Commission (see Comments and Responses section.)

TABLE 5—CONCURRENT PILE DRIVING SCENARIOS AND PREDICTED SOURCE LEVELS
[All vibratory hammers]

Concurrent pile driving scenarios	Predicted RMS (dB re 1 μ Pa) at 10 m
66-inch Steel Pipe Pile $\times$ 2	173
66-inch Steel Pipe Pile with Sheet Pile	170
Sheet Pile $\times$ 2	163
24-inch Steel Pipe Pile with Sheet Pile	165
24-inch Steel Pipe Pile $\times$ 2	166

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition topography. The general formula for underwater TL is: $TL = B * \log_{10} (R_1/R_2)$,

Where:

TL = transmission loss in dB;

B = transmission loss coefficient;

R_1 = the distance of the modeled SPL from the driven pile; and

R_2 = the distance from the driven pile of the initial measurement.

Absent site-specific acoustical monitoring with differing measured transmission loss, a practical spreading value of 15 is used as the transmission loss coefficient in the above formula. Project and site-specific transmission loss data for 8 Star Alaska's project area in Cook Inlet are not available;

therefore, the default coefficient of 15 is used to determine the distances to the Level A and Level B harassment thresholds for all pile driving. All Level B harassment isopleths are reported in table 7. However, as discussed in the Monitoring and Reporting section, 8 Star Alaska will conduct SSV for pile driving. Following the analysis of SSV results, 8 Star Alaska may propose revised estimated Level A and Level B harassment zones (for the purpose of monitoring and reporting) and adjusted shutdown zones accordingly for NMFS review and approval.

The ensoufied area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the 2024 Updated Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal

density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as impact and vibratory pile driving and AHTs engaged in anchor handling, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur AUD INJ. Inputs used in the optional User Spreadsheet tool are provided in table 6, and the resulting estimated isopleths are reported in table 7.

TABLE 6—USER SPREADSHEET INPUT PARAMETERS USED FOR CALCULATING LEVEL A HARASSMENT ISOPLETHS

[Source levels provided in Tables 4 and 5]

Pile	Piles per day	Strikes per pile	Duration to drive pile (min)	Weighting factor adjustment (WFA)
Impact				
Sheet Pile	30	1,000	N/A	2
24-inch Steel Pipe Pile	4	1,000	N/A	2
48-inch Steel Pipe Pile	3	1,000	N/A	2
60-inch Steel Pipe Pile	4	1,000	N/A	2
Vibratory				
Sheet Pile	30	N/A	15	2.5
24-inch Steel Pipe Pile	8	N/A	15	2.5
66-inch Steel Pipe Pile	7	N/A	15	2.5
Concurrent Pile Driving with Two Vibratory Hammers				
66-inch Steel Pipe Pile × 2	1	N/A	*105	2.5
66-inch Steel Pipe Pile with Sheet Pile	1	N/A	*450	2.5
Sheet pile × 2	1	N/A	*450	2.5
24-inch Steel Pipe Pile with Sheet Pile	1	N/A	*450	2.5
24-inch Steel Pipe Pile × 2	1	N/A	*120	2.5

* This value represents the maximum duration of concurrent activity.

TABLE 7—CALCULATED DISTANCES TO LEVEL A AND LEVEL B HARASSMENT ISOPLETHS FOR PILE DRIVING

Pile	Level A harassment zone (m)					Level B harassment zone (m)
	LF cetacean	HF cetacean	VHF cetacean	Phocids	Otariids	
Impact						
Sheet Pile	6,061	773	9,380	5,385	2,007	1,000
24-inch Steel Pipe Pile	998	127	1,545	887	331	1,000
48-inch Steel Pipe Pile *	1,306	167	2,021	1,160	432	2,154
60-inch Steel Pipe Pile	3,408	435	5,274	3,028	1,120	2,154
Vibratory						
Sheet Pile	30	12	25	39	13	4,642

TABLE 7—CALCULATED DISTANCES TO LEVEL A AND LEVEL B HARASSMENT ISOPLETHS FOR PILE DRIVING—Continued

Pile	Level A harassment zone (m)					Level B harassment zone (m)
	LF cetacean	HF cetacean	VHF cetacean	Phocids	Otariids	
24-inch Steel Pipe Pile	20	8	16	26	9	7,356
66-inch Steel Pipe Pile	53	21	44	69	23	21,544
Concurrent Pile Driving with Two Vibratory Hammers						
66-inch Steel Pipe Pile × 2	85	33	69	109	37	34,146
66-inch Steel Pipe Pile with Sheet Pile	141	54	115	181	61	21,544
Sheet Pile × 2	48	19	39	62	21	7,356
24-inch Steel Pipe Pile with Sheet Pile	32	12	26	41	14	11,659
24-inch Steel Pipe Pile × 2	65	25	53	84	28	10,000

* The Level A and Level B harassment isopleths for impact installation of 48-inch steel pipe piles have changed since the publication of the proposed rule due to changes in source levels since publication of the proposed rule (see table 4).

Except for Level B harassment areas of ensonification for the single hammer vibratory installation of 66-inch steel pipe pile, the concurrent vibratory installation of two 66-inch piles, and the concurrent vibratory installation of a 66-inch steel pipe pile with a sheet pile, estimated areas of ensonification were calculated for pile driving using the formula of $\frac{1}{2}\pi r^2$, where r is the respective isopleth. For the single hammer vibratory installation of 66-inch steel pipe pile, the concurrent vibratory

installation of two 66-inch piles, and the concurrent vibratory installation of a 66-inch steel pipe pile with a sheet pile, the Level B harassment isopleths were truncated by land, and therefore $\frac{1}{2}\pi r^2$ was not representative of the area of ensonification. Therefore, mapping software was used to draw the estimated area of ensonification. Estimated Level A and Level B harassment areas of ensonification are in table 8.

NMFS used the following formula to estimate the area of ensonification for

AHTs engaged in anchor handling, where distance traveled per day is the linear distance that the AHTs would be expected to travel over the course of a day, and r is the radial distance of the Level B harassment isopleth (3.85 km). 8 Star Alaska estimates the pipelay rate to be 2,500 feet/day (0.762 km/day), so 0.762 km was used as the distance traveled per day.

Area of ensonification = (Distance traveled per day × 2r) + πr^2

TABLE 8—CALCULATED LEVEL A AND B HARASSMENT AREAS OF ENSONIFICATION

Pile	Level A harassment areas of ensonification (km ²)					Level B harassment area of ensonification (km ²)
	LF cetacean	HF cetacean	VHF cetacean	Phocids	Otariids	
Impact						
Sheet Pile	57.7	0.94	138.21	45.47	6.33	1.57
24-inch Steel Pipe Pile	1.56	0.03	3.75	1.24	0.17	1.57
48-inch Steel Pipe Pile*	2.68	0.17	6.47	2.11	0.29	7.29
60-inch Steel Pipe Pile	18.24	0.3	43.69	14.4	2.0	7.29
Vibratory						
Sheet Pile	0.00	0.00	0.00	0.00	0.00	33.85
24-inch Steel Pipe Pile	0.00	0.00	0.00	0.00	0.00	24.89
66-inch Steel Pipe Pile	0.00	0.00	0.00	0.00	0.00	62.54
66-inch Steel Pipe Pile × 2	0.01	0.00	0.01	0.02	0.00	1,426.4
66-inch Steel Pipe Pile with Sheet Pile	0.03	0.00	0.02	0.05	0.01	722.5
Sheet Pile × 2	0.00	0.00	0.00	0.01	0.00	85
24-inch Steel Pipe Pile with Sheet Pile	0.01	0.00	0.00	0.01	0.00	157.08
24-inch Steel Pipe Pile × 2	0.00	0.00	0.00	0.00	0.00	213.5
AHTs						
Anchor Handling	0.00	0.00	0.00	0.01	0.00	52.4

* Areas of ensonification for impact installation of 48-inch steel pipe piles have changed since the publication of the proposed rule due to changes in the Level A and Level B harassment isopleths (see table 7).

Level A harassment zones are typically smaller than Level B harassment zones. However, in some cases, the calculated Level A harassment isopleth is greater than the

calculated Level B harassment isopleth. Calculation of Level A harassment isopleths include a duration component, which in the case of impact pile driving, is estimated through the total number of

daily strikes and the associated pulse duration. For a stationary sound source, we assume here that an animal is exposed to all of the strikes expected within a 24-hour period. Calculation of

a Level B harassment zone does not include a duration component. Depending on the duration included in the calculation, the calculated Level A harassment isopleths can be larger than the calculated Level B harassment isopleth for the same activity.

Mainline Installation

8 Star Alaska intends to use AHTs to position a pipelaying barge in order to install the pipe on the seafloor for the Mainline across Cook Inlet. For the nearshore pipelay, planned for year 3, an AHT will engage in anchor handling to moor a pull barge, and is expected to be used for two days of work, one day on the west coast near Beluga and one day on the east coast near Suneva Lake. For offshore pipelay, AHTs will be engaged in anchor handling to repeatedly position the barge during the duration of pipelay. Consistent with other tug activities, including those for tugs towing a jack-up rig (Furie Operating Alaska, LLC Natural Gas Activities, 89 FR 77836 (September 24, 2024); Hilcorp Alaska, LLC, 89 FR 79529 (September 30, 2024)), NMFS anticipates that the AHTs will operate at approximately 50 percent power during anchor handling activities.

Because of the similarities to tugging activities planned by Hilcorp in Cook Inlet (89 FR 79529, September 30, 2024), NMFS determined it appropriate to adopt analysis provided for those activities for 8 Star Alaska's planned tugging activities. In addition, we refer here to an existing literature review of available source level data for tugs under load in varying power output scenarios (87 FR 27597, May 9, 2022). Please see that notice for the detailed analysis. While that analysis is for tugs

under load towing a jack-up rig, NMFS expects the AHT power output for the anchor handling is to be consistent with that assumed for tugs towing a jack-up rig (Furie Operating Alaska, LLC Natural Gas Activities, 89 FR 77836 (September 24, 2024); Hilcorp Alaska, LLC, 89 FR 79529 (September 30, 2024)), and, therefore, NMFS determined that this analysis represents the best scientific evidence available for considering the appropriate source level proxy for 8 Star Alaska's AHT use during anchor handling.

In addition to the literature review referenced above, which indicates that a source level of 180 dB for a single AHT would be appropriate, we also consider other relevant information to adequately consider 8 Star Alaska's planned use of three AHTs to handle anchors. If all three tugs were operating simultaneously at 180 dB RMS, the overall source emission levels would be expected to increase by approximately 5 dB when logarithmically adding the sources (*i.e.*, to 185 dB RMS). To further support this level as an appropriate proxy, an SSV study performed by JASCO Applied Sciences (JASCO) in Cook Inlet in October 2021 (Lawrence *et al.*, 2022) measured the sound source level from three tugs pulling a jack-up rig in Cook Inlet at various power outputs. Lawrence *et al.* (2022) reported a source level of 167.3 dB RMS for the 20 percent-power scenario and a source level of 205.9 dB RMS for the 85 percent-power scenario. Assuming a linear scaling of tug power, a source level of 185 dB RMS was calculated as a single point source level for three tugs operating at 50 percent power output. Therefore, the analyses presented below use a mean tug sound source level

scenario of 185 dB RMS to estimate distances to the 120 dB RMS isopleth for three tugs operating at 50 percent power output. In practice, the load condition of the three tugs is unlikely to be identical at all times, so sound emissions would be dominated by the single tug in the group that is working hardest at any point in time. NMFS, therefore, has determined it appropriate to use the source level of 185 dB RMS at 1 m to represent the use of three AHTs. Modeling using this source level resulted in an estimated distance to the 120-dB isopleth of 3,850 m. Please see 89 FR 79529 (September 30, 2024) for full detail.

As noted previously, NMFS determined that Level A harassment would not be a reasonably likely outcome of the use of AHTs. In order to characterize the extent of the Level A harassment isopleths to provide additional quantitative support for this determination, NMFS used the NMFS user spreadsheet to calculate Level A harassment zones for each hearing group for AHTs conducting anchor handling. NMFS used Tab A (Non-Impulse-Stat-Cont) in the spreadsheet and used a WFA of 2, a 6-hour duration of sound production within a 24-hour period, and a propagation loss coefficient of 18.129. Weston and SLR (2022) determined the average 120 dB isopleth was 3,850 m for a continuous noise source of 185 dB rms SPL across 25 locations in middle Cook Inlet. The coefficient is calculated as $(185 \text{ dB} - 120 \text{ dB}) / \log_{10}(3850/1) = 18.129 \text{ dB per decade}$. Estimated Level A and Level B harassment isopleths for AHTs engaged in anchor handling are reported in table 9.

TABLE 9—LEVEL A AND LEVEL B HARASSMENT ISOPLETHS FROM AHTS ENGAGED IN ANCHOR HANDLING

Sound source	Level A harassment isopleths (m) ¹					Level B harassment isopleth (m) ²
	LF	HF	VHF	Phocid	Otariid	
3 AHTs	53	21	28	62	21	3,850

¹ Level A harassment isopleths calculated using NMFS User spreadsheet.

² Level B harassment isopleth determined using results from Hilcorp's modeling.

Marine Mammal Occurrence

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

8 Star Alaska requested take of humpback whale, killer whale, beluga whale, harbor porpoise, and harbor seal. In addition to those species, NMFS determined that minke whale, gray

whale, fin whale, Dall's porpoise, Pacific white-sided dolphin, Steller sea lion, and California sea lion are likely to occur in the project area during 8 Star Alaska's activities and, accordingly, is authorizing take for these species.

Densities for marine mammals in Cook Inlet were derived from NMFS AFSC's Marine Mammal Laboratory (MML) aerial surveys, typically flown in June, from 2000 to 2022 (Rugh *et al.*,

2005; Sheldon *et al.*, 2013, 2015b, 2017, 2022; Sheldon and Wade, 2019; Goetz *et al.*, 2023) except for beluga whales, for which other density data exist, or for Steller sea lions, fin whale, Pacific white-sided dolphins, and California sea lions, which occur too rarely to support development of density estimates. Total survey area was not reported for the 2021 or 2022 survey years (Sheldon *et al.*, 2022, Goetz *et al.*, 2023) so total

survey area for 2021 and 2022 was estimated as 8,377.2 km² for each year based on previous reports. While the surveys are concentrated for a few days in summer annually, which may skew densities for seasonally present species, they represent the best available long-term dataset of marine mammal sightings available in Cook Inlet. To estimate the average density, the maximum number of individuals per species was divided by the area surveyed, and NMFS used the average across all survey years for each species.

CIBW densities estimated from the AFSC surveys across regions are low; however, there is a known effect of seasonality on their distribution. Thus, densities derived directly from these summer surveys might underestimate the density of CIBWs in lower Cook Inlet at other ice-free times of the year. Therefore, NMFS used the Goetz *et al.* (2012a) habitat-based model to determine CIBW density. This model is derived from sightings and incorporates depth soundings, coastal substrate type, environmental sensitivity index, anthropogenic disturbance, and anadromous fish streams to predict densities throughout Cook Inlet. The output of this model is a density map of Cook Inlet, which predicts spatially explicit density estimates for CIBW. Using the resulting grid densities, average densities were calculated for three regions applicable to 8 Star Alaska's operations (table 10). The densities applicable to the area of activity (*i.e.*, the Marine Terminal near Nikiski, the Mainline in middle Cook Inlet, and the Mainline MOF near Tyonek) are provided in table 10 and were carried forward to the exposure estimates as they were deemed to be the most representative estimates available.

Although data exists for Steller sea lions and fin whales in Cook Inlet from AFSC aerial surveys, this data is based on sightings of Steller sea lions and fin whales that were mostly observed in lower Cook Inlet and is not representative of middle Cook Inlet, where 8 Star Alaska plans to conduct construction. Therefore, in order to calculate take of these species, NMFS used marine mammal occurrence.

For Steller sea lions, NMFS used monitoring data from the Port of Alaska (POA) in Anchorage, as these animals would be expected to pass through middle Cook Inlet and therefore be observed in 8 Star Alaska's Project Area. In 2020–2022 and 2024 (61 North

Environmental, 2021, 2022a, 2022b, 2025; Easley-Appleyard and Leonard, 2022), the maximum number of Steller sea lions observed at POA was nine animals, eight during Petroleum and Cement Terminal (PCT) observations (61 North Environmental, 2022a) and one during NMFS 2021 monitoring effort (Easley-Appleyard and Leonard, 2022). Therefore, NMFS anticipates that up to nine Steller sea lions may occur in the project area per year during the course of 8 Star Alaska's project.

During seismic surveys conducted in 2019 by Hilcorp in the lower Cook Inlet, fin whales were recorded in groups ranging in size from one to 15 individuals (Fairweather, 2020). During the NMFS aerial surveys in Cook Inlet from 2000 to 2018, 10 sightings of 26 estimated individual fin whales in lower Cook Inlet were observed (Shelden *et al.*, 2013, 2015, 2016, 2019). Therefore, NMFS anticipates that one group of two fin whales (the lower end of the range of common group sizes) may occur in the project area per year during the course of 8 Star Alaska's project.

No density estimates are available for Pacific white-sided dolphins and California sea lions, as they are so infrequently sighted. Therefore, NMFS is authorizing take of these species based on group number (see table 11).

Due to the paucity of data of Pacific white-sided dolphins in this region, there is no available density for Pacific white-sided dolphins. They are considered rare in most of Cook Inlet, including in the lower entrance, but their presence was documented in Iniskin Bay and mid-inlet through passive acoustic recorders in 2019 (Castellote *et al.*, 2020). In 2014, during Apache's seismic survey program, three Pacific white-sided dolphins were reported (Lomac-MacNair *et al.*, 2014).

While California sea lions are uncommon in Cook Inlet, two were seen during the 2012 Apache seismic survey in Cook Inlet (Lomac-MacNair *et al.*, 2013). California sea lions in Alaska are typically alone but may be seen in small groups usually associated with Steller sea lions at their haul outs and rookeries (Maniscalco *et al.*, 2004).

TABLE 10—CALCULATED DENSITIES

Species	Density (animals/km ²)
Gray whale	0.00070
Humpback whale	0.00185

TABLE 10—CALCULATED DENSITIES—Continued

Species	Density (animals/km ²)
Minke whale	0.00003
Killer whale	* 0.00061
Beluga whale (Marine Terminal)	0.00016
Beluga whale (Mainline Crossing)	0.01070
Beluga whale (Mainline MOF)	0.03680
Dall's porpoise	0.00014
Harbor porpoise	0.00380
Harbor seal	0.26819

* The density for killer whales in this table has changed from the proposed rule to reflect the correct density (see Changes from Proposed Rule section).

TABLE 11—MARINE MAMMAL OCCURRENCE *

Species	Expected occurrence (animals/year)
Fin whale	2
Pacific white-sided dolphin ...	3
California sea lion	2
Steller sea lion	9

* Marine mammal occurrence is used when density data is unavailable or not representative of the project area.

Take Estimation

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and is authorized.

To estimate take by Level B harassment for all species except for fin whale, Pacific white-sided dolphin, California sea lion, and Steller sea lion, 8 Star Alaska multiplied the area (km²) estimated to be ensounded above the Level B harassment thresholds (table 8) for each activity by the duration (days) of that activity by the calculated density for each species (number of animals/km²). As described above, take of fin whale, Pacific white-sided dolphin, California sea lion, and Steller sea lion were calculated using group numbers and estimated frequency of occurrence (table 11).

For species where calculated take by Level B harassment was less than the average group size for that species, NMFS rounded up the take estimate to the anticipated group size as displayed in table 12 and described below.

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Table 12 -- Estimated Take by Level B Harassment by Species, Pile Size and Type, and Installation/Removal Method

Structure	Activity	Days	Gray whale	Fin whale	Hump back whale	Minke whale	Killer whale	Pacific white-sided dolphin	Beluga whale	Dall's porpoise	Harbor porpoise	California sea lion	Steller sea lion	Harbor seal
Year 1														
Marine Terminal MOF Combi-Wall	66-inch Steel Pipe Pile x 2 Concurrent (Vibratory)	16	1.60	N/A	42.22	0.68	13.92	N/A	3.61	3.20	86.73	N/A	N/A	6120.74
	66-inch Steel Pipe Pile with Sheet Pile Concurrent (Vibratory)	6	0.30	N/A	8.02	0.13	2.64	N/A	0.68	0.61	16.47	N/A	N/A	1162.60
Marine Terminal MOF Cofferdam Cell	Sheet Pile x 2 Concurrent (Vibratory)	33	0.20	N/A	5.19	0.08	1.71	N/A	0.44	0.39	10.66	N/A	N/A	752.25
	24-inch Steel Pipe Pile With Sheet Pile Concurrent (Vibratory)	23	0.25	N/A	6.68	0.11	2.20	N/A	0.57	0.51	13.73	N/A	N/A	968.93
Total Calculated Year 1		78	2.35	N/A	62.11	1.01	20.48	N/A	5.3	4.7	127.59	N/A	N/A	9004.51
Total Estimated Take by Level B Harassment Year 1			3*	2*	62	3*	20	3*	11*	6*	128	2*	9*	9,005

Year 2													
Marine Terminal MOF Coffey Cell	Sheet Pile x 2 Concurrent (Vibratory)	32	0.19	N/A	5.03	0.08	1.66	N/A	0.43	0.38	10.34	N/A	729.45
	24-inch Steel Pipe Pile with Sheet Pile Concurrent (Vibratory)	22	0.24	N/A	6.39	0.10	2.11	N/A	0.55	0.48	13.13	N/A	926.80
Marine Terminal MOF RoRo Dolphin Quads	48-inch Steel Pipe Pile (Impact)	7	0.00	N/A	0.09	0.00	0.03	N/A	0.01	0.01	0.19	N/A	13.68
	24-inch Steel Pipe Pile (Impact)	7	0.00	N/A	0.02	0.00	0.01	N/A	0.00	0.00	0.04	N/A	2.95
Mainline MOF	Sheet Pile (Vibratory)	7	0.02	N/A	0.44	0.01	0.14	N/A	8.72	0.03	0.90	N/A	63.54
	Sheet Pile (Impact)	7	0.00	N/A	0.02	0.00	0.01	N/A	0.40	0.00	0.04	N/A	2.95
Total Calculated Year 2		83	0.45	N/A	12.00	0.19	3.96	N/A	10.1	0.90	24.65	N/A	1739.37
Total Estimated Take by Level B Harassment Year 2			3*	2*	12	3*	10*	3*	11*	6*	25	2*	1739
Year 3													
PLF E-W Trestle	60-inch Steel Pipe	42	0.02	N/A	0.57	0.01	0.19	N/A	0.05	0.04	1.16	N/A	82.09

[illegible]

	Pile (Impact)																		
PLF Mooring dolphin	48-inch Steel Pipe Pile (Impact)	2	0.00	N/A	0.03	0.00	0.01	N/A	0.00	0.00	0.06	N/A	N/A	0.06	N/A	N/A	3.91		
	60-inch Steel Pipe Pile (Impact)	2	0.00	N/A	0.03	0.00	0.01	N/A	0.00	0.00	0.06	N/A	N/A	0.06	N/A	N/A	3.91		
PLF N-S Trestle	48-inch Steel Pipe Pile (Impact)	12	0.01	N/A	0.16	0.00	0.05	N/A	0.01	0.01	0.33	N/A	N/A	0.33	N/A	N/A	23.45		
Mainline	Anchor handling	53	0.19	N/A	5.14	0.08	1.70	N/A	29.74	0.39	10.56	N/A	N/A	10.56	N/A	N/A	745.30		
Total Calculated Year 4		105	0.22	N/A	5.84	0.09	1.93	N/A	29.78	0.44	12.0	N/A	N/A	12.0	N/A	N/A	846.93		
Total Estimated Take by Level B Harassment Year 4			3*	2*	6	3*	10*	3*	30	6*	12	2*	9*	847					
Year 5																			
PLF Mooring dolphin	48-inch Steel Pipe Pile (Impact)	6	0.00	N/A	0.08	0.00	0.03	N/A	0.01	0.01	0.17	N/A	N/A	0.17	N/A	N/A	11.73		
	60-inch Steel Pipe Pile (Impact)	14	0.01	N/A	0.19	0.00	0.06	N/A	0.02	0.01	0.39	N/A	N/A	0.39	N/A	N/A	27.36		
PLF Catwalk	60-inch Steel Pipe	16	0.01	N/A	0.22	0.00	0.07	N/A	0.02	0.02	0.44	N/A	N/A	0.44	N/A	N/A	31.27		

[illegible]

*Take number adjusted for group size

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During Apache's 2012 seismic program, nine sightings of a total of nine

gray whales were observed in June and July (Lomac-MacNair *et al.*, 2013). In

2014, one gray whale was observed during Apache's seismic program

(Lomac-MacNair *et al.*, 2014) and in 2015, no gray whales were observed during SAExploration's seismic survey (Kendall and Cornick, 2015). No gray whales were observed during the 2018 Cook Inlet Pipeline (CIPL) Extension Project (Sitkiewicz *et al.*, 2018) or during the 2019 Hilcorp seismic survey in lower Cook Inlet (Fairweather Science, 2020). The greatest densities of gray whales in Cook Inlet occur from November through January and March through May; the former are southbound, the latter are northbound (Ferguson *et al.*, 2015). Based on this information, NMFS is authorizing three takes by Level B harassment annually for gray whales. This is higher than the exposure estimate for each to allow for the potential occurrence of a group, or several individuals, per year.

During annual aerial surveys conducted in Cook Inlet from 2000 to 2016, humpback group sizes ranged from 1 to 12 individuals, with most groups comprised of 1 to 3 individuals (Shelden *et al.*, 2013). Three humpback whales were observed in Cook Inlet during SAExploration's seismic study in 2015: two near the Forelands and one in Kachemak Bay (Kendall and Cornick, 2015). In total, 14 sightings of 38 humpback whales (ranging in group size from 1 to 14) were recorded in the 2019 Hilcorp lower Cook Inlet seismic survey in the fall (Fairweather Science, 2020). Two sightings totaling three individual humpback whales were recorded near Ladd Landing north of the Forelands on the recent Harvest Alaska CIPL Extension Project (Sitkiewicz *et al.*, 2018). Based on documented observations from the CIPL Extension Project, which is the data closest to 8 Star Alaska's project area, NMFS is authorizing three takes by Level B harassment for humpback whales for years 3 and 5. For years 1, 2, and 4, the calculated take exceeds the estimated group size.

Groups of up to three minke whales have been recorded in recent years, including one group of three southeast of Kalgin Island (Lomac-MacNair *et al.*, 2014). Other recent surveys in Cook Inlet typically have documented minke whales traveling alone (Shelden *et al.*, 2013, 2015, 2017; Fairweather Science, 2020). As the occurrence of minke whales is expected to be lower in middle Cook Inlet than lower Cook Inlet and considering the observed group sizes, NMFS is authorizing three takes of minke whale by Level B harassment for each year of 8 Star Alaska's project.

Killer whale pods typically consist of a few to 20 or more animals (NMFS, 2025b). During seismic surveys conducted in 2019 by Hilcorp in lower

Cook Inlet, 21 killer whales were observed. Although also observed as single individuals, killer whales were recorded during this survey in groups ranging in size from two to five individuals (Fairweather Science, 2020). One killer whale group of two individuals was observed during the 2015 SAExploration seismic program near the North Foreland (Kendall and Cornick, 2015). Based on recent documented sightings, observed group sizes, and the established presence of killer whales in Cook Inlet, NMFS is authorizing 10 takes (2 groups of 5 animals, the upper end of recently recorded group size) by Level B harassment for killer whales for years 2–5.

The 2018 MML aerial survey (Shelden and Wade, 2019) estimated a median group size of approximately 11 beluga whales, although group sizes were highly variable (2 to 147 whales) as was the case in previous survey years (Boyd *et al.*, 2019). Over 3 seasons of monitoring at the Port of Alaska, 61 North reported groups of up to 53 belugas, with a median group size of 3 and a mean group size of 4.4 (61 North Environmental, 2021, 2022a, 2022b, 2022c). Additionally, vessel-based surveys in 2019 observed beluga whale groups in the Susitna River Delta that ranged from 5 to 200 animals (McGuire *et al.*, 2022). The very large groups seen in the Susitna River Delta are not expected in the areas of 8 Star Alaska's construction. However, smaller groups (*i.e.*, around the median group size) could be traveling through to access the Susitna River Delta and other nearby coastal locations, particularly in the shoulder seasons when belugas are more likely to occur in middle Cook Inlet. Therefore, NMFS is authorizing 11 takes by Level B harassment of beluga whale in years 1–3, and 5, in which calculated exposures were below the median group size. Calculated takes of beluga whales was greater than the median group size in year 4 and therefore were not adjusted for group size.

Dall's porpoises are usually found in groups averaging between 2 and 12 individuals (NMFS, 2025a). During seismic surveys conducted in 2019 by Hilcorp in lower Cook Inlet, Dall's porpoises were recorded in groups ranging from two to seven individuals (Fairweather Science, 2020). The 2012 Apache survey recorded two groups of three individual Dall's porpoises (Lomac-MacNair *et al.*, 2014). NMFS is authorizing six takes by Level B harassment per year for Dall's porpoises. This is greater than the exposure estimate for each year, but allows for at least one group at the higher end of

documented group size or a combination of small groups.

8 Star Alaska will shut down at the Level A harassment isopleth for all vibratory pile driving activities if a marine mammal is detected approaching the Level A harassment zone. The largest Level A harassment isopleth during vibratory pile driving is 181 m, and NMFS anticipates that 8 Star Alaska will be able to adequately monitor these zones and shutdown appropriately. NMFS, therefore, does not expect and does authorize Level A harassment due to vibratory pile driving for any species. As discussed in the *Acoustic Impacts* section, due to the characteristics of noise produced by AHTs (*e.g.*, low-intensity source levels relative to impact pile driving, and transitory nature of occurrence of marine mammal species in this area), auditory injury is not a likely outcome of this activity. Therefore, NMFS does not expect, and does not authorize, take by Level A harassment due to AHTs engaging in anchor handling.

To estimate take by Level A harassment from impact pile driving, 8 Star Alaska multiplied the area (km²) estimated to be ensonified above the Level A harassment thresholds (table 8) for each impact pile driving activity by the duration (days) of that activity by the calculated density for each species (number of animals/km²). Due to the infrequency of occurrence of fin whales, Pacific white-sided dolphins, California sea lions, and Steller sea lions in middle Cook Inlet, NMFS does not expect these species to enter Level A harassment zones for sufficient duration to incur injury, and is not authorizing take by Level A harassment of these species.

When attributing take to respective humpback whale stocks for each year, NMFS assumed that 89 percent of calculated take would be from the Hawai'i stock, 10.7 percent would be from the Mexico-North Pacific stock, and 0.3 percent would be from the Western North Pacific stock, as described in Wade (2021) (see table 14). Although the number calculated for the Western North Pacific stock is less than 0.5 animals, NMFS is conservatively attributing one take by Level B harassment to the Western North Pacific stock of the humpback whale.

For species for which take by Level A harassment is anticipated, those estimated takes by Level A harassment were subtracted from the estimated takes by Level B harassment to avoid double-counting the same exposures as both Level A and Level B harassment. Adjustments are reflected in table 14.

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Table 13 -- Estimated Take by Level A Harassment by Species, Pile Size and Type, and Installation/Removal Method*

Structure	Activity	Days	Gray whale	Fin whale	Hump back whale	Minke whale	Killer whale	Pacific white-sided dolphin	Beluga whale	Dall's porpoise	Harbor porpoise	California sea lion	Steller sea lion	Harbor seal
Year 2														
Marine Terminal MOF RoRo Dolphin Quads	48-inch Steel Pipe Pile (Impact)	7	0	N/A	0.03	0	0	N/A	0	0.01	0.17	N/A	N/A	3.97
	24-inch Steel Pipe Pile (Impact)	7	0	N/A	0.02	0	0	N/A	0	0	0.1	N/A	N/A	2.32
Mainline MOF	Sheet Pile (Impact)	7	0	N/A	0.75	0	0	N/A	0.02	0.14	3.68	N/A	N/A	85.35
Total Calculated Year 2		83	0	N/A	0.79	0.01	0	N/A	0	0.15	3.95	N/A	N/A	91.64
Total Estimated Take by Level A Harassment Year 2			0	0	1	0	0	0	0	0	4	0	0	92
Year 3														
PLF E-W Trestle	60-inch Steel Pipe Pile (Impact)	42	0.05	N/A	1.42	0.02	0.01	N/A	0	0.26	6.97	N/A	N/A	162.23
PLF Berths	48-inch Steel Pipe Pile (Impact)	16	0.00	N/A	0.08	0.00	0.00	N/A	0	0.01	0.39	N/A	N/A	9.07

PLF N-S Trestle	48-inch Steel Pipe Pile (Impact)	16	0.00	N/A	0.08	0.00	0.00	N/A	0.2	0.01	0.39	N/A	N/A	9.07
Total Calculated Year 3		75	0.06	N/A	1.58	0.02	0.01	N/A	0	0.28	7.75	N/A	N/A	180.37
Total Estimated Take by Level A Harassment Year 3			0	0	2	0	0	0	0	0	8	0	0	180
Year 4														
PLF E- W Trestle	60-inch Steel Pipe Pile (Impact)	14	0.02	N/A	0.47	0.01	0.00	N/A	0	0.09	2.32	N/A	N/A	54.08
PLF Operatio ns Platform	60-inch Steel Pipe Pile (Impact)	6	0.01	N/A	0.20	0.00	0.00	N/A	0	0.04	1.00	N/A	N/A	23.18
PLF Breasting dolphin berths	48-inch Steel Pipe Pile (Impact)	4	0.00	N/A	0.02	0.00	0.00	N/A	0	0.00	0.10	N/A	N/A	2.27
	60-inch Steel Pipe Pile (Impact)	12	0.02	N/A	0.41	0.01	0.00	N/A	0	0.07	1.99	N/A	N/A	46.35
PLF Mooring dolphin	48-inch Steel Pipe Pile (Impact)	2	0.00	N/A	0.01	0.00	0.00	N/A	0	0.00	0.05	N/A	N/A	1.13
	60-inch Steel	2	0.00	N/A	0.07	0.00	0.00	N/A	0	0.01	0.33	N/A	N/A	7.73

Table 14 -- Authorized Level A Harassment and Level B Harassment Takes of Marine Mammals Incidental to All Activities Over the Course of 8 Star Alaska's 5-Year Project

Marine Mammal species	Stock	Year 1		Year 2		Year 3		Year 4		Year 5		Five Year Total	
		Level A	Level B	Level A	Level B	Level A	Level B	Level A	Level B	Level A	Level B	Level A	Level B
Gray whale	Eastern North Pacific	0	3	0	3	0	3	0	3	0	3	0	15
Fin whale	Northeast Pacific	0	2	0	2	0	2	0	2	0	2	0	10
Humpback whale	Hawai'i	0	56	1	11	2	1	1	4	1	2	5	74
	Mexico-North Pacific	0	6	0	1	0	0	0	1	0	0	0	8
	Western North Pacific	0	1	0	0	0	0	0	0	0	0	0	1
Minke whale	Alaska	0	3	0	3	0	3	0	3	0	3	0	15
Killer whale	Eastern North Pacific Alaska Resident	0	21	0	10	0	10	0	10	0	10	0	61
	Eastern North Pacific Gulf of Alaska, Aleutian Islands, and Bering Sea Transient												
Pacific white-sided dolphin	North Pacific	0	3	0	3	0	3	0	3	0	3	0	15
Beluga whale	Cook Inlet	0	11	0	11	0	11	0	30	0	11	0	74
Dall's	Alaska	0	6	0	6	0	6	0	6	0	6	0	30

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summed with the maximum number of Level B harassment takes in any one year for each species to yield the highest number of estimated take that could

occur in any year (table 15) for each stock. Table 15 also depicts the number of authorized takes relative to the abundance of each stock. We note here that, as a result of the source level changes for impact installation of 48-

inch steel pipe piles (see Changes From the Proposed Rule section) and resultant changes to harassment isopleths, the maximum annual Level A takes of harbor seals changed from 176 in the proposed rule to 180 in this final rule.

This resulted in an increase of the total maximum annual take of harbor seals from 9,181 in the proposed rule to 9,185 in this final rule (see table 15).

TABLE 15—MAXIMUM ANNUAL TAKE AUTHORIZED AND AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock	NMFS stock abundance	Maximum annual Level A harassment	Maximum annual Level B harassment	Maximum annual take	Maximum annual take as a percentage of stock abundance
Gray whale	Eastern North Pacific	26,960	0	3	3	0.01
Fin whale	Northeast Pacific	UND	0	2	2	* N/A
Humpback whale	Hawai'i	11,278	2	56	58	0.58
	Mexico-North Pacific	N/A	0	6	6	* N/A
	Western North Pacific	1,084	0	1	1	0.09
Minke whale	Alaska	N/A	0	3	3	* N/A
Killer whale	Eastern North Pacific Alaska Resident	1,920	0	21	21	1.09
	Eastern North Pacific Gulf of Alaska, Aleutian Islands, and Bering Sea Transient	587				3.58
Pacific white-sided dolphin	North Pacific	26,880	0	3	3	0.01
Beluga whale	Cook Inlet	331	0	30	30	9.06
Dall's porpoise	Alaska	UND	0	6	6	* N/A
Harbor porpoise	Gulf of Alaska	31,046	8	128	136	0.44
California sea lion	U.S	257,606	0	2	2	<0.01
Steller sea lion	Western	49,837	0	9	9	0.02
Harbor seal	Cook Inlet/Shelikof Strait	28,411	180	9,005	9,185	32.32

* See small numbers discussion below for additional information.

Mitigation

In order to promulgate a rulemaking under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity and other means of effecting the least practicable adverse impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses. NMFS regulations require applicants for ITAs to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or

stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), and the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost and impact on operations.

The mitigation requirements described below were proposed by 8 Star Alaska in its adequate and complete application or are the result of subsequent coordination between NMFS and 8 Star Alaska. 8 Star Alaska has agreed that all of the mitigation measures are practicable. NMFS has fully reviewed the specified activities and the mitigation measures to determine if the mitigation measures will result in the least practicable adverse impact on marine mammals and their habitat, as required by the MMPA, and has determined the measures are appropriate. NMFS describes these mitigation requirements below and has included them in the regulations.

Shutdown and Clearance Zones

8 Star Alaska will establish shutdown zones for all pile driving and removal activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity will occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones vary based on the activity type and marine mammal hearing group (see table 16). A minimum shutdown zone of 10 m will be required for all in-water construction activities to avoid physical interaction with marine mammals. Activity-specific shutdown zones are based upon the estimated Level A harassment zones and distances at which 8 Star Alaska expects PSOs will be able to observe the relevant species, with the exception of CIBW.

For CIBWs, 8 Star Alaska will shut down at the estimated Level B harassment isopleth, except when that isopleth is farther than the PSOs can observe. 8 Star Alaska expects that PSOs could observe beluga whales up to 2–3 km under typical conditions. When shutdown zones are larger than the distance that PSOs will be able to observe, 8 Star Alaska is expected to shut down if a beluga whale was observed at any distance.

TABLE 16—SHUTDOWN ZONES FOR PILE DRIVING
[m]

Activity	LF	Non-beluga HF	Beluga whales ¹	VHF	Phocid	Otariids
Impact Pile Driving						
Sheet Pile at Mainline MOF	2,000	400	1,000	400	400	400
24-inch Pipe Pile at Marine Terminal MOF	1,000	130	1,000	400	400	350
48-inch Pipe Pile at PLF and Marine Terminal MOF ²	1,300	170	2,160	400	400	400
60-inch Steel Pipe Pile at PLF	2,000	400	2,160	400	400	400
Vibratory Pile Driving						
Sheet Pile at Mainline MOF and Marine Terminal MOF	30	20	4,642	30	40	20
24-inch Steel Pipe Pile at Marine Terminal MOF	20	10	7,356	20	30	10
66-inch Steel Pipe Pile at Marine Terminal MOF	60	30	21,544	50	70	30
66-inch Steel Pipe Pile × 2 at Marine Terminal MOF	90	40	34,146	70	110	40
66-inch Steel Pipe Pile with Sheet Pile at Marine Terminal MOF	150	60	21,544	120	190	70
Sheet Pile × 2 at Marine Terminal MOF	50	20	7,356	40	60	20
24-inch Steel Pipe Pile with Sheet Pile at Marine Terminal MOF	40	20	11,659	30	50	20
24-inch Steel Pipe Pile × 2 at Marine Terminal MOF	70	30	10,000	60	90	30

¹ When the shutdown zones for beluga whales are larger than what PSOs can observe, pile driving must be shut down when beluga whales are visible within any distance.

² Shutdown zones for LF, non-beluga HF, and beluga whales have changed for impact installation of the 48-inch pipe pile from the proposed rule to this final rule due to changes in Level A and Level B harassment zones (see table 7).

Pile driving will be halted upon observation of a marine mammal entering or within the shutdown zone. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily left and has been visually confirmed beyond the shutdown zone for 30 minutes (large whales and beluga whales) or 15 minutes (pinnipeds and other cetaceans) without re-detection of the animal within the shutdown zone. If work ceases for more than 30 minutes, the shutdown zones must be cleared again for 30 minutes prior to reinitiating pile driving. A determination that the pile driving shutdown zone is clear must be made during a period of good visibility.

If a PSO(s) can no longer effectively monitor the entirety of the corresponding shutdown zone during impact pile driving, or at least 2 km during vibratory pile driving, due to environmental conditions (e.g., fog, rain, wind), pile driving could continue only until the current segment of the pile is driven; no additional sections of pile or

additional piles could be driven until conditions improve such that zone could be effectively monitored. If the shutdown zone cannot be monitored for more than 15 minutes, the entire zone will be cleared again for 30 minutes prior to reinitiating pile driving.

If a species for which authorization has not been granted or a species for which authorization has been granted but the authorized takes have been reached is observed approaching, entering, or within the corresponding zone, in-water work will be delayed (if during pre-clearance) or shut down (except for AHTs engaged in anchor handling). Activities will not resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown or clearance zone indicated in tables 16 and 17 for 30 minutes (for large whales and beluga whales) or 15 minutes (for pinnipeds and other cetaceans) without re-detection of the animal within the shutdown zone.

If a shutdown procedure should be initiated but human safety is at risk, as determined by the best professional

judgment of the vessel operator or project engineer, the in-water activity, including pile driving, will be allowed to continue until the risk to human safety has dissipated. In this scenario, pile driving could continue only until the current segment of the pile is driven; no additional sections of pile or additional piles could be driven until the Lead PSO has determined that the shutdown zones are clear of marine mammals and for CIBW, any observed whale(s) is at least 100 m past the shutdown zone and on a path away from the zone.

AHTs cannot shut down once they have begun positioning anchors. Prior to anchor handling, 8 Star Alaska will implement a clearance zone of 1,500 m around AHTs for all marine mammals other than CIBWs. The clearance zone for beluga whales is equal to the Level B harassment isopleth (3,850 m). This distance is likely farther than what PSOs could reliably monitor. If visibility is less than the Level B harassment isopleth, PSOs are expected to clear the zone around AHTs at the distance visible to PSOs.

TABLE 17—CLEARANCE ZONES FOR AHTs
[m]

Activity	Non-beluga species	Beluga whales*
Anchor handling	1,500	3,850

* When the clearance zone is larger than what PSOs can observe, PSOs will clear the observable zone.

Pre- and Post-Activity Monitoring

Monitoring will take place from 30 minutes prior to initiation of pile driving and anchor handling activities (*i.e.*, pre-clearance monitoring) through 30 minutes post-completion of pile driving and anchor handling. Prior to the start of daily in-water construction activity, or whenever a break in pile driving or anchor handling of 30 minutes or longer occurs, PSOs will observe the clearance zones (anchor handling) or shutdown zones (pile driving) for a period of 30 minutes. If a marine mammal is observed within the shutdown zone or clearance zone, pile driving, including a soft-start (described below), and anchor handling will not proceed until the animal has left the zone or has not been observed for 30 minutes (large whales and beluga whales) or 15 minutes (pinnipeds and other cetaceans). Pre-start clearance monitoring will be conducted during periods of visibility sufficient for the PSO(s) to observe the entirety of the shutdown zone for impact pile driving and at least 2 km for vibratory pile driving and anchor handling, except in cases where tugging operations occur during nighttime hours. In these circumstances, 8 Star Alaska will clear the clearance zones to the maximum extent possible.

Monitoring for Level A and Level B Harassment

8 Star Alaska will monitor for marine mammals in the Level B harassment and Level A harassment zones to the extent practicable and throughout the area as far as visual monitoring can occur. Monitoring enables observers to be aware of and communicate the presence of marine mammals in the project area outside the shutdown zone. Due to some of the large Level A and Level B harassment zones (table 7 and table 9), PSOs will not be able to effectively observe the entire zones during all activities for all species. All marine mammals observed within the visible portion of the harassment zones will be recorded. 8 Star Alaska will also conduct acoustic monitoring as

described in the Monitoring and Reporting section below.

Soft Start

Soft start procedures provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors will be required to provide an initial set of three strikes from the hammer at reduced energy, followed by a 30-second waiting period, then two subsequent three-strike sets before initiating continuous driving. Soft start will be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

Vessel Transit

Operators of vessels will avoid approaching marine mammals within 100 yards (92 m). The vessel operator will avoid placing the vessel in the path of a whale and will not cut in front of the whale in a way or at a distance that causes the whale to change direction of travel or behavior (including breathing/surface pattern). If a whale's course and speed are such that it will likely cross in front of a vessel that is underway, or approach within 100 yards (92 m) of the vessel, and if maritime conditions safely allow, the engine will be put in neutral and the whale will be allowed to pass beyond the vessel. Vessel operators will reduce speed to 10 knots (18.5 km/hour) or less when weather conditions reduce visibility to 1.6 km (1 mile) or less. When within 300 yards (274 m) of a whale, vessels will travel at less than 5 knots (9.3 km/hour), and vessel operators should avoid changes in direction and speed within 300 yards (274 m) of a whale, unless doing so is necessary for maritime safety.

For vessels operating in the Susitna Delta Exclusion Zone (see figure 1), the following will be implemented:

- All project vessels operating within the designated Susitna Delta area will maintain a speed above ground below 4 knots. PSOs will note the numbers, date, time, coordinates, and proximity to

vessels of all belugas observed during operations and report these observations to NMFS in monthly reports.

- Vessel crew will be trained to monitor for ESA-listed species prior to and during all vessel movement within the Susitna Delta Exclusion Zone. The vessel crew will report sightings to the PSO team for inclusion in the overall sighting database and reports.
- Vessel operators will not move their vessels when they are unable to adequately observe the 100-m zone around vessels under power (in gear) due to darkness, fog, or other conditions, unless necessary for ensuring human safety.

The Susitna Delta Exclusion Zone (see figure 1) is defined as the union of the areas defined by:

- (i) A 16-km (10-mile) buffer of the Beluga River thalweg seaward of the MLLW line;
- (ii) A 16-km (10-mile) buffer of the Little Susitna River thalweg seaward of the MLLW line; and
- (iii) A 16-km (10-mile) seaward buffer of the MLLW line between the Beluga River and Little Susitna River.
- (iv) The buffer extends landward along the thalweg to include intertidal waters within rivers and streams up to their mean higher high water (MHHW) line. The seaward boundary has been simplified so that it is defined by lines connecting readily discernable landmarks.

Time/Area Restriction

Pile driving associated with the Mainline MOF will not occur from June 1 to September 7.

Between April 15 and October 15, 8 Star Alaska will not conduct pile driving or AHT activities with Level B harassment isopleths that would extend shoreward of the MLLW line in the Susitna Delta (Beluga River to the Little Susitna River; see figure 1) and project vessel(s) operating in or transiting through Cook Inlet will maintain a distance of at least 1.5 nautical miles (2.8 km) seaward of the MLLW line in the Susitna Delta (Beluga River to the Little Susitna River).

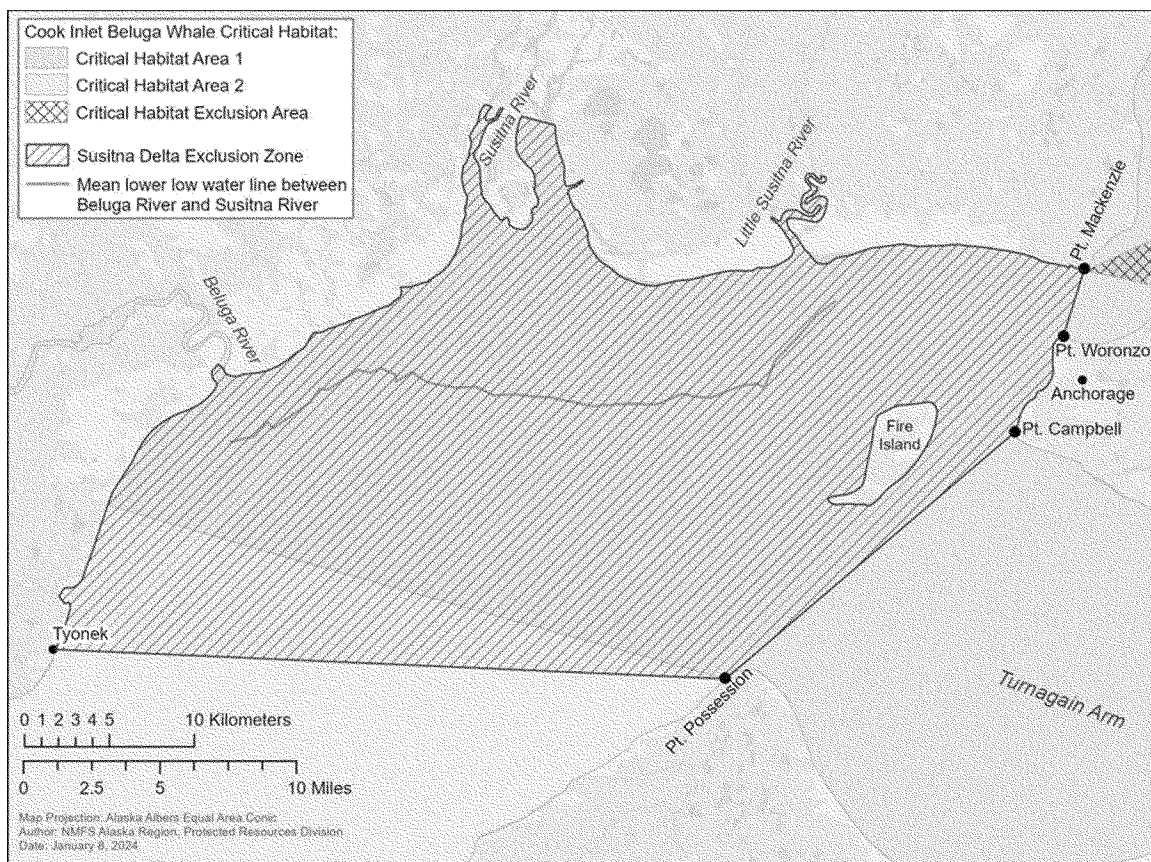


Figure 1—Susitna Delta Exclusion Zone, Showing MLLW Line Between the Beluga and Little Susitna Rivers

Noise Attenuation

8 Star Alaska will use a noise attenuation device, such as a bubble curtain, and test it for effectiveness through SSV (see Monitoring section below) at the beginning of pile driving. If the results show at least a 2 dB source reduction is achieved, 8 Star Alaska will employ the use of noise attenuation, such as bubble curtains, throughout construction. Once the contractor is selected, 8 Star Alaska will work with the contractor and NMFS to identify the appropriate type of noise attenuation system for the specific hammer and equipment.

NMFS conducted an independent evaluation of the mitigation measures and has determined that the mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses.

Monitoring and Reporting

In order to issue an LOA for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS for this project contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (e.g., presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or

environment (e.g., source characterization, propagation, ambient noise); (2) affected species (e.g., life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (e.g., age, calving or feeding areas);

- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;

- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;

- Effects on marine mammal habitat (e.g., marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and

- Mitigation and monitoring effectiveness.

The monitoring and reporting requirements described in the following were proposed by 8 Star Alaska in its adequate and complete application or are the result of subsequent coordination between NMFS and 8 Star Alaska following receipt of the application. 8 Star Alaska has agreed

that all of the mitigation measures are appropriate. NMFS describes these requirements below and has included them in the regulations.

Visual Monitoring

Marine mammal monitoring will be conducted in accordance with 8 Star Alaska's NMFS-approved Marine Mammal Monitoring and Mitigation Plan, dated April 4, 2025, and included as Appendix A in its application.

Marine mammal monitoring during pile driving and removal will be conducted by NMFS-approved PSOs in a manner consistent with the following:

- PSOs must be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods.
- At least one PSO must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization or Letter of Concurrence.
- Other PSOs may substitute other relevant experience, education (degree in biological science or related field), or training for prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization. PSOs may also substitute Alaska native traditional knowledge for experience (NMFS recognizes that PSOs with traditional knowledge may also have prior experience and be eligible to serve as the lead PSO).
- Where a team of three or more PSOs is required, a lead observer or monitoring coordinator must be designated. The lead observer must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization.

- PSOs must be approved by NMFS prior to beginning any activity subject to this rule.

PSOs should have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field of identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction

activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and

- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

For all pile driving activities, a minimum of two PSOs will be on duty at all times. In general, PSOs will be stationed on a stable land-based platform with sufficient height, such as bluffs, to provide excellent viewing conditions for marine mammals, although detection varies by species and is affected by weather conditions. For anchor handling, two PSOs will be on the barge, and one PSO will always be on duty.

PSOs will not exceed 4 consecutive watch hours, will have at least a 2-hour break between watches, and will not exceed a watch schedule of more than 12 hours per 24-hour period. PSOs will have no other construction-related tasks while conducting monitoring. Monitoring will be conducted from 30 minutes prior to activity (pile driving or anchor handling), throughout the time of the activity (pile driving or anchor handling), and for 30 minutes following the conclusion of the activity (pile driving or anchor handling). PSOs will monitor using the naked eye, standard (7x) binoculars, and high-magnification (25x) binoculars. Monitoring distances will be measured with range finders, and distances to animals must be based on the best estimate of the PSO, relative to known distances to objects in the vicinity of the PSO.

Acoustic Monitoring

8 Star Alaska will conduct SSV in accordance with accepted methodology as described in the Sound Source Verification Plan, which 8 Star Alaska will develop after its contractor is selected. NMFS will review and approve the plan prior to implementation. 8 Star Alaska will conduct SSV at the beginning of pile driving to characterize the sound levels associated with different pile and hammer types and assess attenuation devices, such as bubble curtains. The SSV will be conducted in accordance with the following conditions:

- 8 Star Alaska must measure a minimum of two piles of each type and size.
- The following data, at minimum, shall be collected during acoustic monitoring and reported: (1) hydrophone equipment and methods: recording device, sampling rate,

distance (m) from the pile where recordings were made; depth of water and recording device(s); (2) type and size of pile being driven, substrate type, method of driving during recordings (e.g., hammer model and energy), and total pile driving duration; (3) whether a sound attenuation device is used and, if so, a detailed description of the device used and the duration of its use per pile; (4) for impact pile driving (per pile): number of strikes and strike rate; depth of substrate to penetrate; pulse duration and mean, median, and maximum sound levels (dB re: 1 μ Pa): root mean square sound pressure level (SPL_{rms}); cumulative sound exposure level (SEL_{cum}), peak sound pressure level (SPL_{peak}), and single-strike sound exposure level (SEL_{s-s}); (5) for vibratory driving/removal (per pile): duration of driving per pile; mean, median, and maximum sound levels (dB re: 1 μ Pa): root mean square sound pressure level (SPL_{rms}), cumulative sound exposure level (SEL_{cum}) (and timeframe over which the sound is averaged).

An SSV report will be submitted to NMFS for approval within 5 days after finalization of field measurements and report data. If appropriate, the results of the SSV report could be used to adjust the extent of the Level A and Level B harassment zones for in-water pile driving.

Reporting

8 Star Alaska will submit interim monthly reports for all months in which pile driving or anchor handling occurs. Monthly reports will be due 14 days after the conclusion of each calendar month, and must include a summary of marine mammal species and behavioral observations, delays, and activities completed. They will also include an assessment of the amount of work (pile driving and anchor handling) remaining to be completed, in addition to the number of CIBWs observed within estimated harassment zones to date.

8 Star Alaska will submit draft annual reports to NMFS within 90 calendar days of the completion of construction (pile driving, anchor handling) each year. Each report will include an overall description of all work completed, a narrative regarding marine mammal sightings, and associated marine mammal observation data sheets (data must be submitted electronically in a format that can be queried such as a spreadsheet or database). Specifically, the report will include the following information:

- Date and time that monitored activity begins or ends;
- Activities occurring during each observation period, including (a) the

type of activity; (b) the total duration of each type of activity; (c) when nighttime operations were required; (d) the number and type of piles that were driven and the method (*e.g.*, impact, vibratory), and (e) total duration of driving time for each pile (vibratory driving) and total number of strikes for each pile (impact driving);

- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at the beginning and end of the PSO shift and whenever conditions change significantly), including Beaufort sea state, tidal state, and any other relevant weather conditions, including cloud cover, fog, sun glare, overall visibility to the horizon, and estimated observable distance;

- Upon observation of a marine mammal, (a) name of PSO who sighted the animal(s) and PSO location and activity at time of sighting, (b) time of sighting, (c) identification of the animal(s) (*e.g.*, genus/species, lowest possible taxonomic level, or unidentified), (d) PSO confidence in identification and the composition of the group if there is a mix of species, (e) distance and location of each observed marine mammal relative to the AHTs or pile being driven for each sighting, (f) estimated number of animals (min/max/best estimate), (g) estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*), (h) animal's closest point of approach and estimated time spent within the harassment zone, and (i) description of any marine mammal behavioral observations (*e.g.*, observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.*, no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);

- Number of marine mammals detected within the harassment zones, by species; and

- Detailed information about implementation of any mitigation (*e.g.*, shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days of receipt of the draft report, the report will be considered final. If comments are received, 8 Star Alaska will submit a final report addressing NMFS' comments within 30 days following receipt of any NMFS comments on the draft reports.

In the event that personnel involved in 8 Star Alaska's activities discover an injured or dead marine mammal, 8 Star Alaska will report the incident to the Office of Protected Resources, NMFS, and to the Alaska Regional Stranding Coordinator as soon as feasible. If the death or injury was clearly caused by the specified activity, 8 Star Alaska will immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the incidental take authorization. 8 Star Alaska will not resume their activities until notified by NMFS. The report will include the following information:

- Time, date, and location (latitude and longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact 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 (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29,

1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the majority of our analysis applies to all species listed in table 1, except for CIBWs, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. For CIBWs, there are meaningful differences in anticipated responses to activities, impact of expected take on the population, or impacts on habitat; therefore, we provide a separate independent detailed analysis for CIBWs following the analysis for other species for which we are authorizing take.

Marine Mammals Except CIBWs

NMFS has identified several key factors to assess whether potential impacts associated with a specified activity should be considered negligible. These include (but are not limited to) the type and magnitude of taking, the amount and importance of the available habitat for the species or stock that is affected, the duration of the anticipated effect on the individuals, and the status of the species or stock. The potential effects of the specified activity on humpback whales, minke whales, gray whales, fin whales, killer whales, Dall's porpoises, harbor porpoises, Pacific white-sided dolphins, Steller sea lions, harbor seals, and California sea lions are discussed below. These factors also apply to CIBWs; however, additional analysis for CIBWs is provided in a separate sub-section below.

8 Star Alaska's specified activities have the potential to disturb or displace marine mammals, and the number of takes authorized for 8 Star Alaska's activities have been identified above in the Estimated Take of Marine Mammals section. Takes are anticipated to occur when marine mammals are present in zones ensonified above the thresholds for Level B harassment, identified above, while activities are underway. Additionally, for impact pile driving activities, potential takes by Level A harassment could occur if marine mammals are present in zones ensonified above relevant threshold criteria for sufficient periods of time to incur auditory injury. 8 Star Alaska's activities and associated impacts will occur within a limited, confined area of the affected species or stocks' range. Pile driving is planned to occur over a total

of 324 total days over the course of 5 years, ranging from 36 days to 83 days in a single year. The use of AHTs for anchor handling will occur for only 2 days in year 3 and 53 days in year 4. The intensity and duration of take by Level A and Level B harassment will be minimized through use of mitigation measures described herein. NMFS does not anticipate that Level A harassment will occur other than in association with impact pile driving, or that serious injury or mortality will occur, as a result of 8 Star Alaska's planned activity given the nature of the activity, even in the absence of required mitigation.

Exposure to elevated sound levels produced during AHTs engaged in anchor handling and pile driving activities has the potential to cause behavioral disturbance of some individuals within the vicinity of the sound source. Behavioral responses of marine mammals to 8 Star Alaska's AHTs engaged in anchor handling activities are expected to be mild, short term, and temporary. Effects on individuals that are taken by Level B harassment, as enumerated in the Estimated Take of Marine Mammals section, on the basis of reports in the literature as well as monitoring from other similar activities (Horsley and Larson, 2023, 2024), would likely be limited to behavioral response such as increased swimming speeds, changes in directions of travel and diving and surfacing behaviors, increased respiration rates, or interrupted foraging (if such activity were occurring) (Ridgway *et al.*, 1997; Nowacek *et al.*, 2007; Thorson and Reyff, 2006; Kendall and Cornick, 2015; Goldbogen *et al.*, 2013; Blair *et al.*, 2016; Wisniewska *et al.*, 2018; Piwetz *et al.*, 2021). Marine mammals within the Level B harassment zones may not present any visual cues if they are disturbed by activities. Alternatively, they may become alert, avoid the area, leave the area, or have other mild responses that are not observable such as increased stress levels (*e.g.*, Rolland *et al.*, 2012; Bejder *et al.*, 2006; Rako *et al.*, 2013; Pirotta *et al.*, 2015; Pérez-Jorge *et al.*, 2016). They may also exhibit increased vocalization rates (Dahlheim, 1987; Dahlheim and Castellote, 2016), louder vocalizations (Frankel and Gabriele, 2017; Fournet *et al.*, 2018), alterations in the spectral features of vocalizations (Castellote *et al.*, 2012), or a cessation of communication signals (Tsuji *et al.*, 2018). However, Hilcorp's monitoring results from tugging activities have shown little to no observable reactions in marine mammals that have frequented an area similar to where 8

Star Alaska's activities will take place (Horsley and Larson, 2023).

AHTs engaged in anchor handling are slow-moving as compared to typical recreational and commercial vessel traffic. Assuming an animal was stationary, exposure to sound above the Level B harassment threshold from the moving AHT configuration would be on the order of minutes in any particular location. The slow, predictable, and generally straight path of this activity is expected to further lower the likelihood of more than low-level responses to the sound. Also, this slow transit along a predictable path is planned in an area of routine vessel traffic where many large vessels move in slow straight-line paths, and some individuals are expected to be habituated to these sorts of sounds. While it is possible that animals may swim around the project area, avoiding closer approaches to the vessels, we do not expect them to abandon any intended path. Further, most animals present in the region would likely be transiting through the area; therefore, any potential exposure is expected to be brief. Based on the characteristics of the sound source and the other activities regularly encountered in the area, it is unlikely 8 Star Alaska's planned anchor handling activities would be of a duration or intensity expected to result in significant behavioral responses that may be more likely to result in impacts on reproduction or survival.

Effects on individuals that are taken during pile driving, on the basis of reports in the literature as well as monitoring from other similar activities, would likely be limited to reactions such as increased swimming speeds, increased surfacing time, or interrupted foraging (if such activity were occurring; *e.g.*, Thorson and Reyff, 2006; HDR Inc., 2012; Lerma, 2014; ABR, 2016; 61 North Environmental, 2021, 2022a, 2022b, 2022c, 2025). Most likely, individuals would simply move away from the sound source and be temporarily displaced from the areas of pile driving (Degraer *et al.*, 2022). If sound produced by project activities is sufficiently disturbing, animals would be likely to simply avoid the area while the activity is occurring.

Further, most of the species present in the region would only be present temporarily based on seasonal patterns or during transit between other habitats. These temporarily present species would be exposed to even shorter periods of noise-generating activity, further decreasing the impacts. Most likely, individual animals would simply move away from the sound source and be temporarily displaced from the area.

Takes also have the potential to occur during important feeding times. However, the project area represents a small portion of available foraging habitat and impacts on marine mammal feeding for all species should be minimal.

We anticipate that any potential reactions and behavioral changes would subside quickly when the exposures cease, and, therefore, we do not expect long-term adverse consequences from 8 Star Alaska's activities for individuals of any species. The intensity of harassment events will be minimized through use of mitigation measures described herein, which were not quantitatively factored into the take estimates. 8 Star Alaska will use PSOs to monitor for marine mammals before commencing any of the specified activities, which will minimize the potential for marine mammals to be present within the estimated Level A and Level B harassment areas, further reducing the likely amount of any potential Level A or Level B harassment. Further, given the absence of any major rookeries or areas of known biological significance for marine mammals (*e.g.*, foraging hot spots) within the estimated harassment zones (other than critical habitat and a BIA for CIBWs as described below), we predict that potential takes by Level B harassment would have an inconsequential short-term effect on individuals and would not result in population-level impacts.

In addition to evaluating the anticipated impacts of the single instances of takes, it is important to understand the degree to which individual marine mammals may be disturbed repeatedly across multiple days of the year. In this case, given the number of takes by harassment as compared to the number of harbor seals anticipated to occur in the project area, it is likely that some portion of the individuals taken are taken repeatedly over a limited number of days. However, it is unlikely that repeated takes would occur either in numbers or clumped across sequential days in a manner likely to impact foraging success and energetics or other behaviors such that reproduction or survival of any individuals is likely to be impacted.

Theoretically, repeated, sequential exposure to elevated noise from vibratory and impact pile driving and noise from AHTs over a long duration could result in more severe impacts to individuals that could affect individual fitness or reproductive success (via sustained or repeated disruption of important behaviors such as feeding, resting, traveling, and socializing;

Southall *et al.*, 2007). Alternatively, marine mammals exposed to repetitious sounds may become habituated, desensitized, or tolerant after initial exposure to these sounds (reviewed by Richardson *et al.*, 1995; Southall *et al.*, 2007). Cook Inlet is a regional hub of marine transportation and is used by various classes of vessels, including container ships, bulk cargo freighters, tankers, commercial and sport-fishing vessels, and recreational vessels. Off-shore vessels, tug vessels, and tour boats represent 86 percent of the total operating days for vessels in Cook Inlet (Bureau of Ocean Energy Management, 2016). Given that marine mammals still frequent and use Cook Inlet despite being exposed to anthropogenic sounds such as those produced by pile driving, tug boats and other vessels across many years, and that it is unlikely that any individual will be exposed to repeated, sequential exposures or repetitious sounds from 8 Star Alaska's activities, no impacts to the reproduction or survival of any marine mammal individuals from the additional noise produced by the specified activities are anticipated.

NMFS anticipates take by Level A harassment of three species due to the potential that an animal could enter and remain within the area between a Level A harassment zone and shutdown zone during impact pile driving for a duration long enough to be taken by Level A harassment. Any take by Level A harassment is expected to arise from, at most, a small degree of AUD INJ, because animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of AUD INJ. Additionally, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. Because of the small degree anticipated, though, any permanent threshold shift (PTS) or TTS potentially incurred here is not expected to adversely impact individual fitness, let alone annual rates of recruitment or survival.

Impacts to marine mammal prey species are also expected to be minor and temporary and to have, at most, short-term effects on foraging of individual marine mammals and likely no effect on the populations of marine mammals as a whole. Overall, as described above, the area anticipated to be impacted by 8 Star Alaska's planned activities is very small compared to the available surrounding habitat and does not include habitat of particular importance to marine mammals. The most likely impact to prey would be

temporary behavioral avoidance of the immediate area. While AHTs are engaged in anchor handling and pile driving activities, it is expected that some fish would temporarily leave the area of disturbance (e.g., Nakken, 1992; Olsen, 1979; Ona and Godo, 1990; Ona and Toresen, 1988), thus impacting marine mammals' foraging opportunities in a limited portion of their foraging range. But, because of the relatively small area of the habitat that may be affected and lack of any foraging habitat of particular importance, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. Additionally, the habitat within the estimated acoustic footprint is not known to be heavily used by marine mammals.

Finally, 8 Star Alaska will minimize potential exposure of marine mammals to elevated noise levels by implementing mitigation measures for AHTs engaged in anchor handling and pile driving activities. For anchor handling activities conducted by AHTs, 8 Star Alaska will delay anchor handling activities if marine mammals are observed in the clearance zones during the pre-clearance monitoring period. For pile driving, 8 Star Alaska will delay the start of pile driving activities if marine mammals are observed during the pre-clearance monitoring period and will implement hearing group-specific shutdown zones during the activities if marine mammals are observed. 8 Star Alaska will implement soft-start procedures to provide warning and/or give marine mammals a chance to leave the area prior to the hammer operating at full capacity. If SSV shows that bubble curtains are effective to result in at least a 2 dB reduction in sound during pile driving, bubble curtains will be implemented.

In summary and as described above, the following factors (with additional analyses for CIBWs included below) primarily support our determination that the impacts resulting from 8 Star Alaska's activities are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- Take by Level A harassment is authorized for only three species, and the Level A harassment is expected to be of a lower degree that would not impact the fitness of any animals;
- The intensity of anticipated takes by Level B harassment is low for all stocks consisting of, at worst, temporary modifications in behavior, and would

not be of a duration or intensity expected to result in impacts on reproduction or survival;

- Take will not occur in places and/or times where take is more likely to impact reproduction or survival, such as within ESA-designated or proposed critical habitat or BIAs (other than for CIBWs as described below) or other habitats critical to recruitment or survival (e.g., rookery);

- The project area represents a very small portion of the available foraging area for all potentially impacted marine mammal species;

- Take will occur only within middle Cook Inlet, a limited, confined area of any given stock's home range;

- Monitoring reports from previous projects with pile driving and/or tugging activities in Cook Inlet have documented little to no observable effect on individuals of the same species impacted by the specified activities; and

- The required mitigation measures are expected to be effective in reducing the effects of the specified activity by minimizing the numbers of marine mammals exposed to sound and the intensity of the exposures.

Cook Inlet Beluga Whales

For CIBWs, we further discuss our negligible impact findings in addition to the findings discussed above for all species in the context of potential impacts to the endangered stock based on our evaluation of the authorized take (table 14).

All of 8 Star Alaska's activities will be conducted in a manner implementing best management practices to preserve water quality, and no work will occur around creek mouths or river systems leading to prey abundance reductions. In addition, no physical structures will restrict passage, though impacts to the acoustic habitat are relevant and discussed here. While the Recovery Plan for the Cook Inlet Beluga Whale (NMFS, 2016) considers noise to be of high relative concern for the CIBW and the specified activities will occur within CIBW Critical Habitat Area 2 and the CIBW small and resident BIA (see the Description of Marine Mammals in the Area of Specified Activities section in the notice of the proposed rule (90 FR 35762, July 29, 2025)), monitoring data from similar regional activities suggest that the presence of tugs under load does not discourage CIBWs from transiting throughout Cook Inlet and between critical habitat areas and that the whales do not abandon critical habitat areas (e.g., Horsley and Larson, 2023, 2024). In addition, large numbers of CIBWs have continued to use Cook Inlet and pass through the area, likely

traveling to critical foraging grounds in upper Cook Inlet, while noise-producing anthropogenic activities, including vessel use, have taken place during the past two decades (e.g., Shelden *et al.*, 2013, 2015b, 2017, 2022; Shelden and Wade, 2019; Goetz *et al.*, 2023). These findings are not surprising as food is a strong motivation for marine mammals. As described in Forney *et al.* (2017), animals typically favor particular areas because of their importance for survival (e.g., feeding or breeding), and leaving may have significant costs to fitness (reduced foraging success, increased predation risk, increased exposure to other anthropogenic threats). Consequently, animals may be highly motivated to maintain foraging behavior in historical foraging areas despite negative impacts (e.g., Rolland *et al.*, 2012).

Generation of sound may result in avoidance behaviors that will be limited in time and space relative to the larger availability of important habitat areas in Cook Inlet; however, the area ensounded by sound from the specified activity is anticipated to be small compared to the overall available critical habitat for CIBWs to feed and travel. Therefore, the specified activity will not create a barrier to movement through or within important areas. We anticipate that disturbance to CIBWs would manifest in the same manner as other marine mammals described above (i.e., increased swimming speeds, changes in the direction of travel and dive behaviors, increased respiration rates, decreased foraging (if such activity were occurring), or alterations to communication signals). We do not believe exposure to elevated noise levels during transit past 8 Star Alaska's activities will have adverse effects on individuals' fitness for reproduction or survival.

Although data demonstrate that CIBWs are not abandoning the planned project area during anthropogenic activities, results of an expert elicitation (EE) at a 2016 workshop, which predicted the impacts of noise on CIBW survival and reproduction given a specific amount of lost foraging opportunities, helped to inform our assessment of impacts on this stock. The 2016 EE workshop used conceptual models of an interim population consequences of disturbance (PCoD) for marine mammals (National Research Council, 2005; New *et al.*, 2014; Tollit *et al.*, 2016) to help in understanding how noise-related stressors might affect vital rates (survival, birth rate and growth) for CIBW (King *et al.*, 2015). NMFS (2016) suggests that the main direct effects of noise on CIBWs are

likely to be through masking of vocalizations used for communication and prey location and habitat degradation. The 2016 workshop on CIBWs was specifically designed to provide regulators with a tool to help understand whether chronic and acute anthropogenic noise from various sources and projects are likely to be limiting recovery of the CIBW population. The full report can be found at <https://www.smruconsulting.com/publications/> with a summary of the expert elicitation portion of the workshop below.

For each of the noise effect mechanisms chosen for the EE, the experts provided a set of parameters and values that determined the forms of a relationship between the number of days of disturbance a female CIBW experiences in a particular period and the effect of that disturbance on her energy reserves. Examples included the number of days of disturbance during the period April, May, and June that would be predicted to reduce the energy reserves of a pregnant CIBW to such a level that she is certain to terminate the pregnancy or abandon the calf soon after birth, the number of days of disturbance in the period April–September required to reduce the energy reserves of a lactating CIBW to a level where she is certain to abandon her calf, and the number of days of disturbance where a female fails to gain sufficient energy by the end of summer to maintain herself and her calf during the subsequent winter. Overall, median values ranged from 16 to 69 days of disturbance depending on the question. However, for this elicitation, a “day of disturbance” was defined as any day on which an animal loses the ability to forage for at least one tidal cycle (i.e., it forgoes 50–100 percent of its energy intake on that day). The day of disturbance considered in the context of the report is notably more severe than any Level B harassment expected to result from these activities, which as described is expected to be comprised predominantly of temporary modifications in the behavior of individual CIBWs (e.g., faster swim speeds, longer dives, decreased sighting durations, alterations in communication). Also, NMFS is authorizing a maximum of 30 instances of take in one year (with 11 instances of take for each of the other 4 years of the rule), with the instances representing disturbance events within a day—this means that either 30 different individual CIBWs are disturbed on no more than 1 day each, or some lesser number of individuals may be disturbed on more

than 1 day, but with the product of individuals and days not exceeding 30. Given the overall take authorized, it is unlikely that any one CIBW would be disturbed on more than a couple of days.

Further, 8 Star Alaska will implement mitigation measures specific to CIBWs. 8 Star Alaska will not begin anchor handling activities should a CIBW be observed within the Level B harassment zone. In addition, 8 Star Alaska will implement shutdown zones for pile driving for beluga whales that extend to the Level B harassment isopleth, or in cases where the Level B harassment zones are too large to fully observe, to the extent that PSOs can observe, minimizing Level B harassment of beluga whales. While Level B harassment is authorized, these measures, along with other mitigation measures described herein, will limit the severity of the effects of that Level B harassment to behavioral changes such as increased swim speeds, changes in diving and surfacing behaviors, and alterations to communication signals, not the loss of foraging capabilities. NMFS is also requiring time/area restrictions, such that noise will be restricted in the Susitna Delta during critical foraging times and high CIBW density. Finally, take by mortality, serious injury, or Level A harassment of CIBWs is not anticipated or authorized.

In summary, and as described above, the additional following factors primarily support our determination that the impacts resulting from 8 Star Alaska's activities are not expected to adversely affect the CIBWs through effects on annual rates or recruitment or survival:

- The area of exposure will be limited to habitat primarily used for transiting and not areas known to be of particular importance for feeding or reproduction;
- The activities are not expected to result in CIBWs abandoning critical habitat nor are they expected to restrict passage of CIBWs within or between critical habitat areas; and
- Any disturbance to CIBWs is expected to be limited to temporary modifications in behavior and would not be of a duration or intensity expected to result in impacts on reproduction or survival.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares maximum number of individuals taken in any year to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted maximum annual number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers (see 86 FR 5322, January 19, 2021). Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

For all stocks whose abundance estimate is known the amount of taking is less than one-third of the best available population abundance estimate (see table 15). The number of animals authorized for take from these stocks, therefore, would be considered small relative to the relevant stock abundance even if each estimated take occurred to a new individual.

There is no stock-wide abundance estimate for Northeast Pacific fin whales. However, Muto *et al.* (2021) estimate the minimum stock size for the areas surveyed is 2,554. NMFS is authorizing an annual maximum of two takes of this stock. Comparison to the minimum population estimate shows, at most, less than 1 percent of the stock would be expected to be impacted.

Abundance estimates for the Mexico-North Pacific stock of humpback whales are based upon data collected more than 8 years ago and, therefore, current estimates are considered unknown (Young *et al.*, 2024). The most recent minimum population estimates (N_{MIN}) for this population include an estimate of 2,241 individuals between 2003 and 2006 (Martínez-Aguilar, 2011) and 766 individuals between 2004 and 2006 (Wade, 2021). NMFS' Guidelines for Assessing Marine Mammal Stocks suggest that the N_{MIN} estimate of the stock should be adjusted to account for potential abundance changes that may have occurred since the last survey and provide reasonable assurance that the stock size is at least as large as the estimate (NMFS, 2023). The abundance trend for this stock is unclear; therefore, there is no basis for adjusting these estimates (Young *et al.*, 2024). NMFS is

authorizing an annual maximum of 6 takes of the Mexico-North Pacific stock of humpback whale. This represents small numbers of this stock (less than 1 percent of the stock assuming a N_{MIN} of 766 individuals).

A lack of an accepted stock abundance value for the Alaska stock of minke whale did not allow for the calculation of an expected percentage of the population that may be affected. The most relevant estimate of partial stock abundance is 1,233 minke whales in coastal waters of the Alaska Peninsula and Aleutian Islands (Zerbini *et al.*, 2006). NMFS is authorizing an annual maximum of three takes of this stock. Comparison to the best estimate of stock abundance shows that, at most, less than one percent of the stock would be impacted.

The Alaska stock of Dall's porpoise has no official NMFS abundance estimate for this area, as the most recent estimate is greater than 8 years old. As described in the 2021 Alaska SAR (Muto *et al.*, 2022) the minimum population estimate is assumed to correspond to the point estimate of the 2015 vessel-based abundance computed by Rone *et al.* (2017) in the Gulf of Alaska ($N = 13,110$; $CV = 0.22$). NMFS is authorizing an annual maximum of 6 takes of the stock. Comparison to the minimum population estimate shows that, at most, 0.05 percent of the stock would be expected to be impacted.

Based on the analysis contained herein of the activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to promulgate regulations, NMFS must find that the specified activity will not have an "unmitigable adverse impact" on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined "unmitigable adverse impact" in 50 CFR 216.103 as an impact resulting from the specified activity: (1) that is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) causing the marine mammals to abandon or avoid hunting areas; (ii) directly displacing subsistence users; or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of

marine mammals to allow subsistence needs to be met.

The Marine Terminal construction activities on the east side of Cook Inlet will occur closest to the subsistence area used by residents of Nikiski, while the offshore pipeline and Mainline MOF will occur closest to the subsistence use area used by residents of Tyonek. Subsistence hunting in Cook Inlet consists mostly of opportunistic hunting of seals. Subsistence hunting of whales is not known to currently occur in Cook Inlet.

Residents of Nikiski, a small community located on the northwestern end of the Kenai Peninsula on the eastern side of Cook Inlet and just north of the planned Marine Terminal, conduct minimal subsistence harvesting of marine mammals. In a 2014 survey conducted by Alaska Department of Fish & Game (ADF&G) (the most recent subsistence survey conducted here) 0.4 percent of the population reported hunting marine mammals and less than 3 percent reported using harvested marine mammals (Jones and Kostick, 2016). Marine mammal species used included bowhead whales (1 percent of households), harbor seals (2 percent of households), and unknown seal species (1 percent of households) (Jones and Kostick, 2016). The bowhead whales were likely received from hunters that harvested elsewhere, as bowhead whales are a circumpolar species that do not occupy Cook Inlet.

The construction of the Mainline MOF will occur approximately 5 miles (8 km) north of Tyonek. According to a 2013 survey (the last known survey of Tyonek subsistence harvesting), 6.1 percent of households reported harvesting marine mammals, all harbor seals, between June and September (Jones *et al.*, 2015). The search areas encompassed an area stretching approximately 20 miles along the Cook Inlet coast, from the McArthur Flats north to the Beluga River (Jones *et al.*, 2015). Seals were searched for or harvested in the Trading Bay area as well as from the beach adjacent to Tyonek.

8 Star Alaska's pile driving and anchor handling may overlap with subsistence hunting of seals. Subsistence hunting occurs mostly nearshore and near river mouths. The majority of anchor handling activities will occur offshore and are therefore expected to have little overlap with subsistence hunting. Any harassment to harbor seals due to pile driving is anticipated to be short-term, mild, and not result in any abandonment or behaviors that would make the animals unavailable for harvest, nor are the

activities expected to directly displace subsistence users or place physical barriers between the marine mammals and the subsistence hunters.

To further minimize any potential effects of their action on subsistence activities, 8 Star Alaska has prepared a stakeholder engagement plan outlining previous meetings with stakeholders, including subsistence users, throughout the planning process and plans to continue to meet with them throughout the construction process. 8 Star Alaska will coordinate with local Tribes as described in its stakeholder engagement plan, notify the communities of any changes in operation, and work with communities to avoid or mitigate impacts to subsistence harvest through pre-construction planning, communication, or other actions. In addition, in-water mitigation measures to minimize effects on behavior of marine mammals are also expected to minimize effects on opportunities for harvest by subsistence communities.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the mitigation and monitoring measures, NMFS has determined that there will not be an unmitigable adverse impact on subsistence uses from 8 Star Alaska's activities.

Adaptive Management

These regulations contain an adaptive management component. Our understanding of the effects of pile driving and AHTs engaged in anchor handling (*e.g.*, acoustic stressors) on marine mammals continues to evolve, which makes the inclusion of an adaptive management component both valuable and necessary within the context of 5-year regulations.

The monitoring and reporting requirements in this rule will provide NMFS with information that helps us to better understand the impacts of the project's activities on marine mammals and informs our consideration of whether any changes to mitigation and monitoring are appropriate. The use of adaptive management will allow NMFS to consider new information and modify mitigation, monitoring, or reporting requirements, as appropriate, with input from 8 Star Alaska regarding practicability, if such modifications will have a reasonable likelihood of more effectively accomplishing the goals of the measures.

The following are some of the possible sources of applicable data that would be considered through the adaptive management process: (1)

results from monitoring reports, including the monthly and annual reports required; (2) results from research on marine mammals, noise impacts, or other related topics; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or LOAs issued pursuant to these regulations. Adaptive management decisions could be made at any time as new information warrants. NMFS could consult with 8 Star Alaska regarding the practicability of the modifications.

Classification

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency ensure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the promulgation of regulations, NMFS consults internally whenever we propose to authorize take for endangered or threatened species. In this case, NMFS OPR consulted with the NMFS AKRO.

NMFS OPR is authorizing take of fin whale, humpback whale (Northeast Pacific and Mexico-North Pacific), beluga whale (Cook Inlet), and Steller sea lion (Western), which are listed under the ESA.

NMFS OPR has consulted with NMFS AKRO pursuant to Section 7 of the ESA on the promulgation of regulations and issuance of a subsequent LOA. NMFS AKRO issued a Biological Opinion on October 31, 2025, which found that the Alaska LNG project is not likely to jeopardize the continued existence of fin whale, humpback whales of the Northeast Pacific and Mexico-North Pacific DPS, CIBWs, and Steller sea lions of the Western DPS.

National Environmental Policy Act

To comply with NEPA (42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order 216-6A, NMFS must review our action (*i.e.*, promulgation of regulations and subsequent issuance of a 5-year LOA) with respect to potential impacts on the human environment.

NMFS participated as a cooperating agency on the 2020 Alaska LNG Project EIS, which was finalized on March 6, 2020, and is available at <https://www.ferc.gov/industries-data/natural-gas/environment/final-environmental-impact-statement-feis>. When acting as a cooperating agency, as is the case with

this project, NMFS may satisfy its independent NEPA obligations by either preparing a separate NEPA analysis for its issuance of an ITA or, if appropriate, by adopting the NEPA analysis prepared by the lead agency. NMFS independently reviewed and evaluated the 2020 Alaska LNG Project EIS and determined it was adequate and sufficient to meet our responsibilities under NEPA for the issuance of the 2020 Alaska LNG Cook Inlet LOA (85 FR 59291, September 21, 2020). NMFS therefore adopted the 2020 Alaska LNG Project EIS and signed a Record of Decision on February 16, 2021.

NMFS prepared a SIR, which considered minor changes to the project and analyses and new scientific literature, and determined that a supplemental EIS is not warranted. Consistent with NEPA, applicable NOAA NEPA procedures, and the information and analysis contained in this final rule, NMFS has determined that this final rule and subsequent LOA will not result in impacts that were not fully considered in the 2020 Alaska LNG Project EIS. As indicated in this final rule, 8 Star Alaska has made no substantial changes to the activities that are relevant to environmental concerns nor are there substantial new circumstances or information about the significance of adverse effects that bear on the analysis. Therefore, NMFS has determined that the 2020 Alaska LNG EIS remains valid, and there is no need to supplement the document for this rulemaking. NOAA therefore, has adopted the 2020 Alaska LNG EIS. NMFS has prepared a separate Record of Decision. NMFS' Record of Decision for adoption of the 2020 Alaska LNG EIS and issuance of this final rule and subsequent LOA can be found at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-oil-and-gas>.

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this final rule is significant for purposes of Executive Order 12866.

The Alaska LNG project involves an 807-mile pipeline delivering 3.5 billion cubic feet of gas daily. The project would create economic benefits by increasing the capacity to transport LNG, allowing more LNG to come to market more efficiently.

It is important to note that 8 Star Alaska initiated a request for a MMPA incidental take authorization, which suggests that the company is relying on NMFS' authorization to proceed with its proposed action. While a MMPA incidental take authorization is not a

pre-condition for conducting the proposed action (8 Star Alaska is ultimately responsible for this decision), it would provide 8 Star Alaska with two key benefits: (1) a legal exemption from the MMPA's general prohibition on the take of marine mammals (assuming 8 Star Alaska complies with the terms and conditions of its permit); and (2) regulatory certainty because 8 Star Alaska will be fully cognizant of NMFS' expectations in regard to the steps needed to be taken to address risks to marine mammals and how to minimize its legal exposure under the statute. 8 Star Alaska will also incur costs to comply with certain mitigation and monitoring requirements, as required by the MMPA. Despite the additional costs of such measures, the costs related to MMPA compliance for the Alaska LNG project are small compared with expenditures on other aspects of construction and operations, and direct compliance costs of the regulatory requirements are unlikely to result in material impacts to the project.

In addition, cost savings may be generated by the reduced administrative effort required to obtain a LOA under the framework established by a rule compared to what would be required to obtain annual incidental harassment authorizations (IHA) under section 101(a)(5)(D). Absent the rule, to attain equivalent compliance with the MMPA, 8 Star Alaska would need to apply for IHAs annually over the 5-year duration of the rule. Although not monetized, NMFS' analysis indicates that the upfront work associated with the rule (e.g., analyses, modeling, process for obtaining LOA valid for 5 years) likely saves significant time and money.

The rule also results in certain non-monetized benefits. Should 8 Star Alaska proceed with the project, the protection of marine mammals afforded by this rule benefits the regional economic value of marine mammals via tourism and recreation to some extent. Marine mammals within Cook Inlet that overlap with the proposed action are likely to benefit from the extensive suite of mitigation and monitoring measures required by the rule; thereby, helping to ensure their long-term survival and their contribution to tourism and other recreational activities in the region. In addition, some degree of benefits can be expected to accrue solely via ecological benefits to marine mammals and other wildlife as a result of this rulemaking. The published literature is clear that healthy populations of marine mammals and other co-existing species benefit regional economies and provide social welfare benefits to people. However, the literature does not provide a basis for

quantitatively valuing the cost of anticipated incremental changes in environmental disturbance and marine mammal harassment associated with the rule.

Executive Order 14192

This rule is an Executive Order 14192 deregulatory action. The promulgation of incidental take regulations under MMPA section 101(a)(5)(A), as requested by applicants, is deregulatory because issuance allows an otherwise prohibited action (*i.e.*, those expected to result in incidental take of marine mammals) to proceed. The regulations increase flexibility and reduce burden by allowing for authorization of otherwise prohibited marine mammal take.

Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration at the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. No comments were received that would change this determination. As a result, a final regulatory flexibility analysis is not required and none has been prepared.

Paperwork Reduction Act (PRA)

This rule contains collection-of-information requirements subject to the provisions of the PRA. These requirements have been approved by OMB under control number 0648-0151 and include the applications for regulations, subsequent LOAs, and reports. Notwithstanding any other provision of law, no person is 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 PRA unless that collection of information displays a currently valid OMB control number.

Promulgation of This Final Rule

As a result of these determinations, NMFS hereby promulgates regulations that allow for the authorization of take of 12 species (15 stocks) of marine mammals, by Level A harassment (3 species comprising 3 stocks) and Level B harassment (12 species comprising 15 stocks), incidental to 8 Star Alaska's pile driving and AHT activities in Cook Inlet, Alaska for a 5-year period from January 1, 2026, through December 31, 2030, provided the previously

mentioned mitigation, monitoring, and reporting requirements are incorporated.

Waiver of Delay of Effective Date

The Assistant Administrator for Fisheries has determined that there is a sufficient basis under the Administrative Procedure Act (APA) to waive the 30-day delay in the effective date of the regulations contained in the final rule. Section 553 of the APA provides that the required publication or service of a substantive rule shall be made not less than 30 days before its effective date with certain exceptions, including (1) for a substantive rule that relieves a restriction or (2) when the agency finds and provides good cause for foregoing delayed effectiveness (5 U.S.C 553(d)(1) and (d)(3)). Here, the issuance of regulations under section 101(a)(5)(A) of the MMPA relieves a restriction, specifically the incidental taking of marine mammals associated with 8 Star Alaska's specified activities.

The Assistant Administrator for NMFS has also determined that there is good cause to waive the 30-day delay in the effective date of this final rule. No individual or entity, other than 8 Star Alaska, is affected by the provisions of these regulations, and 8 Star Alaska does not require 30 days to prepare for implementation of the regulations. Also, 8 Star Alaska's project has great societal and economic importance and delays in project execution because take authorization has not been effectuated are contrary to the public interest. For these reasons, the subject regulations will be made effective on January 1, 2026.

List of Subjects in 50 CFR Part 217

Administrative practice and procedure, Acoustics, Endangered and threatened species, Fish, Fisheries, Marine mammals, Penalties, Reporting, and recordkeeping requirements, Wildlife.

Dated: December 8, 2025.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, NMFS amends 50 CFR part 217 as follows:

PART 217—REGULATIONS GOVERNING THE TAKE OF MARINE MAMMALS INCIDENTAL TO SPECIFIED ACTIVITIES

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 16 U.S.C 1361 *et seq.*

■ 2. Revise subpart E, consisting of §§ 217.40 through 217.49, to read as follows:

Subpart E—Taking Marine Mammals Incidental to 8 Star Alaska Liquefied Natural Gas Facilities Construction in Cook Inlet, Alaska

Sec.

- 217.40 Specified activity and specified geographical region.
- 217.41 Effective dates.
- 217.42 Permissible methods of taking.
- 217.43 Prohibitions.
- 217.44 Mitigation requirements.
- 217.45 Requirements for monitoring and reporting.
- 217.46 Letters of Authorization.
- 217.47 Modifications of Letters of Authorization.
- 217.48–217.49 [Reserved]

Subpart E—Taking Marine Mammals Incidental to 8 Star Alaska Liquefied Natural Gas Facilities Construction in Cook Inlet, Alaska

§ 217.40 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to 8 Star Alaska or successor entities and those persons it authorizes or funds to conduct activities on its behalf for the taking of marine mammals that occurs in the area outlined in paragraph (b) of this section and that occurs incidental to the activities described in paragraph (c) of this section. Requirements imposed on 8 Star Alaska must be implemented by those persons it authorizes or funds to conduct activities on its behalf.

(b) The taking of marine mammals by 8 Star Alaska may be authorized in a Letter of Authorization (LOA) only if it occurs within 8 Star Alaska's Alaska liquefied natural gas (LNG) facilities' construction areas, which are located between the Beluga Landing shoreline crossing on the north and the Kenai River south of Nikiski on the south in Cook Inlet, Alaska.

(c) The taking of marine mammals during this project is only authorized if it occurs incidental to activities associated with 8 Star Alaska's construction of LNG facilities.

§ 217.41 Effective dates.

Regulations in this subpart are effective January 1, 2026, through December 31, 2030.

§ 217.42 Permissible methods of taking.

(a) Under LOAs issued pursuant to § 216.106 of this chapter and this subpart, the holder of the LOAs and those persons it authorizes or funds to conduct activities on its behalf (hereinafter “8 Star Alaska”) may incidentally, but not intentionally, take

marine mammals within the area described in § 217.40(b) by Level A harassment and Level B harassment associated with construction of LNG facilities, provided the activity is in compliance with all terms, conditions, and requirements of the regulations in this subpart and the appropriate LOA.

(b) [Reserved]

§ 217.43 Prohibitions.

Except for the taking permitted in § 217.42 and authorized by the LOA issued under § 216.106 of this chapter and this subpart, it is unlawful for any person to do any of the following in connection with the activities specified activities in § 217.40:

(a) Violate or fail to comply with the terms, conditions, and requirements of this subpart or the LOA issued under this subpart;

(b) Take any marine mammal not specified in the LOA;

(c) Take any marine mammal specified in the LOA in any manner other than as specified in the LOA;

(d) Take any marine mammal specified in the LOA after NMFS determines such taking results in more than a negligible impact on the species or stock of such marine mammal; or

(e) Take any marine mammal specified in the LOA after NMFS determines such taking results in an unmitigable adverse impact on the species or stock of such marine mammal for taking for subsistence uses.

§ 217.44 Mitigation requirements.

When conducting the activities identified in § 217.40(c), the mitigation measures contained in this section and any LOAs issued under § 216.106 of this chapter and this subpart must be implemented. These mitigation measures include:

(a) A copy of any issued LOA must be in the possession of 8 Star Alaska, its designees, and work crew personnel operating under the authority of the issued LOA.

(b) 8 Star Alaska must employ protected species observers (PSOs) and establish monitoring locations pursuant to § 217.45.

(c) 8 Star Alaska must implement shutdown zones for pile driving and clearance zones for anchor handling with radial distances as identified in any LOA issued under §§ 216.106 of this chapter and 217.46.

(1) Monitoring of shutdown or clearance zones must take place from 30 minutes prior to commencing impact and vibratory pile driving or use of tugs for anchor-handling (AHTs), or if there is a 30-minute lapse in such activities, and must continue for 30 minutes following conclusion of the activity.

(i) Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the PSO(s) to observe the entirety of the shutdown zone for impact pile driving and at least 2 km for vibratory pile driving and anchor handling, except in cases where anchor handling operations occur during nighttime hours. In these circumstances, 8 Star Alaska must ensure the clearance zones are clear of marine mammals to the maximum extent possible.

(ii) The specified activities identified in § 217.40(c) may only commence following 30 minutes of observation when PSOs determine that the shutdown or clearance zones are clear of marine mammals.

(iii) If the activity is delayed or halted due to the presence of a marine mammal, the activity must not commence until either the animal(s) has voluntarily exited and been visually confirmed beyond the shutdown zone or 30 minutes (large whales and beluga whales) or 15 minutes (pinnipeds and other cetaceans) have passed without redetection of the animal in the shutdown zone.

(2) Pile driving must be halted upon observation of a marine mammal entering or within the shutdown zone. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily left and has been visually confirmed beyond the shutdown zone or 30 minutes (large whales and beluga whales) or 15 minutes (pinnipeds and other cetaceans) have passed without redetection in the shutdown zone.

(i) If work ceases for more than 30 minutes, the shutdown zones must be cleared again for 30 minutes prior to reinitiating pile driving. A determination that the pile driving shutdown zone is clear must be made during a period of good visibility.

(ii) If a shutdown procedure should be initiated but human safety is at risk as determined by the best professional judgment of the vessel operator or project engineer, the in-water activity, including pile driving, is allowed to continue until the risk to human safety has dissipated. In this scenario, pile driving may continue only until the current segment of the pile is driven; no additional sections of pile or additional piles may be driven until the Lead PSO has determined that the shutdown zones are clear of marine mammals and for Cook Inlet beluga whales (CIBWs), any observed whale(s) is at least 100 meters (m) past the shutdown zone and on a path away from the zone.

(3) If a PSO(s) can no longer effectively monitor the entirety of the corresponding shutdown zone during impact pile driving, or at least 2 km during vibratory pile driving, due to environmental conditions (e.g., fog, rain, wind), pile driving may continue only until the current segment of the pile is driven; no additional sections of pile or additional piles may be driven until conditions improve such that the zone can be effectively monitored. If the shutdown zone cannot be monitored for more than 15 minutes, the entire zone must be cleared again for 30 minutes prior to reinitiating pile driving.

(4) If a species for which authorization has not been granted or a species for which authorization has been granted but the authorized takes have been reached is observed approaching, entering, or within the corresponding zone, in-water work must be delayed (if during pre-clearance) or shut down (except for AHTs engaged in anchor handling). Activities must not resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown or clearance zone or 30 minutes (large whales and beluga whales) or 15 minutes (pinnipeds and other cetaceans) have passed without re-detection of the animal within the shutdown or clearance zone.

(d) 8 Star Alaska must use soft start techniques when impact pile driving. Soft start requires 8 Star Alaska to conduct three sets of strikes (three strikes per set) at reduced hammer energy with a one-minute waiting period between each set. A soft start must be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

(e) 8 Star Alaska must coordinate with local subsistence communities as described in their stakeholder engagement plan, notify the communities of any changes in operation, and work with communities to avoid or mitigate impacts to subsistence harvest through pre-construction planning, communication, or other actions.

(f) 8 Star Alaska must not conduct pile driving associated with the Mainline Material Offloading Facility (MOF) from June 1 to September 7.

(g) Between April 15 and October 15, 8 Star Alaska must not conduct pile driving or AHT activities with Level B harassment isopleths that would extend shoreward of the mean lower low water (MLLW) line in the Susitna Delta (Beluga River to the Little Susitna River) and project vessel(s) operating in or

transiting through Cook Inlet must maintain a distance of at least 1.5 nautical miles (2.8 km) seaward of the MLLW line in the Susitna Delta (Beluga River to the Little Susitna River).

(h) Operators of vessels must avoid approaching within 100 yards (92 m) of marine mammals.

(i) If a whale's course and speed are such that it would likely cross in front of a vessel that is underway or approach within 100 yards (92 m) of the vessel, if maritime conditions safely allow, and if practicable, the engine must be put in neutral and the whale must be allowed to pass beyond the vessel.

(j) Vessel operators must avoid placing the vessel in the path of a whale and must not cut in front of the whale in a way or at a distance that causes the whale to change direction of travel or behavior (including breathing/surface pattern).

(k) When within 300 yards (274 m) of a whale, vessels must travel at less than 5 knots (9 km/hour), and vessel operators must avoid changes in direction and speed unless doing so is necessary for maritime safety.

(l) Vessel operators must reduce speed to 10 knots (18.5 km/hour) or less when weather conditions reduce visibility to 1.6 km (1 mile) or less.

(m) For vessels operating in the Susitna Delta Exclusion Zone, the following must be implemented:

(1) All project vessels operating within the designated Susitna Delta Exclusion Area must maintain a speed over ground below 4 knots (7.4 km/hour). PSOs must note the numbers, date, time, coordinates, and proximity to vessels of all belugas observed during operations and report these observations to NMFS in monthly PSO reports.

(2) Vessel crew must be trained to monitor for Endangered Species Act (ESA)-listed species prior to and during all vessel movements within the Susitna Delta Exclusion Zone. The vessel crew must report sightings of ESA-listed species to the PSO team for inclusion in the overall sighting database and reports.

(3) Vessel operators must not move their vessels when they are unable to adequately observe the 100-m zone around vessels under power (in gear) due to darkness, fog, or other conditions, unless necessary for ensuring human safety.

(4) The Susitna Delta Exclusion Zones is defined as the union of the areas defined by:

(i) A 16-km (10-mile) buffer of the Beluga River thalweg seaward of the MLLW line;

(ii) A 16-km (10-mile) buffer of the Little Susitna River thalweg seaward of the MLLW line; and

(iii) A 16-km (10-mile) seaward buffer of the MLLW line between the Beluga River and Little Susitna River.

(iv) The buffer extends landward along the thalweg to include intertidal waters within rivers and streams up to their mean higher high water line (MHHW).

(n) 8 Star Alaska must conduct sound source verification (SSV) measurements at the beginning of all pile driving activities at each location. During SSV, a sound attenuation device must be tested for effectiveness. If the results show that a sound source reduction of at least 2 dB is achieved, 8 Star Alaska must employ the use of the sound attenuation device.

(1) Any sound attenuation device used by 8 Star Alaska must meet minimum requirements as determined by NMFS in the SSV plan.

(2) [Reserved]

(o) 8 Star Alaska must abide by the reasonable and prudent measures and terms and conditions of the Biological Opinion and Incidental Take Statement issued by NMFS pursuant to section 7 of the Endangered Species Act.

§ 217.45 Requirements for monitoring and reporting.

(a) *Visual Monitoring.* Monitoring must be conducted by qualified, NMFS-approved PSOs, in accordance with the following conditions:

(1) PSOs must be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods;

(2) At least one PSO must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization or Letter of Concurrence;

(3) Other PSOs may substitute other relevant experience, education (degree in biological science or related field), or training for prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization. PSOs may also substitute Alaska native traditional knowledge for experience;

(4) Where a team of three or more PSOs is required, a lead observer or monitoring coordinator must be designated. The lead observer must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;

(5) PSOs must be approved by NMFS prior to beginning any activity subject to

a NMFS-issued incidental take authorization; and

(6) 8 Star Alaska must adhere to the following marine mammal monitoring protocols:

(i) For all single hammer pile driving activities for the Mainline MOF, between Beluga and Tyonek, and the Marine Terminal near Nikiski, a minimum of two PSOs must be on duty at all times.

(ii) For all concurrent pile driving activities at the Marine Terminal near Nikiski, a minimum of three PSOs must be on duty at all times.

(iii) For anchor handling, two PSOs must be on the barge, and one PSO must be on duty at all times.

(iv) PSOs must monitor for marine mammals from the best available vantage point to allow for an unobstructed view of the water.

(v) When conducting observations from the barge during anchor handling, PSOs must have an unobstructed 360-degree view of the water.

(vi) PSO(s) must use a combination of equipment to scan the appropriate monitoring area and to verify the required monitoring distance from the project site, including the naked eye, standard (7x) binoculars, and high-magnification (25x) binoculars.

(vii) Monitoring distances must be measured with range finders, and distances to animals must be based on the best estimate of the PSO, relative to known distances to objects in the vicinity of the PSO.

(viii) PSOs must not exceed 4 consecutive watch hours; must have a minimum 2-hour break between watches; and may not exceed a combined watch schedule of more than 12 hours in a 24-hour period.

(ix) PSOs must have no other construction-related tasks while conducting monitoring.

(x) Monitoring must take place from 30 minutes prior to initiation of pile driving or anchor handling activity, through 30 minutes post completion of pile driving activity or anchor handling activity.

(b) *Acoustic Monitoring.* Acoustic monitoring must be conducted in accordance with the following conditions:

(1) 8 Star Alaska must conduct SSV at the beginning of pile driving at each location to characterize the sound source levels associated with different pile and hammer types and assess attenuation devices. The SSV must be conducted in accordance with the following conditions:

(i) 8 Star Alaska's SSV plan must be approved by NMFS.

(ii) 8 Star Alaska must measure a minimum of two piles of each type, size, and installation method for single pile driving scenarios.

(iii) The following data, at minimum, shall be collected during acoustic monitoring and reported:

(A) Hydrophone equipment and methods: recording device, sampling rate, distance (m) from the pile where recordings were made; depth of water and recording device(s);

(B) Type and size of pile being driven, substrate type, method of driving during recordings (e.g., hammer model and energy), and total pile driving duration;

(C) Whether a sound attenuation device is used and, if so, a detailed description of the device used and the duration of its use per pile;

(D) For impact pile driving (per pile): Number of strikes and strike rate; depth of substrate to penetrate; pulse duration and mean, median, and maximum sound levels (dB re: 1 μ Pa); root mean square sound pressure level (SPL_{rms}); cumulative sound exposure level (SEL_{cum}), peak sound pressure level (SPL_{peak}), and single-strike sound exposure level (SEL_{s-s});

(E) For vibratory driving/removal (per pile): Duration of driving per pile; mean, median, and maximum sound levels (dB re: 1 μ Pa); root mean square sound pressure level (SPL_{rms}), cumulative sound exposure level (SEL_{cum}) (and timeframe over which the sound is averaged);

(F) Transmission loss values for attenuated and unattenuated impact and vibratory installation of each pile size and type;

(iv) An SSV report must be submitted to NMFS for approval within 5 days after the finalization of field measurements and report data.

(v) If appropriate, the results of the SSV report may be used to adjust the extent of the Level A and Level B harassment zones and shutdown zones for in-water pile driving. NMFS must approve any such adjustments.

(c) *Reporting.* 8 Star Alaska must adhere to the following reporting requirements:

(1) 8 Star Alaska must submit interim monthly reports for all months in which pile driving or anchor handling occurs. Monthly reports are due 14 days after the conclusion of each calendar month. The monthly reports must include the following:

(i) Summary of marine mammal species and behavioral observation, delays, and activities completed.

(ii) Assessment of the amount of work (pile driving and anchor handling) remaining to be completed.

(iii) Number of Cook Inlet beluga whales observed within estimated harassment zones to date.

(2) 8 Star Alaska must submit a draft annual report to NMFS within 90 calendar days of the completion of construction (pile driving and anchor handling) each year. Each report must include an overall description of all work completed, a narrative regarding marine mammal sightings, and associated marine mammal observation data sheets (data must be submitted electronically in a format that can be queried such as a spreadsheet or database). Specifically, the report must include the following information:

(i) Date and time that monitored activity begins and ends;

(ii) Activities occurring during each observation period, including:

(A) The type of activity,

(B) The total duration of each type of activity,

(C) When nighttime operations were required,

(D) The number and type of piles that were driven and the method (e.g., impact, vibratory), and

(E) Total duration of driving time for each pile (vibratory driving) and total number of strikes for each pile (impact driving);

(iii) PSO locations during marine mammal monitoring;

(iv) Environmental conditions during monitoring periods (at the beginning and end of the PSO shift and whenever conditions change significantly), including Beaufort sea state, tidal state, and any other relevant weather conditions, including cloud cover, fog, sun glare, overall visibility to the horizon, and estimated observable distance;

(v) Upon observation of a marine mammal:

(A) Name of PSO who sighted the animal(s);

(B) PSO location and activity at time of sighting;

(C) Time of sighting;

(D) Identification of the animal(s) (e.g., genus/species, lowest possible taxonomic level, or unidentified);

(E) PSO confidence in identification and the composition of the group if there is a mix of species;

(F) Distance and location of each observed marine mammal relative to the tugs or pile being driven for each sighting;

(G) Estimated number of animals (min/max/best estimate);

(H) Estimated number of animals by cohort (adults, juveniles, neonates, group composition, etc.);

(I) Animal's closest point of approach and estimated time spent within the harassment zone;

(j) Description of any marine mammal behavioral observations (*e.g.*, observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.*, no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);

(vi) Number of marine mammals detected within the harassment zones, by species; and

(vii) Detailed information about implementation of any mitigation (*e.g.*, shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

(3) If no comments are received from NMFS within 30 days of receipt of the draft annual report, the report shall be considered final. If comments are received, 8 Star Alaska must submit a final report addressing NMFS' comments within 30 days following receipt of any NMFS comments on the draft reports.

(4) In the event that personnel involved in 8 Star Alaska's activities discover an injured or dead marine mammal, 8 Star Alaska must report the incident to NMFS Office of Protected Resources (OPR) and to the Alaska Regional Stranding Coordinator no later than 24 hours after the initial observation. If the death or injury was caused by the specified activity, 8 Star Alaska must immediately cease the specified activities until NMFS OPR is able to review the circumstances of the incident. 8 Star Alaska must not resume their activities until notified by NMFS. The report must include the following information:

(i) Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);

(ii) Species identification (if known) or description of the animal(s) involved;

(iii) Condition of the animal(s) (including carcass condition if the animal is dead);

(iv) Observed behaviors of the animal(s), if alive;

(v) If available, photographs or video footage of the animal(s); and

(vi) General circumstances under which the animal was discovered.

§ 217.46 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to this subpart, 8

Star Alaska must apply for and obtain an LOA;

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed December 31, 2030, the expiration date of this subpart;

(c) In the event of projected changes to the activity or to mitigation and monitoring measures required by the LOA, 8 Star Alaska must apply for and obtain a modification of the LOA as described in § 217.47;

(d) The LOA must set forth:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact (*i.e.*, mitigation) on the species, its habitat, and on the availability of the species for subsistence uses; and

(3) Requirements for monitoring and reporting.

(e) Issuance of the LOA must be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under the regulations of this subpart; and

(f) Notice of issuance or denial of the LOA must be published in the **Federal Register** within 30 days of a determination.

§ 217.47 Modifications of Letters of Authorization.

(a) An LOA issued under §§ 216.106 of this chapter and 217.46 for the specified activities may be modified upon request by 8 Star Alaska, provided that:

(1) The specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for this subpart (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section); and

(2) NMFS' OPR determines that the mitigation, monitoring, and reporting measures required by the previous LOA under this subpart were implemented.

(b) For an LOA modification request by 8 Star Alaska that includes changes to the specified activity or the mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section), the LOA shall be modified, provided that:

(1) NMFS' OPR determines that the changes to the activity or the mitigation, monitoring, or reporting do not change

the findings made for the regulations in this subpart and do not result in more than a minor change in the total estimated number of takes (or distribution by species or years); and

(2) NMFS' OPR may, if appropriate, publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 216.106 and 217.46 of this chapter for the specified activity may be modified by NMFS OPR under the following circumstances:

(1) Through adaptive management, NMFS' OPR may modify (including delete, modify, or add to) the existing mitigation, monitoring, or reporting measures (after consulting with 8 Star Alaska regarding the practicability of the modifications) if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring;

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA include, but are not limited to:

(A) Results from the 8 Star Alaska's monitoring;

(B) Results from other marine mammal and/or sound research or studies; and

(C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by this subpart or subsequent LOA.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS' OPR shall publish a notice of proposed LOA in the **Federal Register** and solicit public comment.

(2) If NMFS' OPR determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in the LOA issued pursuant to §§ 216.106 of this chapter and 217.46, the LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within 30 days of the action.

§§ 217.48–217.49 [Reserved]

[FR Doc. 2025–22513 Filed 12–10–25; 8:45 am]

BILLING CODE 3510–22–P



FEDERAL REGISTER

Vol. 90

Thursday,

No. 236

December 11, 2025

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 512

Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5544–P]

RIN 0938–AV65

Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the Increasing Organ Transplant Access (IOTA) Model for Performance Year (PY) 2.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by February 9, 2026.

ADDRESSES: In commenting, please refer to file code CMS–5544–P.

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–5544–P, 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–5544–P, 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:

CMMItransplant@cms.hhs.gov, for questions related to the Increasing Organ Transplant Access Model.

Thomas Duvall, (410) 786–8887, for questions related to the Increasing Organ Transplant Access Model.

Christina McCormick, (410) 786–4012, for questions related to the

Increasing Organ Transplant Access Model.

Lina Gebremariam, (410) 786–8893, for questions related to the Increasing Organ Transplant Access Model.

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 commenter will take actions to harm an 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.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at <https://www.regulations.gov/>.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This proposed rule would make changes to the Increasing Organ Transplant Access (IOTA) Model for Performance Year (PY) 2, which will begin on July 1, 2026, and future PYs.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this proposed rule. A general summary of the changes in this proposed rule is presented in section II.B of the preamble of this proposed rule.

a. IOTA Participants

In the 2024 Final Rule, CMS finalized that a kidney transplant hospital is eligible to be selected as an IOTA participant if it meets both of the following criteria: (1) The kidney transplant hospital annually performed 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, each of the baseline years; and (2) the kidney transplant hospital annually performed more than 50 percent of its kidney transplants on patients 18 years of age or older each of

the baseline years. However, per section 1835(d) of the Social Security Act (the Act) as codified in 42 CFR 411.6, Medicare does not pay for services furnished by a Federal provider of services or other Federal agency, nor does Medicare pay for services that are paid for directly or indirectly by a government entity, with only limited exceptions. Therefore, we are proposing to modify the eligible kidney transplant hospital criteria to exclude Department of Veteran’s Affairs (VA) medical facilities and Military medical treatment facilities (MTFs) from the IOTA Model for PYs 2 through 6, as described in section II.B.1.b. of this proposed rule.

In the 2024 Final Rule, CMS established a low volume threshold requiring kidney transplant hospitals to have performed 11 or more kidney transplants for patients aged 18 years or older annually in each of the 3 baseline years in order to be eligible for selection into the IOTA Model, designed to protect beneficiary confidentiality and align with minimum CMS data display standards while ensuring statistical significance. However, in response to some IOTA participants expressing concern about their ability to participate in the model and our experience in operating the model, we believe it is necessary to reevaluate the low volume threshold requiring a kidney transplant hospital to have performed at least 11 kidney transplants annually in each of the 3 baseline years in order to be eligible for selection into the IOTA Model. As such, as described in section II.B.1.b. of this proposed rule, we are proposing to raise the low volume threshold from a minimum of 11 kidney transplants performed annually during each of the baseline years to a minimum of 15 kidney transplants performed annually during each of the baseline years.

b. Performance Assessment

In the 2024 Final Rule, we finalized a policy to assess IOTA participant performance each PY in the quality domain on post-transplant outcomes using the composite graft survival rate. While the model performance period has begun, we indicated that for certain policies, such as the inclusion of a risk-adjustment methodology when calculating the composite graft survival rate to account for the complexities of donors and recipients, and their associated risks, we would go through rulemaking in the future to promulgate new or updated policies that would be finalized after the model start date. Therefore, as described in section II.B.2.b.(2).(a). of this proposed rule, we are proposing updates to the composite

graft survival rate metric that would include the following modifications:

- Adding a risk-adjustment methodology that includes several transplant recipient and donor characteristics (for example, transplant recipient and donor age, diabetes status, sex, kidney function (eGFR/creatinine).
- Excluding multi-organ transplants from the composite graft survival rate exclusion and inclusion criteria, in recognition of their more complicated results for kidney transplant recipients.
- Updating the allocation of points awarded for performance on the composite graft survival rate.

A detailed description of each proposed policy change and the corresponding scoring criteria can be found in section II.B.2.b. of this proposed rule.

c. Payment

As finalized in the 2024 Final Rule, each IOTA participant's final performance score will determine whether: (1) CMS will pay an upside risk payment to the IOTA participant; (2) the IOTA participant will fall into a neutral zone where no performance-based incentive payment will be paid to or owed by the IOTA participant; or (3) the IOTA participant will owe a downside risk payment to CMS. For a final performance score greater than 60, CMS will apply the formula for the upside risk payment, which will be equal to the IOTA participant's final performance score minus 60, then divided by 40, then multiplied by \$15,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare fee-for-service (FFS) as their primary or secondary payer during the PY. Final performance scores below 60 in PY 1 and final performance scores of 40 to 60 (inclusive) in PYs 2 through 6 will fall in the neutral zone where there will be no payment owed to the IOTA participant or CMS.

Currently, IOTA Model regulations stipulate that IOTA participants must remit the downside risk payment to CMS in a single payment at least 60 days after the date on which the demand letter is issued. As described in section II.B.3.c.(2). of this proposed rule, CMS is proposing to modify the policy previously finalized in the 2024 Final Rule such that IOTA participants must remit the downside risk payment to CMS in a single payment within 60 days after the date on which the demand letter is issued. As proposed in section II.B.3.c.(2). of this proposed rule, if full payment is not received by CMS within 60 days after demand is made, the

remaining amount owed will be considered a delinquent debt.

Finally, in the 2024 Final Rule, CMS established an Extreme and Uncontrollable Circumstance (EUC) payment policy recognizing that events may occur outside the purview and control of the IOTA participant that may affect their performance in the model. Under the current provision in the IOTA Model, CMS applies determinations made by the Quality Payment Program (QPP) with respect to whether an EUC has occurred, and the areas impacted during the PY. As currently finalized, in the event of an extreme and uncontrollable circumstance, as determined by the QPP, CMS may reduce the downside risk payment, if applicable, prior to recoupment. CMS determines the amount of the reduction by multiplying the downside risk payment by both the percentage of total months during the PY affected by the EUC and the percentage of attributed patients who reside in an area affected by the EUC. As described in section II.B.3.c.(3). of this proposed rule, CMS recognizes that QPP policies may not be appropriate for the IOTA Model due to different payment calculation inputs and program goals. CMS also acknowledges the limited nature of the current EUC provision to account for broader impacts that an EUC might have on an IOTA participant's ability to perform in the model, which only potentially reduces downside payments without accounting for changes in model inputs or reporting periods that may affect an IOTA participant's performance score. Therefore, this proposed rule updates to the EUC provisions that would provide CMS sole discretionary authority to do the following:

- Apply flexibilities to IOTA participants located in emergency areas during emergency periods as defined in section 1135(g) of the Act with Secretary-issued waivers and in counties, parishes, or tribal governments designated under major disaster declarations pursuant to the Stafford Act.
- Extend payment and reporting accommodations to IOTA participants impacted by EUC.
- Adjust the upside risk payment or downside risk payment amount for the IOTA participant if the IOTA participant is participating in the IOTA Model when such an emergency period has been declared.

d. Other Requirements

In the 2024 Final Rule, CMS finalized several other model requirements for IOTA participants, including

transparency requirements, public reporting requirements, and a health equity plan requirement which is optional for the IOTA Model performance period. In the 2024 Final Rule, CMS signaled that there were several policies that would be updated through future rulemaking. In addition, there were several policy considerations raised subsequent to the publication of the 2024 Proposed Rule, including through public comment, which CMS would like to incorporate into the IOTA Model, but were unable to add to the 2024 Final Rule. Therefore, this proposed rule proposes updates to other requirements in the IOTA Model.

a. Transparency

In the 2024 Final Rule CMS finalized that IOTA participants must publicly post their patient selection waitlist criteria on a website by the end of PY 1. CMS also stated its intent to use future rulemaking to determine the cadence of updating this website and patient selection criteria. As such, this proposed rule proposes updates to this requirement that includes the following modifications:

- For all subsequent PYs after PY1, the IOTA participant must review its publicly posted patient selection waitlist criteria and ensure that the information on its website is up to date by the end of each relevant PY.
- IOTA participants performing living donor transplants must publicly post their living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients by the end of PY 2. IOTA participants must ensure the accuracy of this information by the end of each subsequent PY.

Each of the proposed provisions is discussed in detail in section II.B.4.a.(1). of this proposed rule.

CMS also finalized its intent in the 2024 Final Rule to identify each IOTA participant for each PY and to post performance across the achievement domain, efficiency domain, and quality domain for each IOTA participant on the IOTA Model website annually, as they become available. As proposed in section II.B.4.a.(2). of this proposed rule, we are proposing to publish IOTA participant waitlist selection criteria and the proposed living donor selection criteria, as described in section II.B.4.a.(1). of this proposed rule, on the IOTA Model website by the end of the second quarter of each subsequent PY.

As discussed in the 2024 Final Rule, those active on a kidney transplant waitlist may receive organ offers at any time. However, there is currently no requirement for providers to discuss organ offers with their patients. A

provider may decline an organ offer for any number of reasons; however, declining without disclosing the rationale with the patient may miss an important opportunity for shared decision-making. As described in the 2024 Final Rule, CMS proposed monthly transparency requirements for IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries about declined organ offers and the reasons for declination. However, following feedback from 2024 Proposed Rule public comments that this policy would impose a significant administrative burden on IOTA participants, CMS decided not to finalize this transparency requirement and instead committed to consider alternatives, such as alternative frequencies for sharing declined organ offers with Medicare beneficiaries, while remaining invested in evaluating alternative transparency opportunities for patients on the waiting list with the transplant community to fulfill this important need. In this proposed rule, we are proposing an alternative approach for the model, as described in section II.B.4.a.(3). of this proposed rule. As proposed in section II.B.4.a.(3). of this proposed rule, beginning in PY 3, IOTA participants must provide semi-annual (that is, at least once every 6 months) notifications to “eligible IOTA waitlist beneficiaries,” as defined in section II.B.4.a.(3). of this proposed rule, detailing the number and reasons for organ declinations made on their behalf, with eligible IOTA waitlist beneficiaries retaining the right to opt out of receiving these notifications.

In the 2024 Final Rule, CMS finalized a requirement that IOTA participants must review organ offer acceptance criteria with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist. IOTA participants have since requested that CMS provide clarification on what acceptance criteria information should be reviewed. Therefore, as described in section II.B.4.(a).(4). of this proposed rule, we aim to clarify that review of acceptance criteria pertains to individual patient transplant organ offer acceptance criteria and not organ offer filters or kidney transplant hospital level acceptance criteria. For purposes of the model, we are also proposing to define “transplant organ offer acceptance criteria” as individualized patient acceptance parameters that kidney waitlist patients, as defined at § 512.402, may elect regarding the categories of organ offers they are prepared to accept for transplantation.

Lastly, CMS is proposing the adoption of the following provisions for IOTA participants to notify its IOTA waitlist patients who are Medicare beneficiaries when their waitlist status has changed (that is, from active to inactive) only if it is not redundant with other HHS guidance: If finalized, the IOTA participant would be required to: (1) inform IOTA waitlist patients who are Medicare beneficiaries any time their status on its waitlist is changed that would impact their ability to receive an organ offer; (2) include the reason, and information about how IOTA waitlist patients who are Medicare beneficiaries could become active again; and, (3) notify the dialysis facility (as defined at 42 CFR 494.10) and managing clinician (as defined at 42 CFR 512.310) or nephrologist if applicable. IOTA participants would be required to notify these IOTA waitlist patients who are Medicare beneficiaries of status changes within 10 days when they become ineligible for organ offers (if not redundant with existing HHS guidance). This proposed provision is discussed in detail in section II.B.4.a.(5). of this proposed rule.

b. Health Equity Plans

In the 2024 Final Rule, CMS finalized that an IOTA participant may voluntarily submit a health equity plan (HEP) to CMS. CMS finalized voluntary health equity plan submissions aiming to address reducing health disparities for attributed patients. However, in an effort to align with priorities of the Administration and address concerns of added burdens on IOTA participants in a mandatory model, we decided to remove the voluntary health equity plan submissions and are proposing to remove all health equity plan provisions and related definitions from the IOTA Model as described in section II.B.4.b. of this proposed rule. This proposed policy change would enable IOTA participants to focus limited resources on care redesign activities that would improve their model performance and the quality of care and experience for the attributed patient. While CMS is not currently proposing a replacement for these policies, CMS may consider incorporating elements that align with the current Administration’s focus on Making America Healthy Again (MAHA) in future years through notice and comment rulemaking.

e. Beneficiary Protections

CMS finalized in the 2024 Final Rule that IOTA participants must provide notice to each attributed patient of its participation in the IOTA Model. As described in section II.B.5. of this

proposed rule, we are proposing updates to this provision that would include the following modifications:

- Limit these notification requirements to Medicare beneficiaries only.
- Allow IOTA participants to distribute this notification in a paper notification at the first in office or outpatient visit, or to distribute the notification in an electronic format in cases where the attributed patient has affirmatively opted out of receiving paper communications.

f. Monitoring

In the 2024 Final Rule, we finalized a comprehensive list of monitoring activities to ensure compliance and promote the safety of attributed patients and the integrity of the IOTA Model. However, we inadvertently omitted monitoring of the review of acceptance criteria provision as described in § 512.442. Therefore, in this proposed rule we are proposing to include that CMS may monitor the following transparency provisions as described in section II.B.6 of this proposed rule:

- Informing eligible IOTA waitlist patients who are Medicare beneficiaries, as defined in section II.B.4.a.(3). of this proposed rule, of the number of times an organ is declined on the Medicare beneficiary’s behalf in accordance with proposed § 512.442(b);
- Reviewing selection criteria with IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist as specified in § 512.442(c); and
- Notifying IOTA waitlist patients who are Medicare beneficiaries when their waitlist status has changed from active to inactive in accordance with proposed § 512.442(d).

g. Remedial Action and Termination

In the 2024 Final Rule, we finalized a comprehensive list of reasons for which CMS may immediately or with advance notice terminate an IOTA participant from the IOTA Model. As mentioned in section II.B.7. of this proposed rule, we inadvertently omitted the Department of Health and Human Services (HHS) and the Organ Procurement and Transplantation Network (OPTN) as sources of vital information regarding potential events by IOTA participants identified as presenting a risk to patient safety, public health, and related concerns that may lead CMS to terminate IOTA participants. Therefore, in this proposed rule we are proposing to include that CMS may terminate an IOTA participant from the IOTA Model if HHS or the

OPTN has determined that an IOTA participant has violated the OPTN's policies, OPTN's Management and Membership policies, or the HHS's regulation (42 CFR 121) upon a review conducted pursuant to 42 CFR 121.10, along with minor technical corrections to accommodate this proposal as described in section II.B.7 of this proposed rule.

h. Request for Information (RFI) on Topics Relevant to IOTA Model

As part of the Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Proposed Rule (2024 Proposed Rule) published in the **Federal Register** in May 2024 (89 FR 43518), we stated that our goal for the quality domain within the IOTA Model is to achieve acceptable post-transplant outcomes while incentivizing increased kidney transplant volume.¹ We are seeking public input and comments on a future access to waitlist quality process measure to be specified, tested, and implemented for future years of the IOTA Model, titled "Pre-transplantation Access Process Measure".

In the 2024 Final Rule, CMS finalized monitoring allocation out-of-sequence (AOOS) kidneys as a monitoring activity. In response to the 2024 Proposed Rule, we received numerous comments from the public worried about the impact of the IOTA Model on further promoting AOOS. Additionally, on August 30, 2024, HRSA provided a critical comment letter to the OPTN and OPTN contractor regarding a complaint that they received, in which HRSA emphasized the OPTN policies requiring each OPO to maintain a plan for equitable organ allocation among transplant patients consistent with OPTN obligations. While we did not make any changes in the 2024 Final Rule based on the comments received, AOOS remains an issue of concern for CMS and HRSA. As such, in this proposed rule, we would like to seek public comments on potential policies CMS could consider to address AOOS as part of the IOTA Model or through separate regulatory efforts.

3. Summary of Costs and Benefits

The IOTA Model aims to incentivize transplant hospitals to overcome system-level barriers to kidney transplantation. The chronic shortfall in

kidney transplants results in poorer outcomes for patients and increases the burden on Medicare in terms of payments for dialysis and dialysis-based enrollment in the program. In section V of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected IOTA participants and beneficiaries. We estimate that as a result of the proposed changes to the IOTA Model, net Federal savings would increase by \$21 million.

B. Model Overview and Background

The Increasing Organ Transplant Access (IOTA) Model is a 6-year mandatory alternative payment model tested by the CMS Innovation Center under section 1115A of the Social Security Act (the Act) that began on July 1, 2025, and will end on June 30, 2031. The model appeared in the December 4, 2024 **Federal Register** (89 FR 96280) titled "Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model" (hereinafter referred to as the 2024 Final Rule), and this proposed rule would update IOTA Model provisions in response to improvement opportunities that arose during implementation and to better align the model with new administration priorities. The IOTA Model is aimed at kidney transplant hospitals with the goal of increasing the number of kidney transplants, improving quality, and improving patient experience during the transplant process.

II. Proposed Changes to the Increasing Organ Transplant Access (IOTA) Model

A. Background

1. Purpose

The Increasing Organ Transplant Access (IOTA) Model is a 6-year mandatory alternative payment model tested by the CMS Innovation Center that began on July 1, 2025, and will end on June 30, 2031. The IOTA Model is testing whether performance-based incentives paid to or owed by participating kidney transplant hospitals can increase access to kidney transplants for kidney transplant waitlist patients, while preserving or enhancing quality of care and reducing Medicare expenditures. CMS has selected 103 kidney transplant hospitals to participate in the IOTA Model and will be measuring and assessing the participating kidney transplant hospitals' performance during each performance year (PY) across three performance domains: achievement, efficiency, and quality.

The IOTA Model was established through notice and comment rulemaking, finalized in the Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Final Rule (2024 Final Rule), CMS–5535–F, published December 4, 2024. In the 2024 Final Rule, CMS signaled that there were several policies that could be addressed through future rulemaking, including: the addition of a risk-adjustment methodology in the calculation of the composite graft survival rate, the addition of transplants furnished to Medicare Advantage beneficiaries to the definition of Medicare kidney transplants, and the addition of a monthly transparency requirement for IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries about declined organ offers and the reasons for declination. In addition, there were a number of policy considerations raised subsequent to the publication of the Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model Proposed Rule (2024 Proposed Rule), including through public comment, which CMS would like to incorporate into the IOTA Model, but were unable to add to the 2024 Final Rule. Therefore, this proposed rule proposes updates to the IOTA Model. The policies delineated in this proposed rule reflect our commitment to ensuring that the IOTA Model's incentive structure enhances the care delivery capabilities and efficiency of kidney transplant hospitals selected for participation, with the goal of improving quality of care while reducing program spending.

2. Statutory Authority and Background

Section 1115A of the Act authorizes the Center for Medicare and Medicaid Innovation (the "Innovation Center") to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures, while preserving or enhancing the quality of care furnished to such programs' beneficiaries. We have designed and tested both voluntary Innovation Center models—governed by participation agreements, cooperative agreements, and model-specific addenda to existing contracts with CMS—and mandatory Innovation Center models that are governed by regulations. Each voluntary and mandatory model features its own specific payment methodology, quality metrics, and certain other applicable policies, but each model also features numerous provisions of a similar or identical nature, including provisions

¹ We note that the definition and criteria for "acceptable" post-transplant outcomes has not been defined and, as stated in section II.B.2.b(2) of this proposed rule, we are seeking comment on how to define an acceptable level (for example, 1 standard deviation of the national risk-adjusted rate or some other way).

regarding cooperation in model evaluation; monitoring and compliance; and beneficiary protections.

Under the authority of section 1115A of the Act, through notice-and-comment rulemaking, the CMS Innovation Center established the IOTA Model in the 2024 Final Rule that appeared in December 4, 2024, **Federal Register** (89 FR 96280). The intent of the IOTA Model is to reduce Medicare expenditures and improve performance in kidney transplantation by creating performance-based incentive payments for participating kidney transplant hospitals tied to access and quality of care for ESRD patients on the hospitals' waitlists.

Participation in the IOTA Model is mandatory for approximately 50 percent of all eligible kidney transplant hospitals in the United States, which were selected by a stratified random sampling of donation service areas ("DSAs"). Mandatory participation in the IOTA Model was determined to be necessary to minimize the potential for selection bias and to ensure a representative sample size nationally, thereby guaranteeing that there would be adequate data to evaluate the model test. Eligible kidney transplant hospitals included those that: (1) performed at least 11 kidney transplants for patients 18 years of age or older annually regardless of payer type during the 3-year period ending 12 months before the model's start date; and (2) furnished more than 50 percent of the hospital's annual kidney transplants to patients 18 years of age or older during that same period. As this is a mandatory model, the selected kidney transplant hospitals are required to participate.

CMS measures and assesses IOTA participant performance during each PY across three performance domains: achievement, efficiency, and quality. The achievement domain assesses each IOTA participant on the number of kidney transplants performed during a PY, relative to a participant-specific transplant target. The efficiency domain assesses the performance of IOTA participants on the organ offer acceptance rate ratio relative to national ranking. The quality domain is focused on improving the quality of care and measures IOTA participants' performance on the composite graft survival rate relative to national ranking to assess post-transplant outcomes. Each IOTA participant's performance score across these three domains determines its final performance score and corresponding amount for the performance-based incentive payment that CMS will pay to or the payment that will be owed by the IOTA

participant. The upside risk payment will be a lump sum payment paid by CMS after the end of a PY to an IOTA participant with a final performance score of 60 or greater. Conversely, beginning PY 2, the downside risk payment will be a lump sum payment paid to CMS by any IOTA participant with a final performance score of 40 or lower. There is no downside risk payment for PY 1 of the IOTA Model.

B. Provisions of the Proposed Regulation

1. IOTA Participants

a. Background

In the 2024 Final Rule (89 FR 96304), we defined "IOTA participant" as a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model pursuant to § 512.412. In addition, we noted that the definition of "model participant" contained in 42 CFR 512.110, would include an IOTA participant. We also proposed and finalized at § 512.402 the definition of "transplant hospital," "kidney transplant hospital," and "kidney transplant." We stated that kidney transplant hospitals are the focus of the IOTA Model because they are the entities that furnish kidney transplants to ESRD patients on the waiting list and ultimately decide to accept donor recipients as transplant candidates (89 FR 96303). Kidney transplant hospitals play a key role in managing transplant waitlists and patient, family, and caregiver readiness. They are also responsible for the coordination and planning of kidney transplantation with the organ procurement organizations (OPO) and donor facilities, staffing and preparation for kidney transplantation, and oversight of post-transplant patient care, and they are largely responsible for managing the living donation process. The IOTA Model is intended to promote improvement activities across selected kidney transplant hospitals that reduce access barriers, thereby increasing the number of transplants, quality of care, and cost-effective treatment. The IOTA Model aims to improve quality of care for ESRD patients on the waiting list pre-transplant, during transplant, and during post-transplant care.

b. Mandatory Participation

In the 2024 Final Rule (89 FR 96308), we finalized that participation in the IOTA Model would be mandatory. We proposed and finalized that all kidney transplant hospitals that meet the eligibility requirements at § 512.412(a), and that are selected through the participation selection process at § 512.412(b) and (c) would be required to participate in the IOTA Model.

Lastly, we also finalized our provisions for participant eligibility criteria for kidney transplant hospitals at § 512.412(a) for all eligible kidney transplant hospitals selected for participation in the model.

As stated in the 2024 Final Rule (89 FR 96308), we proposed kidney transplant hospital participant eligibility criteria that would increase the likelihood that: (1) individual kidney transplant hospitals selected as IOTA participants represent a diverse array of capabilities across the performance domains; and (2) the results of the model test would be statistically valid, reliable, and generalizable to kidney transplant hospitals nationwide should the model test be successful and considered for expansion under section 1115A(c) of the Act.

We proposed and finalized our participant eligibility criteria for kidney transplant hospitals at § 512.412(a) in the 2024 Final Rule (89 FR 96311). Specifically, that eligible kidney transplant hospitals are those that: (1) performed 11 or more transplants for patients aged 18 years or older annually, regardless of payer type, each of the baseline years and (2) furnished more than 50 percent of its kidney transplants annually to patients over the age of 18 during each of the baseline years. We also finalized the definition of "non-pediatric facility" and "baseline years" at § 512.402.

In the 2024 Final Rule, we finalized at § 512.412(a)(1) a low volume threshold requiring a kidney transplant hospital to have performed 11 or more kidney transplants for patients aged 18 years or older annually in each of the 3 baseline years in order to be eligible for selection into the IOTA Model.

In our initial proposal in the 2024 Proposed Rule, we stated that we alternatively considered using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the 3 baseline years (89 FR 43541). However, we found that many kidney transplant hospitals consistently perform between 11 and 50 transplants per year. We received several comments expressing concern with the proposed low-volume kidney transplant threshold for IOTA participants. As described in the 2024 Final Rule at 89 FR 96309, a commenter noted that there may be some unforeseen or unintended consequences of advantaging programs classified as "low volume," where the volume is close to the dividing line, and vice versa. Additional commenters shared concerns that the low volume threshold of 11 kidney transplants performed will

disadvantage kidney transplant hospitals that furnish a smaller number of kidney transplants, as these transplant programs do not meet the requirements for Center of Excellence (COE) programs and have limited contracts with payers, and the low volume threshold does not ensure statistical significance. Several commenters recommended that CMS should increase the low volume threshold, setting the number of kidney transplants at a value such as 25, 50, or 100, to ensure statistical significance and avoid burden on kidney transplant hospitals that furnish a smaller number of kidney transplants. Finally, a commenter suggested CMS should only use the number of Medicare kidney transplants to determine eligibility, rather than 11 kidney transplants across all payers. Additionally, as described at *89 FR 96308* a commenter expressed concerns about the impact of the IOTA Model on small kidney transplant hospitals if participation was made mandatory. The commenter suggested that a low volume threshold of 100 kidney transplants, regardless of payer type, would be more appropriate. This, the commenter believed, would ensure small kidney transplant hospitals were excluded and protect access to kidney transplants in less populated areas.

In the 2024 Final Rule, we stated that the low volume threshold was designed to protect the confidentiality of Medicare and Medicaid beneficiaries and that this low volume threshold aligns with the minimum standards for CMS data display, preventing the release of information that could identify individual beneficiaries while ensuring statistical significance (*89 FR 96309*). Additionally, we stated that we excluded these low-volume kidney transplant hospitals that may lack the capacity to comply with the model's policies.

Since publication of the 2024 Final Rule, some IOTA participants close to the current low volume threshold have expressed concern about their ability to participate in the model and we believe it is necessary to reevaluate the low volume threshold requiring a kidney transplant hospital to have performed 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, annually in each of the 3 baseline years in order to be eligible for selection into the IOTA Model. We also received multiple comments from the 2024 Proposed Rule urging us to increase the low volume threshold. As such, in this proposed rule, we are proposing at § 512.412(a)(1) to raise this low volume threshold from a minimum of 11 kidney transplants

performed annually during each of the baseline years to a minimum of 15 kidney transplants performed annually during each of the baseline years. We are also proposing this provision in response to our experience in operating the model. IOTA participants who are above the current minimum threshold of 11 kidney transplants performed annually, but below the updated proposed threshold of a minimum of 15 kidney transplants performed annually are still quite small and have indicated structural difficulties in achieving the goals of the model and complying with the requirements of the model. This updated low volume threshold is designed to balance accommodating the needs of smaller kidney transplant hospitals to ensure that their transplant programs can remain viable and continue to serve their communities, while also trying to ensure a sufficient volume of kidney transplant hospitals to be able to test the model.

We alternatively considered higher low volume thresholds, such as 20 kidney transplants or 25 kidney transplants performed for patients aged 18 years or older annually, regardless of payer, during each of the baseline years, but think that a low volume threshold of 15 kidney transplants or more performed to patients aged 18 years or older annually best balances excluding the smallest kidney transplant hospitals, while still being able to ensure that the model has sufficient power to be able to test the model. This proposed updated low volume threshold would only result in the removal of one IOTA participant as of the model start date, while higher thresholds would result in additional IOTA participants being removed, which could diminish the ability to evaluate the model.

We seek comment on our proposal to adjust the low volume threshold at § 512.412(a)(1) to require that to be eligible for model participation, a kidney transplant hospital must have performed a minimum of 15 kidney transplants to patients aged 18 years or older annually, regardless of payer, each of the baseline years, rather than a minimum of 11 kidney transplants. We also seek public comment on the alternatives considered.

Additionally, since publication of the 2024 Final Rule, CMS has completed IOTA participant selection and notified IOTA participants of their selection to participate in the IOTA Model. Upon completion of selecting IOTA participants for inclusion in the model, we realized that an unintended consequence of the current participant eligibility criteria at § 512.412(a) is that Department of Veterans Affairs (VA)

medical facilities or military medical hospitals, also known as military medical treatment facilities (MTFs) could be selected to participate even though Medicare does not provide reimbursement for VA medical facilities or MTFs. A total of 103 kidney transplant hospitals were selected to participate in the model, including four VA medical facilities and one MTF.

Per *42 CFR 411.6(a)*, Medicare does not pay for services rendered by Federal providers of services or other Federal agencies. Additionally, Medicare does not provide payment for services that receive direct or indirect funding from a governmental entity (see *42 CFR 411.8*). As such we propose to update the participant eligibility criteria at § 512.412(a). Specifically, we are proposing at § 512.412(a)(3) to exclude kidney transplant hospitals that are a MTF or VA medical facility from being eligible to participate in the IOTA Model. We propose at § 512.402 to define a “VA medical facility” as defined at *38 CFR 17.1505* to mean a VA hospital, a VA community-based outpatient clinic, or a VA health care center, any of which must have at least one full-time primary care physician, but not a Vet Center or Readjustment Counseling Service Center. Additionally, we propose at § 512.402 to define a “military medical treatment facility (MTF)” as it is currently defined at *10 U.S.C. 1073c(j)(3)* to mean: (1) any fixed facility of the Department of Defense that is outside of a deployed environment and used primarily for health care; and (2) any other location used for purposes of providing healthcare services as designated by the Secretary of Defense.

Given that Medicare does not provide coverage for services furnished by a federal provider, federal agency, or any other government entity, whether the services are paid for directly or indirectly by a government source, we believe that VA medical facilities and MTFs should not be eligible to participate in the IOTA Model. Additionally, we do not believe that our proposal to exclude kidney transplant hospitals that are also a VA medical hospital or MTF from being eligible to participate in the IOTA Model would negatively affect the remaining IOTA participants or impact the IOTA Model nor CMS's ability to evaluate the model. Moreover, the model's evaluation would benefit from an analysis that only focuses on Medicare-participating kidney transplant hospitals. Since the fundamental purpose of the IOTA Model is to test interventions specifically within the Medicare system to improve quality of care and reduce

Medicare expenditures, including non-Medicare participating facilities like VA medical facilities and MTFs would introduce confounding variables that could obscure the model's true effectiveness. VA medical facilities and MTFs operate under entirely different payment structures, regulatory frameworks, and patient populations compared to Medicare-participating hospitals, making direct performance comparisons inappropriate and potentially misleading.

By excluding these facilities, the model evaluation can focus on a group of hospitals that all operate under similar Medicare reimbursement conditions, face comparable regulatory requirements, and serve similar patient populations, thereby providing more accurate data on whether the model's performance-based payment incentives actually drive improvements in transplant outcomes and cost efficiency within the Medicare system. This approach would also eliminate the analytical complexity of trying to account for the vastly different operational contexts between Medicare-participating kidney transplant hospitals and federal facilities, ultimately yielding more actionable insights for potential broader implementation of the IOTA Model across the Medicare program.

We seek comment on our proposal at proposed § 512.412(a)(3) to exclude kidney transplant hospitals that are a MTF or VA medical facility as eligible to participate in the model. We also seek comments on our proposed definitions of MTF and VA medical facility at proposed § 512.402.

Lastly, to account for our proposed kidney transplant hospital participant eligibility criteria modifications at proposed § 512.412(a)(1) and (3), we propose updating the language at § 512.412(a). Specifically, we propose replacing “meets both” with “meets all” to specify that a kidney transplant hospital is eligible to be selected as an IOTA participant, in accordance with the methodology described in proposed § 512.412(b)(3), if the kidney transplant hospital meets all of the eligibility criteria at § 512.412(a).

We seek comment on our proposal at proposed § 512.412(a) to update existing language to account for our proposals at proposed § 512.412(a)(1) and (3).

2. Performance Assessment

a. Method and Scoring Overview

In the 2024 Final Rule (89 FR 96326), we finalized provisions to assess IOTA participants in the achievement domain, efficiency domain and quality domain

and performance scoring approach at § 512.422(a). We also finalized at § 512.402 the definition of “final performance score” as the aggregate sum of scores earned by the IOTA participant across all three domains for a designated PY.

b. Quality Domain

(1) Background

In the 2024 Final Rule (89 FR 96358), we finalized at § 512.402 the definition of “quality domain” as the performance assessment category in which CMS assesses the IOTA participant's performance using a performance measure focused on improving the quality of transplant care as described in § 512.428. We also finalized general provisions for the quality domain at § 512.424(a).

We stated at 89 FR 96358, that our goal for the quality domain within the IOTA Model is to achieve acceptable post-transplant outcomes while incentivizing increased kidney transplant volume.² We continue to believe that transplant hospital accountability for patient-centricity and clinical outcomes continues post-transplantation. While transplant outcomes have historically received the most attention, often at the exclusion of other factors, we sought to encourage a better balance in the system to offer the benefits of transplant to more patients.

(2) Post Transplant Outcomes

In the 2024 Final Rule (89 FR 96361), we finalized at § 512.428(b)(1) a provision to assess IOTA participant performance each PY on post-transplant outcomes using the composite graft survival rate. We also proposed and finalized at § 512.402 the definition of composite graft survival rate (89 FR 96361).

(a) Calculation of Metric

In the 2024 Final Rule (89 FR 96364), we proposed and finalized provisions for calculating the composite graft survival rate at § 512.428(b)(1).

In our initial proposal in the 2024 Proposed Rule (89 FR 43563), we stated that we had considered incorporating a risk-adjustment methodology into our proposed composite graft survival equation, such as the one used by Scientific Registry of Transplant Recipients (SRTR) for 1-year post-transplant outcomes conditional on 90-

day survival or constructing our own. We also stated at 89 FR 43563 that we were interested in comments on whether risk-adjustments were necessary, and which ones, such as transplant recipient and donor characteristics, would be significant and clinically appropriate in the context of our proposed approach. We received over 15 comments expressing concern that the lack of risk-adjustment in the composite graft survival rate metric could have adverse consequences and would add additional administrative burden. As described at 89 FR 96362, many commenters expressed concern that the unadjusted composite graft survival rate does not account for the clinical risk factors of the transplant recipient or the donor; therefore, it may inadvertently lead to disparities in transplant access by incentivizing IOTA participants to select healthier patients for transplantation. Several commenters believe that the proposed measure misaligned with the model's goal of increasing kidney transplants in a more complex population without risk-adjusting for allograft and recipient factors. Without proper risk-adjustment, these commenters suggested the proposed measure could cause IOTA participants to be more risk averse with the types of organs they accept or disincentivize IOTA participants from transplanting candidates who have a higher likelihood of graft failure, such as older candidates or those with more comorbid conditions. Some commenters suggested specific transplant recipient and donor characteristics that CMS should risk-adjust for when calculating the proposed composite graft survival rate.

In the 2024 Final Rule (89 FR 96363), we stated that in light of commenters suggestions, we considered finalizing a risk-adjustment methodology that adjusted for donor age, recipient age, and recipient diabetes. However, we decided to finalize the provisions as proposed as we did not believe that adjusting for these three variables alone was appropriate. Organ availability affects kidney transplantation, leading transplant teams to expand the criteria for accepting organ donors.³ In these circumstances, we believe that analysis of the impact of the donor's characteristics on graft survival becomes mandatory before incorporating a risk-adjustment methodology. Additionally, given that the IOTA Model is 6 years,

² We note that the definition and criteria for “acceptable” post-transplant outcomes has not been defined and we are seeking comment on how to define an acceptable level (for example, 1 standard deviation of the national risk-adjusted rate or some other way), as stated in section II.B.2.b(2) of this proposed rule.

³ Olawade, D.B., Marinze, S., Qureshi, N., Weerasinghe, K., & Teke, J. (2024). Transforming organ donation and transplantation: Strategies for increasing donor participation and system efficiency. *European Journal of Internal Medicine*. <https://doi.org/10.1016/j.ejim.2024.11.010>.

and the measure is rolling, meaning that it measures the rolling total number of functioning grafts relative to the total number of adult kidney transplants performed for all 6 years, as described in the 2024 Final Rule at 89 FR 96324, we wanted to continue discussions to ensure that this measure eventually includes a robust and appropriate risk-adjustment methodology. Furthermore, we continue to believe that the lack of risk-adjustment for PY 1 would be minimal in terms of impacting IOTA participants scores and note that IOTA participants do not owe a downside risk payment in PY 1, as described in § 512.430(b)(3)(i). We also note that in the 2024 Final Rule at 89 FR 96364, we stated that while we were finalizing our provision for calculating the composite graft survival rate as proposed, we would be stratifying the data from the composite graft survival rate measure to inform a risk-adjustment methodology for this measure and might consider future notice and comment rulemaking on this topic.

Since publication of the 2024 Final Rule, many IOTA participants have urged CMS to include a risk-adjustment methodology in the composite graft survival rate calculation. As such, in this proposed rule, we are proposing at § 512.428(b)(2) to include a risk-adjustment methodology in the composite graft survival rate calculation. Specifically, we propose at § 512.428(b)(2)(i)(A) and (B) that CMS would, in accordance with § 512.428(b)(1) through (3), risk-adjust the composite graft survival rate to account for multiple transplant recipient and donor characteristics, that includes at minimum the following:

- Transplant recipient characteristics:
 - ++ Age.
 - ++ Sex.
 - ++ Kidney function (eGFR/creatinine).
 - ++ Diabetes status.
 - ++ Hypertension with or without cardiovascular disease.
 - ++ Human leukocyte antigen (HLA) mismatch.
 - ++ Plasma renin activity (PRA) levels.
- Donor characteristics:
 - ++ Age.
 - ++ Sex.
 - ++ Kidney function (eGFR/creatinine).
 - ++ Diabetes status.
 - ++ Hypertension history with or without cardiovascular disease.
 - ++ Cardiovascular disease.
 - ++ Human leukocyte antigen (HLA) mismatch.
 - ++ Plasma renin activity (PRA) levels.

++ Cause of death.

++ Donation after cardiac death.

We believe that the proposed transplant recipient and donor characteristics represent well-established, non-modifiable predictors that significantly influence graft survival independent of care quality. For example, advanced transplant recipient age increases mortality and cardiovascular complications, while sex-based differences in immune response and medication metabolism create distinct risk profiles requiring fair assessment.^{4 5} Diabetes, hypertension, and cardiovascular disease represent major outcome determinants present at transplantation that are largely beyond transplant hospitals' short-term control.^{6 7 8} Donor age correlates with reduced nephron mass and shorter graft lifespan, while cause of death and donation type significantly affect both immediate function and long-term survival, creating substantial organ quality variation across centers.⁹ Higher HLA mismatch increases rejection likelihood independent of clinical management quality, while elevated PRA levels indicate pre-existing sensitization creating immunological barriers that require intensive immunosuppression—both characteristics determined by factors largely beyond a kidney transplant

⁴ Schwager, Y., Littbarski, S.A., Nolte, A., Kaltenborn, A., Emmanouilidis, N., Kleine-Döpke, D., Klempnauer, J., & Schrem, H. (2019). Prediction of Three-Year Mortality After Deceased Donor Kidney Transplantation in Adults with Pre-Transplant Donor and Recipient Variables. *Annals of Transplantation*, 24, 273–290. <https://doi.org/10.12659/aot.913217>.

⁵ So, S., Au, E.H., Lim, W.H., Lee, V.W., & Wong, G. (2020). Factors influencing Long-Term patient and allograft outcomes in elderly kidney transplant recipients. *Kidney International Reports*, 6(3), 727–736. <https://doi.org/10.1016/j.ekir.2020.11.035>.

⁶ Schwager, Y., Littbarski, S.A., Nolte, A., Kaltenborn, A., Emmanouilidis, N., Kleine-Döpke, D., Klempnauer, J., & Schrem, H. (2019). Prediction of Three-Year Mortality After Deceased Donor Kidney Transplantation in Adults with Pre-Transplant Donor and Recipient Variables. *Annals of Transplantation*, 24, 273–290. <https://doi.org/10.12659/aot.913217>.

⁷ So, S., Au, E.H., Lim, W.H., Lee, V.W., & Wong, G. (2020). Factors influencing Long-Term patient and allograft outcomes in elderly kidney transplant recipients. *Kidney International Reports*, 6(3), 727–736. <https://doi.org/10.1016/j.ekir.2020.11.035>.

⁸ Nishio, A.G., Patel, A., Mehta, S., Yadav, A., Doshi, M., Urbanski, M.A., Concepcion, B.P., Singh, N., Sanders, M.L., Basu, A., Harding, J.L., Rossi, A., Adebisi, O.O., Samaniego-Picota, M., Woodside, K.J., & Parsons, R.F. (2024). Expanding the access to kidney transplantation: Strategies for kidney transplant programs. *Clinical Transplantation*, 38(5). <https://doi.org/10.1111/ctr.15315>.

⁹ Watson, C.J.E., Johnson, R.J., Birch, R., Collett, D., & Bradley, J.A. (2012). A Simplified Donor Risk Index for Predicting Outcome After Deceased Donor Kidney Transplantation. *Transplantation*, 93(3), 314–318. <https://doi.org/10.1097/tp.0b013e31823f14d4>.

hospital's control.^{10 11} Given the scarcity of donor organs and the IOTA Model's imperative to maximize transplant opportunities, risk-adjusted allocation strategies support accepting suboptimal immunological compatibility when clinically appropriate.¹²

We propose at § 512.428(b)(2)(ii)(A) that CMS would analyze the transplant recipient and donor characteristics as specified at proposed § 512.428(b)(2)(i)(A) and (B). We also propose at § 512.428(b)(2)(ii)(B) that CMS would then apply a risk score to each individual IOTA transplant patient, as defined at § 512.402, based on the analysis of the transplant recipient and donor characteristics at proposed § 512.428(b)(2)(ii)(A). Lastly, we propose at § 512.428(b)(2)(ii)(C)(1) and (2) that CMS would use the calculated composite graft survival rate risk scores identified at proposed § 512.428(b)(2)(ii)(B) to—

- Normalize the composite graft survival rate outcome to control for differences in kidney transplant patient risk; and
- Adjust the composite graft survival rate, based on the normalized composite graft survival rate outcome.

We believe this systematic approach to risk-adjusting kidney transplantation ensures standardized care delivery while accommodating individual kidney transplant patient needs and optimizing long-term outcomes through evidence-based protocols, and continuous quality improvement initiatives. Risk-adjustment accounts for factors that are associated with the outcome, vary across providers, and are unrelated to quality of care, so that measure scores reflect true differences in quality of care.¹³ Accounting for case-mix differences is important because it recognizes that some IOTA participants care for older or sicker kidney transplant patients who have lower graft survival rates. Through the proposed

¹⁰ Ibid.

¹¹ Schwager, Y., Littbarski, S.A., Nolte, A., Kaltenborn, A., Emmanouilidis, N., Kleine-Döpke, D., Klempnauer, J., & Schrem, H. (2019). Prediction of Three-Year Mortality After Deceased Donor Kidney Transplantation in Adults with Pre-Transplant Donor and Recipient Variables. *Annals of Transplantation*, 24, 273–290. <https://doi.org/10.12659/aot.913217>.

¹² Riley S, Zhang Q, Tse WY, Connor A, Wei Y. Using information available at the time of donor offer to predict kidney transplant survival Outcomes: A Systematic Review of Prediction Models. *Transplant International*. 2022;35. <https://doi.org/10.3389/tp.2022.10397>.

¹³ So, S., Au, E.H., Lim, W.H., Lee, V.W., & Wong, G. (2020). Factors influencing Long-Term patient and allograft outcomes in elderly kidney transplant recipients. *Kidney International Reports*, 6(3), 727–736. <https://doi.org/10.1016/j.ekir.2020.11.035>.

risk-adjustment modeling, we believe an appropriate outcome rate is set for IOTA participants who care for kidney transplant patients with certain risk factors, decreasing the incentive to select younger, healthier patients for transplantation.

We seek comments on our proposed composite graft survival rate risk-adjustment methodology at proposed § 512.428(b)(2). We also seek comment on what transplant recipient and donor characteristics, infectious disease status or other medically complex factors, transplant recipient comorbidity burden, and immunological risk factors would be significant and clinically appropriate to include in the proposed risk-adjustment methodology for the composite graft survival rate metric.

We considered all recommendations made by public commenters in the 2024 Final Rule. For example, a commenter believed that CMS should risk-adjust for at least a small number of factors that would allow for a simple model that is understandable by including the biggest drivers for variation in outcomes and thereby disincentivize the creation of additional hurdles for more complex transplant recipients (89 FR 96361). The same commenter believed that a risk-adjustment model that includes age, ESRD vintage, and diabetes mellitus (y/n) would leverage currently available data and remain easily measurable and understood. We strongly considered this recommendation and chose to propose a similar approach with different factors to account for more scenarios and to reduce the chance of disincentivizing transplantation.

Multiple commenters in the 2024 Final Rule and some IOTA participants advocated for the adoption of the SRTR risk-adjustment methodology, which is presently utilized by both the Organ Procurement and Transplantation Network (OPTN) and CMS in existing programs. The SRTR risk-adjustment framework incorporates comprehensive adjustments for both transplant recipient and donor characteristics, undergoes annual updates to maintain currency, and is subject to validation and testing protocols. During each transplant program-specific report (PSR) cycle, the SRTR conducts a comprehensive refit of the graft survival prediction model, systematically evaluating numerous potential predictor variables to optimize the model's predictive accuracy and clinical relevance. The SRTR calculates the kidney donor risk index (KDRI) in accordance with the methodology

established by Rao et al.¹⁴ As such, we also considered, but did not propose, using SRTR's 1-year post-transplant outcomes risk-adjustment methodology for adult (18+) kidney graft survival with deceased and living donors, which includes a defined list of transplant recipient and donor characteristics included in the calculation that are updated periodically.¹⁵ There is empirical support for sophisticated risk-adjustment methodologies like SRTR's, while acknowledging the need for ongoing refinement as unmeasured risk factors are identified and measurement precision improves.^{16 17} However, we believe this would require increased sophistication and attention from IOTA participants to interpret the additional information required and also require additional communications and education resources at transplant hospitals, potentially at Organ Procurement Organizations (OPO), and national levels.¹⁸

Additionally, SRTR implements more frequent model rebuilds in addition to refitting the models every 6 months. The purpose of rebuilding each cycle is to ensure that new transplant recipient and donor characteristics are incorporated into the risk-adjustment methodology. Therefore, for the purposes of risk-adjusting the composite graft survival rate, we considered, but did not propose, using only SRTR's post-transplant outcomes adult kidney model strata and most recently available set of coefficients. Alternatively, we also considered but did not propose utilizing a more limited set of characteristics than

those employed by SRTR for simplification purposes.

A primary criticism of the SRTR risk-adjustment framework concerns the potential for encouraging risk aversion.^{19 20 21 22 23 24} Kidney transplant hospitals may prioritize statistical performance over kidney transplant waitlist patient access to care, potentially limiting transplant opportunities for kidney transplant waitlist patients who would benefit despite higher risk profiles.²⁵ There have been persistent questions about "whether the OPTN data are adequate for risk-adjustments used in SRTR program-specific reporting."²⁶ While the current methodology provides adequate risk-adjustment for available data, the collection of additional risk factors such as local comorbidity indexes, community risk factors, cardiovascular risk factors, and anatomical abnormalities or vascular injury in donor kidneys could further

¹⁹ Schenk, A.D., Logan, A.J., Sneddon, J.M., Faulkner, D., Han, J.L., Brock, G.N., & Washburn, W.K. (2022). Textbook Outcome as a Quality Metric in Living and Deceased Donor Kidney Transplantation. *Journal of the American College of Surgeons*, 235(4), 624–642. <https://doi.org/10.1097/xcs.0000000000000301>.

²⁰ Kasiske, B.L., Salkowski, N., Wey, A., Israni, A.K., & Snyder, J.J. (2018). Scientific Registry of Transplant Recipients program-specific reports: where we have been and where we are going. *Current Opinion in Organ Transplantation*, 24(1), 58–63. <https://doi.org/10.1097/mot.0000000000000597>.

²¹ Jay, C., & Schold, J.D. (2017). Measuring Transplant Center Performance: the Goals Are Not Controversial but the Methods and Consequences Can Be. *Current Transplantation Reports*, 4(1), 52–58. <https://doi.org/10.1007/s40472-017-0138-9>.

²² Snyder, J.J., Salkowski, N., Wey, A., Israni, A.K., Schold, J.D., Segev, D.L., & Kasiske, B.L. (2016). Effects of High-Risk Kidneys on Scientific Registry of Transplant Recipients Program Quality Reports. *American Journal of Transplantation*, 16(9), 2646–2653. <https://doi.org/10.1111/ajt.13783>.

²³ Bowring, M.G., Massie, A.B., Craig-Schapiro, R., Segev, D.L., & Nicholas, L.H. (2018). Kidney offer acceptance at programs undergoing a Systems Improvement Agreement. *American Journal of Transplantation*, 18(9), 2182–2188. <https://doi.org/10.1111/ajt.14907>.

²⁴ Abecassis, M.M., Burke, R., Klintmalm, G.B., Matas, A.J., Merion, R.M., Millman, D., Olthoff, K., & Roberts, J.P. (2009). American Society of Transplant Surgeons Transplant Center Outcomes Requirements—A Threat to Innovation. *American Journal of Transplantation*, 9(6), 1279–1286. <https://doi.org/10.1111/j.1600-6143.2009.02606.x>.

²⁵ Kasiske, B.L., Salkowski, N., Wey, A., Israni, A.K., & Snyder, J.J. (2018). Scientific Registry of Transplant Recipients program-specific reports: where we have been and where we are going. *Current Opinion in Organ Transplantation*, 24(1), 58–63. <https://doi.org/10.1097/mot.0000000000000597>.

²⁶ Schenk, A.D., Logan, A.J., Sneddon, J.M., Faulkner, D., Han, J.L., Brock, G.N., & Washburn, W.K. (2022). Textbook Outcome as a Quality Metric in Living and Deceased Donor Kidney Transplantation. *Journal of the American College of Surgeons*, 235(4), 624–642. <https://doi.org/10.1097/xcs.0000000000000301>.

¹⁴ Rao, P.S., Schaubel, D.E., Guidinger, M.K., Andreoni, K.A., Wolfe, R.A., Merion, R.M., Port, F.K., & Sung, R.S. (2009). A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index. *Transplantation*, 88(2), 231–236. <https://doi.org/10.1097/TP.0b013e3181ac620b>.

¹⁵ Technical methods for the Program-Specific reports. (n.d.–b). <https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/>.

¹⁶ Axelrod, D.A., Schwantes, I.R., Harris, A.H., Hohmann, S.F., Snyder, J.J., Balakrishnan, R., Lentine, K.L., Kasiske, B.L., & Schnitzler, M.A. (2022). The need for integrated clinical and administrative data models for risk adjustment in assessment of the cost transplant care. *Clinical Transplantation*, 36(12), e14817. <https://doi.org/10.1111/ctr.14817>.

¹⁷ Israni, A.K., Hirose, R., Segev, D.L., Hart, A., Schaffhausen, C.R., Axelrod, D.A., Kasiske, B.L., & Snyder, J.J. (2022). Toward continuous improvement of Scientific Registry of Transplant Recipients performance reporting: Advances following 2012 consensus conference and future consensus building for 2022 consensus conference. *Clinical Transplantation*, 36(8), e14716. <https://doi.org/10.1111/ctr.14716>.

¹⁸ Technical methods for the Program-Specific reports. (n.d.–b). <https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/>.

enhance the accuracy and fairness of IOTA Model evaluations.²⁷ Given that the objective of the IOTA Model is to increase kidney transplant volume, we did not propose using SRTR's risk-adjustment methodology or using only SRTR's post-transplant outcomes adult kidney model strata and most recently available set of coefficients due to concerns that it creates stronger incentives for risk aversion compared to alternative approaches. Additionally, given that the composite graft survival rate is a rolling measure, we also had operational concerns in the use of SRTRs risk-adjustment methodology in future PYs.

We also considered but did not propose a risk-adjustment methodology that utilizes a Cox regression model,²⁸ which accounts for time-to-event data and can handle censored observations, making it a strong potential option for risk-adjustment in transplant outcome studies. In this methodology, censored observations²⁹ would include transplant recipients still alive at the end of the follow-up period, transplant recipients lost to follow-up before experiencing death or graft failure, and transplant recipients who withdrew from the study before the event occurred including two donor and five recipient variables.³⁰ Cox regression models have been cited for strong performance with extreme categories, discriminative

power, and interpretable results.^{31 32 33} This methodology also exhibits several inherent limitations, including restrictive assumptions concerning proportional hazards and linear effects of variables, inadequate handling of outliers within continuous variables and variable interactions, and constraints regarding the limited number of variables that can be incorporated into the modeling framework.^{34 35} While we recognize the importance of incorporating a time-to-event model in the risk-adjustment methodology to account for the length of graft survival, we chose not to propose a Cox regression model because it shows only moderate prediction accuracy overall and needs more validation.

We considered, but did not propose, a direct standardization risk-adjustment approach. This method applies standard population risk profiles³⁶ to all IOTA participants. Advantages to this method include simple interpretation and

precedence in Care Compare.³⁷ Disadvantages are that it requires large sample sizes and is less precise for smaller kidney transplant hospitals. We chose not to propose this method because it could disadvantage smaller IOTA participants.

We considered, but did not propose, an indirect standardization (observed-to-expected ratios) risk-adjustment approach, which compares observed outcomes to expected outcomes based on a risk model. Advantages to this method are that it preserves competitive scoring while ensuring fairness, works well with small sample sizes, provides precise estimates, and has precedence with the ESRD Quality Incentive Program (QIP) Standardized Mortality Ratio (SMR).^{38 39} We chose not to propose this approach because of the complexity of designing a robust risk model.

We considered, but did not propose, a hierarchical logistic regression approach with indirect standardization. This approach models graft survival probability at the individual transplant recipient level and accounts for kidney transplant hospital-level clustering effects.^{40 41} It produces observed-to-expected ratios for fair comparison and is compatible with cumulative measure calculation. The hierarchical logistic regression statistical model structure we considered using is illustrated in Equation 1:

Equation 1: Considered Hierarchical Logistic Regression Equation

$$\text{logit}(P_{ij}) = \beta_0 + \beta_1(\text{Age}_{ij}) + \beta_2(\text{Diabetes}_{ij}) + \beta_3(\text{DialysisVintage}_{ij}) + \beta_4(\text{KDPI}_{ij}) + \beta_5(\text{DCD}_{ij}) + \beta_6(\text{PRA}_{ij}) + u_j$$

Where:

P_{ij} = probability of graft survival for kidney transplant patient i in IOTA participant j

$u_j \sim N(0, \sigma_u^2)$ represents random IOTA participant—level effects

β^0 = intercept

β^1 – β^6 = fixed effect coefficients for risk adjustment variables

³⁷ Schokkaert, E., & Van De Voorde, C. (2008). Direct versus indirect standardization in risk adjustment. *Journal of Health Economics*, 28(2), 361–374. <https://doi.org/10.1016/j.jhealeco.2008.10.012>.

³⁸ Ibid.

³⁹ Scheffner, I., Gietzelt, M., Abeling, T., Marschollek, M., & Gwinner, W. (2020). Patient Survival After Kidney Transplantation: Important Role of Graft-sustaining Factors as Determined by Predictive Modeling Using Random Survival Forest Analysis. *Transplantation*, 104(5), 1095–1107. <https://doi.org/10.1097/tp.0000000000002922>.

⁴⁰ Hoffman, J.I. (2015). Survival analysis. In *Elsevier eBooks* (pp. 621–643). <https://doi.org/10.1016/b978-0-12-802387-7.00035-4>.

⁴¹ Hoffman, J.I. (2015a). Logistic regression. In *Elsevier eBooks* (pp. 601–611). <https://doi.org/10.1016/b978-0-12-802387-7.00033-0>.

²⁷ Snyder, J.J., Salkowski, N., Wey, A., Israni, A.K., Schold, J.D., Segev, D.L., & Kasiske, B.L. (2016). Effects of High-Risk Kidneys on Scientific Registry of Transplant Recipients Program Quality Reports. *American Journal of Transplantation*, 16(9), 2646–2653. <https://doi.org/10.1111/ajt.13783>.

²⁸ Cox regression, formally designated as Cox proportional hazards regression, constitutes a statistical methodology employed to examine the relationship between the time to event occurrence and one or more predictor variables. This analytical approach represents a robust statistical tool for investigating survival data, particularly when addressing time-to-event outcomes where the event of interest may encompass mortality, disease onset, or other clinically relevant occurrences.

²⁹ In the context of risk-adjustment, a censored observation refers to incomplete information about the true timing or occurrence of an outcome of interest, where only certain boundaries are known rather than the exact value. This phenomenon is particularly prevalent in healthcare risk adjustment models when tracking patient outcomes such as readmissions, complications, or mortality events. Properly accounting for censored observations through survival analysis methods is crucial in risk adjustment because ignoring censoring can lead to biased risk estimates, inaccurate patient stratification, and flawed predictive models that may unfairly penalize or reward healthcare providers based on incomplete outcome data.

³⁰ Senanayake, S., Kularatna, S., Healy, H., Graves, N., Baboolal, K., Sypek, M.P., & Barnett, A. (2021). Development and validation of a risk index to predict kidney graft survival: the kidney transplant risk index. *BMC Medical Research Methodology*, 21(1). <https://doi.org/10.1186/s12874-021-01319-5>.

³¹ Ibid.

³² Abd ElHafeez, S., D'Arrigo, G., Leonardis, D., Fusaro, M., Tripepi, G., & Roumeliotis, S. (2021). Methods to Analyze Time-to-Event Data: The Cox Regression Analysis. *Oxidative Medicine and Cellular Longevity*, 2021(1), 1–6. <https://doi.org/10.1155/2021/1302811>.

³³ Wey, A., Hart, A., Salkowski, N., Skeans, M., Kasiske, B.L., Israni, A.K., & Snyder, J.J. (2020). Posttransplant outcome assessments at listing: Long-term outcomes are more important than short-term outcomes. *American Journal of Transplantation*, 20(10), 2813–2821. <https://doi.org/10.1111/ajt.15911>.

³⁴ Senanayake, S., Kularatna, S., Healy, H., Graves, N., Baboolal, K., Sypek, M.P., & Barnett, A. (2021). Development and validation of a risk index to predict kidney graft survival: the kidney transplant risk index. *BMC Medical Research Methodology*, 21(1). <https://doi.org/10.1186/s12874-021-01319-5>.

³⁵ Scheffner, I., Gietzelt, M., Abeling, T., Marschollek, M., & Gwinner, W. (2020). Patient Survival After Kidney Transplantation: Important Role of Graft-sustaining Factors as Determined by Predictive Modeling Using Random Survival Forest Analysis. *Transplantation*, 104(5), 1095–1107. <https://doi.org/10.1097/tp.0000000000002922>.

³⁶ Standard population risk profiles represent a methodological framework that establishes a reference population to enable fair and meaningful comparisons between healthcare centers when patient populations exhibit different risk characteristics. The methodology employs all patients from all providers as the reference population, creating a uniform baseline against which all centers can be evaluated equitably. The process involves estimating the relationship between patient characteristics (represented as a vector of covariates X reflecting potential risk factors) and clinical outcomes for each healthcare center. This established relationship is then applied to all patients within the reference population to calculate expected outcomes as if every patient in the reference population had received treatment at each specific center under evaluation. Mathematically, this direct standardization approach can be expressed as $d_c = (1/N) \times \sum \hat{p}_c(X_i)$, where d_c represents the standardized outcome for center c , N denotes the total number of patients in the reference population, and $\hat{p}_c(X_i)$ represents the estimated probability for patient i 's characteristics at center c .

This equation risk-adjusts for age, diabetes status, dialysis vintage, Kidney Donor Profile Index (KDPI), Donation after Cardiac Death (DCD), which describes donors who are declared dead based on the cessation of circulatory and respiratory functions, and Panel Reactive Antibody (PRA). While we acknowledge that this approach demonstrates substantial technical merit, we believe that the level of complexity inherent in a hierarchical logistic regression statistical model structure would introduce operational risks and administrative burden. Transplant hospital-level variation may not be significant enough to warrant the added complexity,⁴² as such, we did not believe this was appropriate to propose for the IOTA Model.

We further considered, but did not propose, using machine learning-based risk-adjustment methodology, which uses ensemble methods (random forests, gradient boosting) for risk prediction. Machine learning-based risk-adjustment methodology captures complex interactions and has high predictive accuracy, but we chose not to propose it due to concerns that stakeholders may resist the “black box” machine learning-based risk-adjustment methodology and the limited precedence in quality measurement or at CMS.⁴³

We seek comment on the alternatives considered. Although we are not proposing to include a risk-adjustment methodology that also accounts for time-to-event data, we seek comment on whether a risk-adjustment methodology that considers transplant recipient and donor characteristics in addition to time-to-event data would be appropriate for calculating the composite graft survival rate in the quality domain and the best approach to use. We also seek comments on whether the proposed risk adjustment methodology should also include a time-to-event model when calculating the composite graft survival rate in the quality domain.

In the 2024 Final Rule (89 FR 96364), we finalized inclusion and exclusion criteria for the numerator and denominator when calculating the composite graft survival rate at § 512.428(b)(1)(iii) and (iv)(A). Since publication, many IOTA participants have asked CMS to clarify whether multi-organ transplants are included in both the numerator and denominator

when calculating the composite graft survival rate. Specifically, questions surrounded the current regulation at § 512.428(b)(1)(iii)(E), which states that CMS will exclude offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone) from the numerator. We clarified that this exclusion pertains to the offer phase of the transplant process. The actual transplant outcomes, when including a kidney, remain within the measurement scope. This interpretation ensures standardized application of the exclusion criterion while maintaining the measure’s intended focus on kidney transplant outcomes, regardless of concurrent multi-organ status. We also noted that the denominator calculation, as finalized in the 2024 Final Rule, does not contain exclusions for multi-organ transplants, which allows for comprehensive tracking of all kidney transplant outcomes. Since CMS clarified that multi-organ transplants are included in the calculation of the composite graft survival rate, many IOTA participants have urged CMS to exclude them from the metric due to the additional complexity of multi-organ transplantation.

In this proposed rule, we are proposing to update the regulation at § 512.428(b)(1)(iii)(E) to exclude multi-organ transplants (except for kidney/pancreas transplants) from the numerator. As a result, we are also proposing to update the provision at § 512.428(b)(1)(iv)(A) to read as follows: When calculating the composite graft survival rate, CMS only includes single-organ kidney transplants and kidney/pancreas transplants for transplant recipients who are 18 years of age and older at the time of the kidney transplant or kidney/pancreas transplant in the number of kidney transplants performed by the IOTA participant during each PY in the denominator. For purposes of the model, we propose at § 512.402 to define “single-organ kidney transplant” as a procedure in which a kidney alone is surgically transplanted from a living or deceased donor. We seek comment on our proposed definition of single-organ kidney transplant at proposed § 512.402.

We are proposing to exclude multi-organ transplants—procedures in which a kidney is surgically transplanted from deceased donor to a transplant recipient along with one or more organs transplanted simultaneously—except for kidney/pancreas transplants from the composite graft survival rate metric in recognition of the increased complexity of clinical outcomes associated with

these procedures.⁴⁴ In acknowledgment that multi-organ transplantation represents a distinct clinical scenario with potentially different risk profiles, complication rates, and outcomes compared to single-organ kidney transplantation, we believe it would be methodologically sound to analyze multi-organ transplant recipients separately from single-organ kidney transplant and kidney/pancreas transplant recipients. We are proposing to include kidney/pancreas transplants because, although these procedures are associated with greater surgical complexity and higher perioperative risk, clinical evidence demonstrates improved recipient survival compared with kidney transplantation alone among patients with Type 1 Diabetes Mellitus.⁴⁵ Kidney/pancreas transplantation offers a potential cure for both diabetes and kidney failure in this population.⁴⁶ Additionally, the inclusion of kidney/pancreas transplants within the composite graft survival rate metric aligns with established SRTR methodology, which includes kidney/pancreas transplants while excluding other multi-organ transplant procedures from their graft survival criteria.⁴⁷ We further note that that including kidney/pancreas transplants in the composite graft survival rate metric is consistent with the efficiency domain as described at § 512.426(b)(1)(iii)(E) where multi-organ kidney transplant offers (except for kidney/pancreas candidates that are also listed for kidney alone) are excluded from the organ offer acceptance rate ratio measure calculation.

We seek comment on our proposals at proposed §§ 512.428(b)(1)(iii)(E) and 512.428(b)(1)(iv)(A) to exclude multi-organ transplants except for kidney/pancreas transplants from the numerator and denominator when calculating the composite graft survival rate in the quality domain.

We considered retaining the inclusion of multi-organ transplantation in the calculation of the composite graft survival rate and solely revising the text

⁴⁴ Schold, J.D., & Mohan, S. (2021). A deeper dive into the impact of multiple-organ transplant policy on kidney transplant candidate prognoses. *American Journal of Transplantation*, 21(6), 2004–2006. <https://doi.org/10.1111/ajt.16508>.

⁴⁵ Ibid.

⁴⁶ Nagendra, L., Fernandez, C.J., & Pappachan, J.M. (2023). Simultaneous pancreas-kidney transplantation for end-stage renal failure in type 1 diabetes mellitus: Current perspectives. *World Journal of Transplantation*, 13(5), 208–220. <https://doi.org/10.5500/wjt.v13.i5.208>.

⁴⁷ Technical methods for the Program-Specific reports. (n.d.-b). <https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/>.

⁴² Leyland, A.H., & Groenewegen, P.P. (2020b). Multilevel Modelling for Public Health and Health Services Research. In *Springer eBooks*. Springer Nature. <https://doi.org/10.1007/978-3-030-34801-4>.

⁴³ Weissman, G.E., & Maddox, K.E.J. (2023). Guiding risk adjustment models toward machine learning methods. *JAMA*, 330(9), 807. <https://doi.org/10.1001/jama.2023.12920>.

of the regulation for clarification purposes. From 2000 to 2020 deceased donor kidney transplant volume doubled, while multi-organ transplants involving kidneys increased 6-fold during the same period.⁴⁸ Including multi-organ transplants in metrics could allow for more robust monitoring of multi-organ transplant outcomes and provide a more comprehensive assessment of transplant hospital capabilities and outcomes across all transplant types, ensuring a fair comparison of overall program performance.⁴⁹ However, we chose not to propose including multi-organ transplants because it would require rigorous analysis considering organ scarcity, dynamic decision-making, and heterogeneous practice patterns to develop risk-adjustment methodologies to account for multi-organ transplant allocation policies.⁵⁰

We considered excluding all multi-organ transplants, including kidney/pancreas transplants, from the

composite graft survival rate due to the increased surgical complexity and perioperative complications.⁵¹ However, we chose not to proposed excluding all multi-organ transplants because we believe that the improved clinical outcomes for kidney/pancreas transplants compared to kidney transplantation alone for Type 1 Diabetes Mellitus patients outweighed the added surgical complexity and potential perioperative complications.⁵² We seek comment on the alternatives considered. We also seek comment on whether CMS should include multi-organ transplants in the numerator and denominator and which multi-organ transplants should CMS include or exclude.

(b) Calculation of Points

In the 2024 Final Rule (89 FR 43518) that established the IOTA Model, we acknowledged commenter concerns about the proposed points allocation for the composite graft survival rate,

arguing that it unfairly penalizes transplant hospitals that accept higher-risk patients and suggesting modifications including lowering the threshold for maximum points from the 80th to 60th percentile for IOTA participants (89 FR 96365). In response to comments, we finalized an alternate scoring methodology, such that IOTA participants would be awarded points based on the national quintiles, as outlined in Table 1, such that IOTA participants that perform—

- At or above the 80th percentile would earn 20 points;
- In the 60th percentile to below the 80th percentile would earn 18 points;
- In the 40th percentile to below the 60th percentile would earn 16 points;
- In the 20th to below the 40th percentile would earn 14 points;
- In the 10th to below the 20th percentile would earn 12 points; and
- Below the 10th percentile would receive 10 points for the composite graft survival rate.

TABLE 1: COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to National Ranking	Points Earned
80 th Percentile ≤	20
60 th ≤ and < 80 th Percentile	18
40 th ≤ and < 60 th Percentile	16
20 th ≤ and < 40 th Percentile	14
10 th ≤ and < 20 th Percentile	12
< 10 th Percentile	10

In addition, we stated that we recognized that for PY 2 and future PYs there would be more events and a longer time horizon and plan to implement a more robust methodology that could account for both the likelihood of graft failure based on the donor and the recipient and could account for relative benefits of transplantation over remaining on dialysis (89 FR 96365). We direct readers to the 2024 Final Rule for a full discussion of this policy, our rationale for this approach, and alternatives considered (89 FR 96364 through 96366).

Upon further review of our methodology, we are proposing to modify the composite graft survival rate scoring methodology to allow for a more even scoring distribution for IOTA participants. Specifically, we propose in

Table 1 to paragraph (d) at § 512.428 that points earned would be based on the IOTA participants' performance on the composite graft survival rate relative to national ranking, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants, as outlined in Table 2.

We propose that points continue to be awarded based on national quintiles, as outlined in Table 2. We maintain our belief that utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score, as described in 42 CFR 512.430(b), where average performance yields half the number of points. The scoring is normalized, meaning an average performing IOTA participant earns 10

points out of 20, 50 percent of the total possible points. We recognize that there is an upper limit to the benefits of quality, and quintiles combine the highest 20 percent of performers in a point band.

In accordance with § 512.428, we propose the following updates to the allocation of points for the composite graft survival rate in Table 1 to paragraph (d) at § 512.428, as illustrated in Table 2:

- IOTA participants in the 80th percentile and above, 20 points.
- IOTA participants in the 60th to below the 80th percentile of performers, 15 points.
- IOTA participants in the 40th to below the 60th percentile of performers, 10 points.

⁴⁸ Husain, S. A., Hippen, B., Singh, N., Parsons, R. F., Bloom, R. D., Anand, P. M., & Lentine, K. L. (2023). Right-Sizing multiorgan allocation involving Kidneys. *Clinical Journal of the American Society of Nephrology*, 18(11), 1503–1506. <https://doi.org/10.2215/cjn.0000000000000242>.

⁴⁹ Ibid.

⁵⁰ Schold, J. D., & Mohan, S. (2021). A deeper dive into the impact of multiple-organ transplant policy on kidney transplant candidate prognoses. *American Journal of Transplantation*, 21(6), 2004–2006. <https://doi.org/10.1111/ajt.16508>.

⁵¹ Callaghan, C. J., Ibrahim, M., Counter, C., Casey, J., Friend, P. J., Watson, C. J., & Karydis, N.

(2021). Outcomes after simultaneous pancreas–kidney transplantation from donation after circulatory death donors: A UK registry analysis. *American Journal of Transplantation*, 21(11), 3673–3683. <https://doi.org/10.1111/ajt.16604>.

⁵² Ibid.

- IOTA participants in the 20th to below the 40th percentile of performers, 5 points.
- IOTA participants who are below the 20th percentile of performers, 0 points.

TABLE 2: PROPOSED COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80 th Percentile relative to target OR for comparison	Equals 80 th percentile	Greater than 80 th percentile	20
60 th Percentile	Equals 60 th percentile	Less than 80 th percentile	15
40 th Percentile	Equals 40 th percentile	Less than 60 th percentile	10
20 th Percentile	Equals 20 th percentile	Less than 40 th percentile	5
20 th Percentile	N/A	Less than 20 th percentile	0

Utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score, as described in 42 *CFR* 512.430(b), where average performance yields half the number of points. The scoring is normalized, meaning an average performing IOTA participant earns 10 points out of 20, 50 percent of the total possible points. We recognize that there is an upper limit to the benefits of quality, and quintiles combine the highest 20 percent of performers in a point band.

Additionally, in the 2024 Final Rule (89 *FR* 96379), we stated that we would continue to assess our quality domain methodology and how to best balance incentives in the efficiency domain and quality domain and address a new or updated policy pursuant to future notice and comment rule making. Furthermore, as proposed in section II.B.2.b.(2).(a). of this proposed rule, we are proposing to incorporate a risk-adjustment methodology to the calculation of the composite graft survival rate measure. As such, we believe that the proposed allocation of points, as illustrated in Table 2, is necessary to account for the proposed composite graft survival rate risk-adjustment methodology, as described in section II.B.2.b.(2).(a). of this proposed rule, and best balances incentives in the quality domain.

We considered applying a two-scoring system in which we would determine an achievement score and improvement score and award the point equivalent to the higher value between the two scores; similar to the organ offer acceptance rate ratio scoring methodology as described at § 512.426(c). In this considered two-scoring system, the achievement score would reflect the proposed scoring approach on the composite graft survival rate, as illustrated in Table 2 of this section. For improvement scoring on the composite graft survival rate, we considered the following methodologies:

- In accordance with the organ offer acceptance rate ratio improvement

scoring methodology at § 512.426(c)(2)(ii).

- Improvement relative to national ranking from previous PY.
- Improvement over 2 PYs. In this methodology, improvement scoring would only be awarded twice (PYs 4 and 6) and would measure improvement by comparing PYs 1–2 to PYs 3–4 and PYs 3–4 to PYs 5–6.

We considered applying a two-scoring system in which we would determine an achievement score and improvement score and award the point equivalent to the higher value between the two scores because we recognize that if an IOTA participant does not do well one PY on the composite graft survival rate, as described at § 512.428(b)(1), that it may be difficult for it to improve during the model performance period. However, we chose not to propose this methodology (two-scoring system) because we still had concerns over our ability to measure improvement year-over-year due to potentially small numbers. Furthermore, given that we are proposing to incorporate a risk-adjustment methodology, as proposed in section II.B.2(b)(2)(a) of this proposed rule, we believe that our proposed scoring approach rewards both achievement and improvements and is a more rigorous scoring methodology. Although we are not proposing to include this alternative, we seek comment on whether a two-scoring system methodology would be appropriate for the composite graft survival rate and the best approach for measuring improvement.

We seek comment on our proposed composite graft survival rate scoring methodology at proposed Table 1 to Paragraph (d) at § 512.428 for purposes of assessing quality domain performance for each IOTA participant. We also seek comments on alternatives considered. Additionally, we seek comment on whether there is a scoring methodology on the composite graft survival rate that recognizes IOTA participants whose post-transplant

outcomes are at an acceptable level and how to define an acceptable level (for example, 1 standard deviation of the national risk-adjusted rate or some other way).

3. Payment

a. Background

For the IOTA Model, we proposed and finalized an alternative payment model (APM) structure that incorporates both upside and downside risk to existing Medicare fee-for-service (FFS) payments for kidney transplantations. The IOTA Model will test whether performance-based payments, including the potential for an upside or downside risk payment, to IOTA participants increases access to kidney transplants for attributed patients while preserving or enhancing quality of care and reducing kidney transplant hospital expenditures.

In the 2024 Final Rule (89 *FR* 43518), we finalized provisions regarding downside risk payments and other payments as described in § 512.430, where, we specified the methodologies for upside risk payments, neutral zone, and downside risk payments for IOTA participants. For upside risk payments, if the IOTA participant's final performance score is 60 points or above, CMS will calculate the IOTA participant's upside risk payment by subtracting 60 from the IOTA participant's final performance score, dividing the resulting amount by 40, multiplying the calculated amount by \$15,000 and multiplying that amount by the total number of Medicare kidney transplants performed by the IOTA participant during the relevant PY. For downside risk payments, beginning in PY 2, CMS will calculate the downside risk payment by subtracting the IOTA participant's final performance score from 40, divide that number by 40, multiplying the resulting amount by \$2,000 and multiplying that amount by the total number of Medicare kidney transplants performed by the IOTA participant during the relevant PY.

b. Alternative Payment Design

In the 2024 Final Rule (*89 FR 96383*), CMS proposed and finalized two-sided performance-based payments for “Medicare kidney transplants,” defined at § 512.402 as kidney transplants furnished to attributed patients whose primary or secondary insurance is Medicare FFS, as identified in Medicare FFS claims with MS–DRGs 008, 019, 650, 651 and 652.

In our initial proposal in the 2024 Proposed Rule (*89 FR 43570*), we stated that we had considered including beneficiaries with Medicare Advantage (MA) as well in the definition of Medicare kidney transplants. As stated at *89 FR 96382*, we decided to finalize the policy as proposed as we did not believe that the additional incentive effects from including MA in the calculation for upside and downside risk payments were necessary at that point to provide sufficient incentive to test the model. We noted our plan to further engage with MA plans to think about the incentives in the IOTA Model and those set up by MA plans. We also planned to monitor relative enrollment of beneficiaries who receive kidney transplants in Medicare FFS as opposed to MA to see if further policy changes would be necessary for future years of the IOTA Model.

Since publication of the 2024 Final Rule, CMS has continued to assess its position regarding the potential inclusion of beneficiaries enrolled in MA within the definition of Medicare kidney transplants for several key reasons. This ongoing evaluation reflects CMS’s commitment to monitoring changes in MA enrollment trends, analyzing potential impacts on model incentives and Medicare Trust Fund savings, and considering the operational and statutory implications of such an inclusion. CMS is soliciting public comment on this issue more broadly, on whether to include MA beneficiaries within the IOTA model, as well as on the specific considerations and requests for input if CMS were to proceed with such an approach.

We seek comment on whether CMS should include MA transplants in the calculation for upside risk payments and downside risk payments. We also seek comment on our consideration to update the definition of Medicare kidney transplants at § 512.402 to include attributed patients with MA, to further the incentive effects of the IOTA Model and in recognition of the growth of MA enrollment relative to Medicare FFS.

Per the Announcement of Calendar Year (CY) 2026 Medicare Advantage

(MA) Capitation Rates and Part C and Part D Payment Policies, Medicare FFS enrollment of the total ESRD population enrolled in Medicare is currently about 45 percent in 2024 and is projected to drop to approximately 40 percent by 2028. This means that updating the definition of Medicare kidney transplant would increase the maximum potential upside risk payments, per the definition in § 512.430(b)(1)(iv), for an IOTA participant given that the number of Medicare kidney transplants performed would on average also be increasing. Under this approach, CMS could decrease the maximum upside risk payment from \$15,000 to \$10,000 per Medicare kidney transplant. CMS analyses project that the decreased upside risk payment multiplier and increased number of kidney transplants that upside and downside risk payments would apply to under such an approach would approximately offset each other and approximately have a net zero impact on model savings from this combination of provisions. CMS could make this change to balance our goals of creating a strong incentive for IOTA participants to increase their number of kidney transplants and ensure savings for the Medicare Trust Fund. We seek comment on our consideration to decrease the maximum upside risk payment from \$15,000 to \$10,000 per Medicare kidney transplant should CMS update the definition of Medicare kidney transplant to include MA beneficiaries.

While there may be benefits to including kidney transplants furnished to MA beneficiaries in the calculation for the upside risk payment and downside risk payment, CMS continues to consider potential concerns or disadvantages. One potential issue is whether the payments made under such an approach could affect the contracting relationship between a Medicare Advantage organization (MAO) and the IOTA participant. We seek feedback from both IOTA participants and from MAOs about any potential effect that inclusion of beneficiaries with MA in the definition of Medicare kidney transplants in the IOTA Model could have on their contracting relationships.

Pursuant to the non-interference clause in section 1854(a)(6)(B)(iii) of the Act, CMS does not interfere in payment arrangements between MA organizations and their contracted providers. At the same time, CMS is interested in the potential in achieving greater alignment between MA and Medicare FFS payment methodologies.

Given the factors described in this section, CMS is soliciting comments from a broad range of stakeholders and

interested parties, including MA plans, beneficiary advocates, healthcare providers, and industry experts. We are particularly interested in comments on how MA could play a role in the IOTA Model. Specifically, we are inviting public comment on the following:

- What are any innovative transplant-related strategies being tested by MAOs?
- What are the anticipated effects that implementation of this contemplated policy modification would have on the kidney transplant strategic initiatives currently under consideration by MAOs?

- How does the growth of MA compared to Medicare FFS affect participation and incentives in the IOTA Model?

- What do MA plans consider as their role in the kidney transplant process?

- What performance metrics do MA plans consider when evaluating kidney transplant hospitals?

- What performance metrics are the most important for a kidney transplant hospital?

- What are kidney transplant hospitals’ experiences with kidney transplant performance metrics from private insurers and MAOs, outside of their experience with the IOTA Model?

- How do the IOTA Model performance metrics play a role in the relationship between an MA plan and a contracted provider?

- If any, what are potential effects that MA inclusion in the model could have on a contracting relationship between providers and MA plans (for example, negotiation of terms)?

- If any, what are potential unintended consequences of MA inclusion on utilization management tools employed by MAOs?

- Would an MA plan consider implementing similar performance metrics to those included in the IOTA Model?

- Under what circumstances is it appropriate for CMS to consider directly incentivizing a behavior change from a provider contracted in an MA plan?

We extend our sincere appreciation in advance to all commenters, as their valuable feedback will serve to inform future CMS policy actions in this domain.

c. Performance-Based Payment Method

(1) Determine Final Performance Score Range Category

In the 2024 Final Rule (*89 FR 96384*), we finalized using the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone at § 512.430(a), as illustrated in Table 3. Additionally, we

finalized the definitions of downside

risk payment, upside risk payment, and
neutral zone at § 512.402.

TABLE 3: PERFORMANCE-BASED PAYMENTS BY FINAL PERFORMANCE SCORE

Final Performance Score	PY 1	PY 2 – 6
60-100	Upside Risk Payment	Upside Risk Payment
41-59 (Inclusive)	Neutral Zone	Neutral Zone
0 - 40	Neutral Zone	Downside Risk Payment

We previously finalized for PYs 2 through 6 that an IOTA participant would qualify for the neutral zone if their final performance scores were between 41 and 59 points (inclusive) at § 512.430(b)(2)(ii), as illustrated in Table 3. Since publication some IOTA participants have expressed confusion about final performance scores of 40 points and 60 points. In this proposed rule, we are proposing to update this provision to clarify language about final performance scores of 40 points and 60 points. Given the final performances scores described in Table 3, a score of 40 points results in zero downside risk payments and a score of 60 points results in zero upside risk payments. As a result, we are proposing to clarify the language in the rule to address this point and to further clarify the endpoints where an IOTA participant could receive an upside risk payment, be in the neutral zone, or receive a downside risk payment.

We propose at § 512.430(b)(1) to clarify that if in PYs 1–6, the IOTA participant’s final performance score is above 60 points, the IOTA participant qualifies for an upside risk payment. Additionally, we propose at § 512.430(b)(2)(ii) to clarify that for PYs 2 through 6, if an IOTA participant’s final performance is between 40 to 60 points (inclusive), the IOTA participant qualifies for the neutral zone. Finally, we propose at § 512.430(b)(3) to clarify that if an IOTA participant’s final performance score is below 40 points in PYs 1 through 6, the IOTA participant qualifies for a downside risk payment.

We seek comment on our proposals at proposed § 512.430(b)(1), 512.430(b)(2)(ii), and 512.430(b)(3)(i) to clarify the appropriate final performance score ranges for an IOTA participant to be eligible to receive an upside risk payment, be in the neutral zone, or receive a downside risk payment.

(2) Downside Risk Payment

In the 2024 Final Rule (89 FR 96386), we finalized provisions regarding

downside risk payments and other payments as described in § 512.430. Additionally, we finalized the definition of downside risk payment and established the methodology for its calculation. Since publication, we recognized that this section contains a typographical error that should be corrected regarding the deadline for downside risk payments and lacks specificity regarding what happens if the IOTA participant fails to make the downside risk payment for a given PY.

Therefore, we propose to update the provision at § 512.430(d)(6)(ii) to clarify that the IOTA participant must pay the downside risk payment to CMS in a single payment within 60 days, rather than at least 60 days, after the date on which the demand letter is issued. Where the IOTA participant fails to repay CMS in full for all monies owed, CMS would invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, pursuant to 31 U.S.C. 3711(g).

We seek comment on our proposal at proposed § 512.430(d)(6)(ii) to clarify that full payment of a downside risk payment must be received within 60 days after the demand is made and that it will be considered delinquent debt if not received within that time period.

(3) Extreme and Uncontrollable Circumstances

In the 2024 Final Rule (89 FR 96389), we finalized provisions regarding a policy related to Extreme and Uncontrollable Circumstances (EUC) at § 512.436. We finalized that for the IOTA Model, CMS would apply determinations made under the QPP with respect to whether an extreme and uncontrollable circumstance has occurred and the affected area during the PY and that CMS has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas. If CMS determined then that an EUC occurred, CMS could then reduce the amount of

the IOTA participant’s downside risk payment, if applicable, prior to recoupment and calculate that reduction based on the percentage of total months during the PY affected by the extreme and uncontrollable circumstance and the percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance.

Since publication of the 2024 Final Rule, CMS has been reviewing its policy towards EUC events. The current EUC policy for the IOTA Model reflects the policy used for many accountable care organization (ACO) type models, including the ACO Realizing Equity, Access, and Community Health (ACO REACH) and Kidney Care Choices (KCC) Models. However, CMS recognizes that the policies used for the QPP may not be appropriate for the IOTA Model, given that the QPP policies may not account for broader impacts that an EUC might have on an IOTA participant’s ability to perform in the model if allocation systems were disrupted due to an emergency or if there were disaster conditions that could disproportionately affect post-transplant outcomes. The current provision only potentially reduces downside payments and does not account for any change in the model inputs or reporting period that may affect an IOTA participant’s performance score if their ability to perform on one of more of the measures were disrupted by an EUC event.

Therefore, we propose to update the provision at § 512.436(a)(1) to state that CMS may, at its sole discretion, apply flexibilities if the IOTA participant is located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act and if the IOTA participant is located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act. Additionally, we propose at § 512.436(a)(2) that CMS has the sole discretion to determine the time period during which payment and reporting

flexibilities are provided to the IOTA participant. Finally, we propose at § 512.436(b) that CMS may, at its sole discretion, adjust the direction and the magnitude of the upside or downside risk payments, if applicable, prior to recoupment or payment, for the IOTA participant if the IOTA participant is participating in the IOTA Model when CMS has declared such an emergency period.

We seek comment on our proposal at proposed § 512.436(a)(1) to clarify how CMS will determine if an emergency situation occurs for an IOTA participant beginning in PY 2 of the Model. We also seek comment about the flexibilities at proposed § 512.436(b) that CMS may adjust upside or downside payments to respond to a potential emergency faced by an IOTA participant.

4. Other Requirements

a. Transparency Requirements

(1) Publication of Selection Criteria for Kidney Transplant Evaluations and Waitlisting

In the 2024 Final Rule (*89 FR 96394*) that established the IOTA Model, we finalized that IOTA participants must publicly post their patient selection waitlist criteria on a website by the end of PY 1 at § 512.442(a). Additionally, we discussed commenters' suggestions to provide IOTA participants with flexibility in updating waitlist selection criteria and balancing accuracy with resource constraints. We direct readers to the 2024 Final Rule for a full discussion of this policy, a summary of the comments received, and our responses to those comments (*89 FR 96394* through *96397*).

To advance transparency for individuals seeking transplant waitlist access and to improve patient health literacy regarding transplant program evaluation processes, we propose to revise § 512.442(a). Specifically, we are proposing to revise the paragraph heading at § 512.442(a) to remove "transplant patient" from Publication of transplant patient selection criteria and to redesignate the current requirement from § 512.442(a) to § 512.442(a)(1). For all subsequent PYs, we propose at § 512.442(a)(2) that the IOTA participant must review its publicly posted criteria used for evaluating and selecting patients for addition to its kidney transplant waitlist and ensure that the information on its website is up to date by the end of each relevant PY. The proposed modifications aim to improve patient health and safety while reducing disparities in access to transplant evaluations and seek to strengthen the transparency framework within

transplant program evaluation processes, thereby facilitating improved patient understanding and equitable access to transplant services.

In recognition that transplant hospitals may make changes to its patient selection criteria for determining a patient's suitability for placement on a waitlist we believe that this proposed provision would capture these changes and ensure that the information on its website is up to date in future PYs. We also believe this policy would address commenters' suggestions and provide flexibility in updating its waitlist selection criteria on its website. We seek comment on these proposals at proposed § 512.442(a)(1) and (2).

We alternatively considered requiring IOTA participants to update its publicly posted patient selection waitlist criteria to ensure that this information on its websites remain current within timeframes of 30 days, 60 days, or 90 days following any modification. We acknowledge that these alternative timeframes would provide more accurate and timely information while facilitating informed patient decision-making. However, we are proposing that IOTA participants must review and update its publicly posted patient selection waitlist criteria by the end of each relevant PY to align with current and proposed publication requirements for patient selection criteria, as described in section II.B.4.a.(1). of this proposed rule, in the IOTA Model. We seek public comment on the alternatives considered.

If a transplant program performs living donor transplants, the transplant program's living donor selection criteria must be consistent with the general principles of medical ethics. The program must use written donor selection criteria to determine the suitability of candidates for donation. Transplant programs must also ensure that a prospective living donor receives a medical and psychosocial evaluation, document in the living donor's medical records the living donor's suitability for donation, and document that the living donor has given informed consent. We recognize that the current regulations in the IOTA Model do not address publicly posting living donor selection criteria. As such, for IOTA participants performing living donor kidney transplants, we propose that those IOTA participants must publicly post on its website its living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients by the end of PY 2 at § 512.442(a)(3)(i). For all subsequent PYs, we propose at § 512.442(a)(3)(ii) that the IOTA participant must review

its living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients on its website and ensure that the information publicly posted on its website is correct by the end of each relevant PY.

We believe requiring IOTA participants that perform living donor kidney transplants to publicly post on their website its living donor selection criteria would significantly enhance transparency in the kidney transplant system by making living donor selection criteria readily accessible to patients, families, and referring physicians, allowing them to make more informed decisions about transplant options and understand the specific requirements each IOTA participant uses to evaluate potential living donors. Additionally, we believe this requirement would empower patients by providing them with clear information about what criteria their kidney transplant hospital uses to assess living donors, enabling patients, families, and referring physicians to better prepare potential donors and understand the evaluation process, which could ultimately lead to more successful living donor kidney transplant outcomes. We seek comment on these proposals at proposed § 512.442(a)(3)(i) and (ii). Finally, we propose finalizing these requirements only if they are not redundant with other Department of Health and Human Services (HHS) guidance.

We alternatively considered requiring IOTA participants to update its publicly posted living donor selection criteria to ensure that this information on its websites remains current within timeframes of 30 days, 60 days, or 90 days following any modification. We recognize that this alternative would provide more accurate and timely information while facilitating informed patient decision-making processes. However, we proposed that IOTA participants must review and update their publicly posted living donor selection criteria by the end of each relevant PY to align with current and proposed publication requirements for patient selection criteria, as described in section II.B.4.a.(1). of this proposed rule, in the IOTA Model. We seek public comment on the alternatives considered.

As previously suggested by commenters in the 2024 Final Rule (*89 FR 96396*), we considered creating a standardized waitlist selection criteria template for IOTA participants to use that would include specific details of waitlist selection criteria such as absolute contraindications, financial and insurance requirements, and psychosocial factors that impact listing decisions. We also considered but did

not propose creating a standardized living donor selection criteria template for IOTA participants to use that would be relative or absolute contraindications for donating a kidney. While we are not proposing to provide standardized waitlist selection criteria or living donor selection criteria templates that IOTA participants would be required to use, we are seeking public comment regarding whether the inclusion of such templates would be preferable and would not impose additional administrative burden upon IOTA participants. Additionally, beyond the requirements outlined in 42 CFR 482.90, we seek comment on what specific requirements or specific detail should be included in standardized waitlist selection criteria or living donor selection criteria templates.

(2) Publication of IOTA Participant Selection Criteria

In the Specialty Care Models final rule (85 FR 61114), CMS established certain general provisions in 42 CFR part 512 subpart A that apply to all Innovation Center models. One such general provision pertains to rights in data. Specifically, in the Specialty Care Models final rule, we stated that to enable CMS to evaluate the Innovation Center models as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to § 512.150, in § 512.140(a) we would use any data obtained in accordance with §§ 512.130 and 512.135 to evaluate and monitor the Innovation Center models (85 FR 61124). We also stated that, consistent with section 1115A(b)(4)(B) of the Act, CMS would disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. We stated that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources. We finalized these policies in 42 CFR 512.140(a).

Consistent with these provisions, in the 2024 Final Rule (89 FR 96403) that established the IOTA Model, we finalized our proposals to publish results from all PYs of the IOTA Model. Specifically, we stated that, for each PY, we intend to identify each IOTA participant for the PY and to post performance across the achievement domain, efficiency domain, and quality domain for each IOTA participant on the IOTA Model website annually, as

they become available (89 FR 96403). We maintain our belief that this not only meets CMS requirements but also demonstrates transparency for the transplant community.

Adding to these provisions, we propose to publish IOTA participant waitlist selection criteria and the proposed living donor selection criteria, as described in section II.B.4.a.(1). of this proposed rule, on the IOTA Model website. Specifically, for each PY, we intend to publish waitlist selection criteria and the proposed living donor selection criteria, as described in section II.B.4.a.(1). of this proposed rule, for each IOTA participant on the IOTA Model website by the end of the second quarter of each subsequent PY. We propose to finalize this requirement only if they are not redundant with other HHS guidance. We believe that the release of this information on the IOTA Model website would inform the public about IOTA participants' selection criteria while in the IOTA Model. Furthermore, we believe the release of this information on the IOTA Model website would address previous suggestions from commenters to provide this information in a centralized location (89 FR 96396). Lastly, we note that this would supplement, not replace, the publication of selection criteria requirements in the IOTA Model.

We seek comment on our proposal to post this information to the IOTA Model website, as well as the information we intend to post and the manner and timing of the posting.

(3) Transparency Into Kidney Transplant Organ Offers

As discussed in the 2024 Final Rule (89 FR 96397), those active on a kidney transplant waitlist may receive organ offers at any time. However, there is currently no requirement for providers to discuss organ offers with their patients. A provider may decline an organ offer for any number of reasons;⁵³ however, declining without disclosing the rationale to the patient may miss an important opportunity for shared decision-making.

⁵³ Reasons for declining include concerns about the quality of the donor organ, such as, donor comorbidity, evidence of disease or injury, or other clinical factors that could affect long-term graft survival. Providers may also decline an offer if the organ is not compatible with the candidate's blood type or antibody profile, which could increase the risk of rejection. Patient-specific factors may also play a role, such as the candidate not being medically stable for surgery at the time of the offer, not meeting weight or other health requirements, or having unresolved infections or comorbidities. In some cases, logistical issues like timing, transport of the organ, or operating room availability may contribute to a declined offer.

After 3 years on the waiting list, approximately 27 percent of kidney transplant waitlist patients receive a deceased donor kidney transplant (DDKT), while 33 percent remain on the waitlist.⁵⁴ Communication with waitlisted patients is limited, typically focusing only on discussing eligibility requirements and notifying them when a transplant program plans to accept an organ offer.⁵⁵ Furthermore, the National Academy of Sciences, Engineering, and Medicine (NASEM) released a significant report in 2022 titled "Realizing the Promise of Equity in the Organ Transplantation System."⁵⁷ The report put forth several key recommendations to enhance transparency and patient engagement in the organ transplantation process. Notably, it called for transplant hospitals to increase transparency with patients regarding declined organ offers, including providing specific details about the number of declined offers and the rationale behind these decisions. Secondly, the report advocated for modifications to the OPTN contract, emphasizing the need for transplant hospitals to actively involve patients in the decision-making process when accepting or rejecting organs.

We also note the recent release of two studies related to notifying patients on the waiting list about declined organ offer, since we issued the 2024 Proposed Rule. One study conducted interviews with patients and nephrologists about this issue of organ offer transparency.⁵⁸ This study found that among 755 patient respondents surveyed, 64 percent expressed a preference to

⁵⁴ Lentine, K.L., Smith, J.M., Miller, J.M., Bradbrook, K., Larkin, L., Weiss, S., Handarova, D.K., Temple, K., Israni, A.K., & Snyder, J.J. (2023). *OPTN/SRTR 2021 Annual Data Report: Kidney*. *American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, 23(2 Suppl 1), S21–S120. <https://doi.org/10.1016/j.ajt.2023.02.004>.

⁵⁵ Bergeron, M. (2020). *Transplant Center Criteria and Inequalities Within Transplant Wait Listing Process* [Thesis]. <https://stars.library.ucf.edu/etd2020/175/>.

⁵⁶ Rasheed, H.A., Pensler, M., Diaz, S., Roney, E., Barrett, M., & Sonnenberg, E.M. (2024). Organ Offer Review Cards: Improving Transparency on the Kidney Transplant Waitlist. *Clinical Transplantation*, 38(7). <https://doi.org/10.1111/ctr.15388>.

⁵⁷ National Academies of Sciences, Engineering, and Medicine. (2022a). *Realizing the Promise of Equity in the Organ Transplantation System* (K.W. Kizer, R.A. English, & M. Hackmann, Eds.). National Academies Press. <https://doi.org/10.17226/26364>.

⁵⁸ Husain, S.A., Rubenstein, J.A., Ramsawak, S., Huml, A.M., Yu, M.E., MacLay, L.M., Schold, J.D., & Mohan, S. (2025). Patient and Provider Attitudes Towards Patient-Facing Kidney Organ Offer Reporting. *Kidney International Reports*, 10(4), 1122–1130. <https://doi.org/10.1016/j.ekir.2025.b01.013>.

receive organ offer reports. Of the total patient respondents, 87 percent indicated that transplant hospitals should be mandated to inform candidates about the organ offers they receive, while 62 percent specified that candidates should be notified following each individual offer. Additionally, 73 percent of nephrologists reported that they believe patients should be provided with offer information. The second study, conducted at the University of Michigan in 2022, developed and evaluated an innovative Organ Offer Review Card (OORC) designed to enhance transparency in kidney transplant waitlist processes.⁵⁹ In response to the 2022 NASEM recommendations for increased accountability in organ offer decisions, researchers created a prototype tool that summarizes patients' organ offers and reasons for decline over a 6-month period. This study employed a cross-sectional survey design to assess patients' perceptions, attitudes, and feedback regarding the OORC, while also examining perspectives on shared decision-making for organ offers. The survey found that of 60 randomly selected patients, 43 were reached by phone and 17 (39.5 percent) completed the survey, almost all of whom believed it was important to be involved in the decision-making process about organ offers and all of them wanted to understand why organs were declined on their behalf. The study further found that a vast majority of patients believe the information enhanced their understanding of the transplant process and believed that seeing this information would increase their trust in the transplant hospital. While these two studies have limited sample size, they represent a growing interest in how to foster organ offer transparency and patient-centered care.

As described in the 2024 Final Rule (89 FR 96397), we proposed to add requirements to increase transparency for IOTA waitlist patients who are Medicare beneficiaries regarding the volume of organ offers received on their behalf while on the waitlist. Specifically, we proposed that for each month an organ is offered to an IOTA waitlist patient who is a Medicare beneficiary, an IOTA participant must inform the Medicare beneficiary, on a monthly basis, of the number of times an organ is declined on the Medicare beneficiary's behalf and the reason(s) for

the decline. However, following feedback from public comments that this policy would impose a significant administrative burden on IOTA participants, we did not finalize this transparency requirement to consider alternatives, such as an alternative frequency of sharing declined organ offers with the Medicare beneficiary. We also stated that we remain invested in evaluating alternative transparency opportunities for patients on the waiting list with the transplant community to fulfill this important need. We direct readers to the 2024 Final Rule for more information on the stakeholder comments regarding that proposal and our responses to those comments (89 FR 96397 through 96403).

Based on the feedback we received, we are proposing an alternative approach for the model. Specifically, for PYs 3 through 6 we propose at §§ 512.442(b) and (b)(1) that IOTA participants would be required to notify eligible IOTA waitlist beneficiaries of the number of times an organ is declined on the eligible IOTA waitlist beneficiary's behalf at least once every 6 months that the eligible IOTA waitlist beneficiary is on the IOTA participant's waitlist. For purposes of the model, we propose to define "eligible IOTA waitlist beneficiaries" at § 512.402 as IOTA waitlist patients, as defined at § 512.402, who are Medicare beneficiaries and meet all of the following criteria:

- Are active on the IOTA participant's waitlist; and
- Have accrued a minimum of 3 years of waiting time on the IOTA participant's waitlist.

We note that our rationale for this proposal is explained further later in this section. We seek comment on our proposed definition of eligible IOTA waitlist beneficiaries at proposed § 512.402.

We are proposing that, beginning in PY 3, IOTA participants would be required to provide notification of declined organ offers for eligible IOTA waitlist beneficiaries, as defined at proposed § 512.402, who are on their waitlist every 6 months, starting July 1 of PY 3, subject to the following conditions. IOTA participants would only have to notify eligible IOTA waitlist beneficiaries with at least 3 years of accrued waiting time. IOTA participants would have to provide this notification every 6 months after that time period. For example, if an eligible IOTA waitlist patient has 2 years and 11 months of accrued waiting time on July 1 of PY 3, the IOTA participant would not need to provide this notification to that eligible IOTA waitlist patient

because they have not accrued 3 years of waiting time. Alternatively, if an eligible IOTA waitlist patient has 3 years and 11 months of accrued waiting time on July 1 of PY 3, the IOTA participant would need to provide this notification to that eligible IOTA waitlist patient because they have accrued 3 years of waiting time. This proposed timeframe is designed to balance between the operational burden for IOTA participants and when eligible IOTA waitlist beneficiaries could start getting transplantable offers. To respect beneficiary choice, eligible IOTA waitlist beneficiaries would be able to opt out of this notification.

For each 6-month period in which an organ offer is received and declined, we propose at § 512.442(b)(1)(i)(A) through (F) that the IOTA participant must provide notifications to each eligible IOTA waitlist beneficiary, as defined at proposed § 512.402, and include all of the following:

- How much wait-time the eligible IOTA waitlist beneficiary is currently listed with and their percent panel-reactive antibody (PRA)⁶⁰ value.
- In each 6-month period, how many match-runs, as defined at § 512.402, the eligible IOTA waitlist beneficiary came up on and how many donors they received kidney organ offers from;
- Unique patient-specific considerations for that eligible IOTA waitlist beneficiary for which deceased donor kidneys the IOTA participant would consider for that eligible IOTA waitlist beneficiary.
- The refusal reason(s)⁶¹ why offers were declined based off the OPTN refusal codes in plain language;
- Of the deceased donor kidney organ offers declined for that eligible IOTA waitlist beneficiary how many of those kidneys were transplanted in another kidney transplant patient, as defined at § 512.402; and
- Potential avenues to accelerate access to transplant (for example,

⁶⁰ As defined by the OPTN, the percent PRA value is a measure of a patient's level of sensitization to HLA antigens. It is the percentage of cells from a panel of blood donors against which a potential recipient's serum reacts. The PRA reflects the percentage of the general population that a potential recipient makes antibodies (is sensitized) against. For example, a patient with a PRA of 80 percent will be incompatible with 80 percent of potential donors. Kidney patients with a high PRA are given priority on the waiting list. The higher the PRA, the more sensitized a patient is to the general donor pool, and thus the more difficult it is to find a suitable donor. A patient may become sensitized as a result of pregnancy, a blood transfusion, or a previous transplant.

⁶¹ Refusal reasons, as defined by the OPTN, are number codes used on a match run to show the reason an organ was not accepted for a potential transplant recipient (PTR) receiving the offer.

⁵⁹ Rasheed, H.A., Pensler, M., Diaz, S., Roney, E., Barrett, M., & Sonnenberg, E.M. (2024). Organ Offer Review Cards: Improving Transparency on the Kidney Transplant Waitlist. *Clinical Transplantation*, 38(7). <https://doi.org/10.1111/ctr.15388>.

exploring living donation, being waitlisted at multiple kidney transplant hospitals, reviewing transplant organ offer acceptance criteria or ensuring they meet and maintain the patient criteria for their chosen kidney transplant hospital(s), such as adhering to weight loss recommendations).

We believe that these proposed requirements would best balance transparency for the eligible IOTA waitlist beneficiary and ensure the information is as useful as possible for them. We note that we did not finalize this provision in the 2024 Final Rule and stated that we were very interested in transparency, but due to the many concerns that we received, we recognized that monthly notification to Medicare beneficiaries regarding volume and reason for organ decline could have been very burdensome to IOTA participants and their staff in PY 1 since this was a new initiative and there were not current infrastructure or database resources to aid in minimizing burden on IOTA participants (*89 FR 96397*). We believe though that circumstances have changed relative to when we wrote the 2024 Final Rule for a few reasons:

First, the IOTA Model has already started. The 2024 Final Rule that established the IOTA Model was finalized in December 2024 and IOTA participants were notified of their participation status. IOTA participants have had time to implement their care models. Additionally, IOTA participants would have plenty of notice of CMS' intent in this area, with approximately 18 months from the release date of this proposed rule in Fall 2025 until the start of PY 3 on July 1, 2027, to implement the necessary processes to implement these proposed notification requirements, if finalized.

Next, we believe that this updated provision that we are proposing is responsive to many of the administrative burden concerns that were raised by commenters in response to what we originally proposed in the 2024 Proposed Rule. For example, in this proposed rule we are proposing that the transparency into kidney transplant organ offers requirement would only apply for eligible IOTA waitlist beneficiaries, as defined in section II.B.4.a.(3). of this proposed rule, rather than all IOTA waitlist patients who are Medicare beneficiaries, and IOTA participants would only be required to notify eligible IOTA waitlist beneficiaries every 6 months, rather than monthly.

Additionally, we have been working with the Health Resources and Services Administration (HRSA) with

operational assistance to help to make sure that this information is easily accessible for IOTA participants and in a format that could be easily shared with its eligible IOTA waitlist beneficiaries.

We considered requiring that an IOTA participant begin providing notification of declined organ offers 3 years from when a beneficiary started dialysis, but did not propose that as we know some beneficiaries get onto the waitlist before they start dialysis. We also considered proposing 1 or 2 years of waitlist time, as well as 4 or 5 years, but decided to propose 3 years as a way to balance when it would be appropriate for eligible IOTA waitlist beneficiaries to start being informed of their offers. We seek comment on the alternative considered.

We considered proposing to require IOTA participants to provide this notification to eligible IOTA waitlist beneficiaries once they join the list or with just 1 year or 2 years of waiting list time but decided to propose 3 years to balance informing these patients with the workload for IOTA participants. We also considered proposing other timeframes for potentially notifying eligible IOTA waitlist beneficiaries about kidney transplant organ offers including monthly, quarterly, or annually, but proposed every 6 months to align with the model's review of acceptance criteria requirement at § 512.442(c) and the proposed change in waitlist status requirement, as described in section II.B.4.a.(5). of this proposed rule.

Subsequently, we considered a variation of organ offer notifications, where every 6 months the IOTA participant would be required to also provide the total number of kidney transplant organ offers the IOTA participant received and accepted in the relevant 6-month period in addition to the kidney transplant organ offers for the individual eligible IOTA waitlist beneficiary. For example, a notification in January would include the number of received and accepted kidney transplant offers by the IOTA participant from July 1 to December 31, alongside the number of kidney transplant organ offers that the individual eligible IOTA waitlist beneficiary received during that same time frame. We believe that providing total kidneys accepted by an IOTA participant would help provide a comparison for when eligible IOTA waitlist beneficiaries receive organ offer notifications every 6 months. In recognition of the additional reporting complexity this variation would introduce for IOTA participants, we did not propose this alternative considered.

We considered limiting this proposed requirement exclusively to kidney transplant organ offers that were ultimately transplanted; however, we determined that the requirement to inform eligible IOTA waitlist beneficiaries of the disposition of each kidney transplant organ offer would accomplish the same objectives while providing more comprehensive information to the eligible IOTA waitlist beneficiary. We also considered not requiring the sharing of offers further up in the match run, as defined at § 512.402, at spot 100 or higher to align with the SRTR definition of hard-to-place organ or spot 150, but wanted to err on the side of providing greater transparency to eligible IOTA waitlist beneficiaries. We further considered excluding multi-organ offers from this provision; however, we did not propose such exclusion because we wanted to ensure that eligible IOTA waitlist beneficiaries would receive a more complete perspective regarding their care.

We considered requiring other explanations for why each kidney transplant organ offer was declined, in order to provide additional specificity where appropriate but decided to propose OPTN refusal codes in order to provide a standardized approach for IOTA participants using a format they are already familiar with. We also considered requiring cumulative information of organ offers declined since the eligible IOTA waitlist beneficiary was added to the IOTA participant's waitlist but were unsure if that would provide additional useful information for these beneficiaries.

Lastly, we considered but did not propose creating a standardized notification template for IOTA participants to use that would include the information specified at proposed § 512.442(b)(1)(i)(A) through (F). We think that requiring IOTA participants to use a CMS-provided standardized template for these notification requirements could be beneficial because it would ensure uniform implementation across all IOTA participants, eliminating variability in how critical patient-specific information is communicated and significantly reducing the administrative burden on individual IOTA participants by providing ready-to-use formats rather than requiring each IOTA participant to develop custom systems. Additionally, a standardized template would enhance beneficiary understanding by presenting complex medical information in a consistent, accessible format across all IOTA participants, while also facilitating more efficient CMS oversight

and enabling better aggregation of beneficiary communication data for program evaluation and quality improvement initiatives. We also recognize that requiring IOTA participants to use a CMS-provided notification template presents certain considerations that merit evaluation. While standardization offers benefits, we recognize that it may present challenges in addressing diverse patient populations, varying literacy levels, and unique clinical circumstances that could benefit from tailored communication approaches. Furthermore, a standardized notification template may need to be designed with sufficient flexibility to accommodate the different operational capabilities, existing communication systems, and established beneficiary relationships that individual IOTA participants have developed to avoid potential implementation challenges or reduced effectiveness in patient communication. While we are not proposing to provide a standardized notification template that IOTA participants would be required to use, we are seeking public comment regarding whether the inclusion of such templates would be preferable and would not impose additional administrative burden upon IOTA participants. Additionally, beyond the proposed requirements, we seek comment on what specific requirements or specific details should be included in or excluded from such a notification template.

To communicate with the eligible IOTA waitlist beneficiary effectively, we are proposing at § 512.442(b)(2) that the IOTA participant must provide this notification via patient visit, email, electronically, or mail on an individual basis, unless the eligible IOTA waitlist beneficiary opts out of this notification. We propose at § 512.442(b)(2)(i) IOTA participants must give eligible IOTA waitlist beneficiaries the opportunity to opt out of receiving this notification. We propose at § 512.442(b)(2)(ii) that if an eligible IOTA waitlist beneficiary opts out of receiving this notification, the IOTA participant would be required to do the following:

- Record in the eligible IOTA waitlist beneficiary's medical record all of the following:

- ++ The date on which this notification was declined.

- ++ The method by which this notification was declined.

- Offer to provide this notification once every 6 months at which time the eligible IOTA waitlist beneficiary would have the opportunity to opt out of receiving this notification again.

We note that our rationale for this proposal is explained further later in the section.

We also propose at § 512.442(b)(3)(i) through (iii) that the IOTA participant must record in the eligible IOTA waitlist beneficiary's medical record—

- That the eligible IOTA waitlist beneficiary received the notification specified in proposed § 512.442(b)(1);
- The method by which the notification was delivered; and
- The date by which the notification was delivered.

Additionally, we are proposing at § 512.442(b)(4) that the information at proposed § 512.442(b)(1) must be provided with the eligible IOTA waitlist beneficiary's nephrologist or nephrology professional, to provide the opportunity for questions and clarification of information.

We alternatively considered proposing that the IOTA participant must record in the eligible IOTA waitlist beneficiary's medical record—

- That the eligible IOTA waitlist beneficiary was sent the notification specified in proposed § 512.442(b)(1);
- The method by which the notification was sent; and
- The date by which the notification was sent.

In this alternative considered, requiring IOTA participants to document when a notification was sent rather than when it was delivered recognizes the practical challenges of verifying receipt while still ensuring accountability. The IOTA participant would fulfill its obligation to communicate the required information once a notification was sent, whether by mail, email, or electronically. However, we chose not to propose this alternative because we believe recording only when a notification was sent does not confirm that the information reached the eligible IOTA waitlist beneficiary. We also believe that requiring IOTA participants to document delivery of this notification creates a more accurate medical record, allowing IOTA participants to know with confidence what information eligible IOTA waitlist beneficiaries have in hand when engaging in follow-up discussions or counseling. Furthermore, documenting delivery supports transparency and accountability by demonstrating that IOTA participants are not only generating notices, but also ensuring they arrive, reducing the risk that eligible IOTA waitlist beneficiaries unknowingly miss out on information necessary for shared decision-making. Ultimately, focusing on when it was delivered rather than when it was sent better serves the purpose of the notification requirement: to keep eligible IOTA

waitlist beneficiaries informed and actively engaged in their path to kidney transplantation.

We seek comment on our proposals to provide transparency into kidney transplant organ offers at proposed § 512.442(b). We also seek comment on the alternatives considered.

(4) Review of Acceptance Criteria

As finalized in the 2024 Final Rule (89 FR 96402), IOTA participants will be required to review transplant organ offer acceptance criteria with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist, unless the Medicare beneficiary opts out of this review. Under this provision, the IOTA participant must conduct this review via patient visit, phone, email or mail on an individual basis, unless the Medicare beneficiary declines this review. In the 2024 Final Rule, we stated, in response to comments we received, that we recognized that explaining organ offer filters with waitlisted patients might not promote the same outcome as reviewing organ offer acceptance criteria (89 FR 96398). As such, we finalized the transparency requirements at § 512.442(c) with minor technical edits. Specifically, we added “organ offer” to transplant acceptance criteria that must be disclosed and removed all references to “organ offer filter” from the provision at § 512.442(c). Additionally, at § 512.442(c) we replaced “selection criteria” to now say “acceptance criteria”. We stated that these changes were made in order to clarify the specific provisions regarding the review of transplant organ offer acceptance criteria.

Since publication of the 2024 Final Rule, IOTA participants have requested that CMS provide clarification on what acceptance criteria information should be reviewed. Therefore, in this proposed rule, we aim to clarify at § 512.442(c) that review of acceptance criteria pertains to individual patient transplant organ offer acceptance criteria and not organ offer filters or kidney transplant hospital level acceptance criteria. For purposes of the model, we propose at § 512.402 to define “transplant organ offer acceptance criteria” as individualized patient acceptance parameters that kidney waitlist patients, as defined at § 512.402, may elect regarding the categories of organ offers they are prepared to accept for transplantation. We seek comment on our proposal at proposed § 512.442(c) to clarify the meaning of transplant organ offer acceptance criteria. We also seek comment on the proposed definition for

transplant organ offer acceptance criteria at proposed § 512.402.

As described earlier in this section, in the 2024 Final Rule we finalized at § 512.442(c)(1) that IOTA participants must conduct the review of acceptance criteria via patient visit, phone, email or mail on an individual basis, unless the Medicare beneficiary declines this review. Additionally, in response to comments we received we stated at 89 FR 96399 that we would provide further sub-regulatory guidance on how IOTA waitlist patients who are Medicare beneficiaries can choose to decline the review of their transplant organ offer acceptance criteria. Since publication, we provided sub-regulatory guidance to IOTA participants in the IOTA Model Newsletter on how IOTA waitlist patients who are Medicare beneficiaries can opt out of this review. However, upon further review of the sub-regulatory guidance we provided to IOTA participants, we realized there was a need to clarify this guidance and account for this requirement when CMS conducts monitoring activities in the IOTA Model.

As such, we propose at § 512.442(c)(1)(i) that prior to reviewing transplant organ offer acceptance criteria, as defined at proposed § 512.402, with IOTA waitlist patients who are Medicare beneficiaries, IOTA participants must give these beneficiaries an opportunity to decline this review. We propose at § 512.442(c)(1)(ii) that if the IOTA waitlist patient who is a Medicare beneficiary declines this review, the IOTA participant must record in the IOTA waitlist patient who is a Medicare beneficiary's medical record all of the following:

- The date on which this review was declined; and
- The method by which this review was declined.

We also propose that if an IOTA waitlist patient who is a Medicare beneficiary declines this review, the IOTA participant would then be required to offer the IOTA waitlist patient who is a Medicare beneficiary the opportunity to review transplant organ offer acceptance criteria once every 6 months at which time the IOTA waitlist patient who is a Medicare beneficiary would have the opportunity to decline this review again. We seek comment on these proposed requirements at proposed § 512.442(c)(1)(i) and (ii).

Lastly, to facilitate compliance monitoring, we propose at § 512.442(c)(2)(i) through (iii) that the IOTA participant must record in the IOTA waitlist patient who is a Medicare

beneficiary's medical record all of the following:

- The information specified at § 512.442(c) was reviewed with the IOTA waitlist patient who is a Medicare beneficiary;
- The date on which this review took place; and
- The method by which this review was delivered.

We seek comment on these proposed documentation requirements at proposed § 512.442(c)(2)(i) through (iii).

(5) Change in Waitlist Status

Transplant hospitals are currently required to promptly notify patients awaiting transplantation of any program-related circumstances that could affect their ability to receive a transplant (see 42 CFR 482.102(c)). These regulations mandate that transplant hospitals must inform patients of factors such as the availability of transplant surgeons and changes in the hospital's operational status. Transplant hospitals must also notify patients of any modifications to their Medicare certification status, whether due to voluntary program inactivation or termination. These notification requirements serve as a crucial mechanism to ensure transparency and protect patient interests throughout the transplant waiting period.

Patients on the transplant waiting list are designated as either "active" or "inactive". Individuals with active status are prepared and eligible to be matched with available organs, whereas those with inactive status are not yet ready to, nor can they, receive organ offers. There are over 90,000 people on the waiting list for a kidney transplant, but nearly half (49 percent) of these individuals on the waiting list are listed as "inactive" as of 2025, and unable to receive a kidney transplant.⁶² While awaiting organ transplantation, kidney transplant waitlist patients' status on the waiting list may change between active and inactive multiple times before ultimately receiving a successful transplant. The decision to place a kidney transplant waitlist patient on inactive status can arise from various factors, including hospital admission for vascular access issues, suspected lesions

identified during preoperative screening, or poor compliance with dialysis treatments.⁶³ Any of these concerns may prompt a temporary inactivation until the problem is resolved, allowing for the kidney transplant waitlist patient's reactivation. Barriers to maintaining active status are often multifactorial but frequently modifiable, encompassing symptoms such as fatigue, depression, stress, pain, loss of physical function, social isolation, and decreased health literacy.⁶⁸ Inactive status thus indicates a kidney transplant waitlist patient's ineligibility to be considered for organ offers at a given point in time, for many different reasons such as temporarily too sick, temporarily too well, candidate work-up incomplete, etc.⁷⁰

⁶³ Huang, E., Shye, M., Elashoff, D., Mehrnia, A., & Bunnapradist, S. (2014). Incidence of Conversion to Active Waitlist Status Among Temporarily Inactive Obese Renal Transplant Candidates. *Transplantation*, 98(2), 177–186. <https://doi.org/10.1097/tp.0000000000000037>.

⁶⁴ Hladek, M., Curriero, S., Xue, Q.-L., Crews, D., DeMarco, M.M., Wilson, D., Brennan, D., & Szanton, S. (2024). CAPABLE TRANSPLANT: ADAPTATION OF CAPABLE FOR USE WITH OLDER ADULTS WITH INACTIVE STATUS AWAITING KIDNEY TRANSPLANT. *Innovation in Aging*, 8(Supplement 1), 181–181. <https://doi.org/10.1093/geroni/igae098.0585>.

⁶⁵ Shafi, S., Zimmerman, B., & Kalil, R. (2012). Temporary Inactive Status on Renal Transplant Waiting List: Causes, Risk Factors, and Outcomes. *Transplantation Proceedings*, 44(5), 1236–1240. <https://doi.org/10.1016/j.transproceed.2012.01.126>.

⁶⁶ Tong, A., Hanson, C.S., Chapman, J.R., Halleck, F., Budde, K., Josephson, M.A., & Craig, J.C. (2015). "Suspended in a paradox"—patient attitudes to wait-listing for kidney transplantation: systematic review and thematic synthesis of qualitative studies. *Transplant International*, 28(7), 771–787. <https://doi.org/10.1111/tri.12575>.

⁶⁷ King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology: JASN*, 31(12), 2900–2911. <https://doi.org/10.1681/ASN.2020030335>.

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Numerous research studies have demonstrated that kidney transplant waitlist patients frequently experience confusion and knowledge deficits regarding the transplant evaluation and listing process.^{74 75 76 77 78 79 80 81} These knowledge gaps often contribute to delays in testing and aborted medical evaluations. Kidney transplant waitlist patients have reported a lack of clarity about their status in the listing process,^{82 83 84 85} a belief that they are

already on the waiting list,^{86 87 88} unawareness that tests must be repeated,^{89 90} and misunderstanding about being placed on inactive status on the waiting list.^{91 92} In addition to difficulties navigating the healthcare system, these knowledge deficits can lead to negative perceptions of the transplant process and diminish kidney transplant waitlist patient motivation to complete the required testing. Literature also suggests that kidney transplant waitlist patients who remain in an inactive status for extended periods are less likely to receive a kidney transplant, which is associated with increased waitlist mortality.^{93 94 95 96 97 98}

Furthermore, while a transplant hospital is required to notify patients when they are first added to or removed from a waitlist, there is currently no requirement for transplant hospitals to inform patients on its waitlist when there is a change in waitlist status (that is, from active to inactive).^{99 100} It is important for transplant candidates to be aware of whether they are active or inactive on the waiting list and to understand that they are only eligible to receive an organ for transplant while in an active status.

As such, we are proposing to add new requirements at § 512.442(d) for IOTA participants to notify their IOTA waitlist patients who are Medicare beneficiaries when their waitlist status has changed. Specifically, we propose, at § 512.442(d)(1)(i), that IOTA participants must notify their IOTA waitlist patients who are Medicare beneficiaries any time their status on its waitlist is changed that would impact their ability to receive an organ offer (that is, from active to inactive). We seek comment on our proposal to add a change in waitlist transparency requirement at proposed § 512.442(d)(1)(i).

We considered but did not propose requiring IOTA participants to also notify their IOTA waitlist patients who are Medicare beneficiaries whenever

across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology*, 31(12), 2900–2911. <https://doi.org/10.1681/ASN.2020030335>.

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⁹⁸ Kataria, A., Gowda, M., Lamphron, B.P., Jalal, K., Venuto, R.C., & Gundroo, A.A. (2019b). The impact of systematic review of status 7 patients on the kidney transplant waitlist. *BMC Nephrology*, 20(1). <https://doi.org/10.1186/s12882-019-1362-6>.

⁹⁹ UNOS Transplant Living. (n.d.). *The kidney transplant waitlist*. UNOS Transplant Living. Retrieved April 5, 2025, from <https://transplantliving.org/kidney/the-kidney-transplant-waitlist/>.

¹⁰⁰ While there is currently no requirement for transplant hospitals to inform patients on its waitlist when there is a change in waitlist status, we acknowledge that the OPTN has recently proposed such a policy.

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⁷³ OPTN. (2025). Require Patient Notification for Waitlist Status Changes—OPTN. *Hrsa.gov*. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/require-patient-notification-for-waitlist-status-changes/?j=1275952&sfmc_sub=402742420&l=7077
[HTML&u=77544833&mid=100001876&jb=2001](https://doi.org/10.1186/s12882-019-1362-6).

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⁷⁵ Kazley, A.S., Hund, J.J., Simpson, K.N., Chavin, K., & Baliga, P. (2015). Health literacy and kidney transplant outcomes. *Progress in transplantation (Aliso Viejo, Calif.)*, 25(1), 85–90. <https://doi.org/10.7182/pit2015463>.

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⁸¹ Khalili, M., Cardinal, H., Ballesteros, F., & Fortin, M. (2022). Kidney transplant candidates' and recipients' perspectives on the decision-making process to accept or refuse a deceased donor kidney offer: Trust and graft survival matter. *Clinical Transplantation*, 36(5). <https://doi.org/10.1111/ctr.14604>.

⁸² Kazley, A.S., Simpson, K.N., Chavin, K.D., & Baliga, P. (2012). Barriers facing patients referred for kidney transplant cause loss to follow-up. *Kidney international*, 82(9), 1018–1023. <https://doi.org/10.1038/ki.2012.255>.

⁸³ Kayler, L.K., Dolph, B., Ranahan, M., Keller, M., Cadzow, R., & Feeley, T.H. (2021). Kidney Transplant Evaluation and Listing: Development

and Preliminary Evaluation of Multimedia Education for Patients. *Annals of transplantation*, 26, e929839. <https://doi.org/10.12659/AOT.929839>.

⁸⁴ Khalili, M., Cardinal, H., Ballesteros, F., & Fortin, M. (2022). Kidney transplant candidates' and recipients' perspectives on the decision-making process to accept or refuse a deceased donor kidney offer: Trust and graft survival matter. *Clinical Transplantation*, 36(5). <https://doi.org/10.1111/ctr.14604>.

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⁸⁸ Bergeron, M. (2020). *Transplant Center Criteria and Inequalities Within Transplant Wait Listing Process* [Thesis]. <https://stars.library.ucf.edu/etd2020/175/>.

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⁹³ Hughes, A., Malhotra, D., Brennan, D., Seldon, L., Carberry, H., Morrison, M., & Hladek, M. (2025). Waitlist management for inactive status kidney transplant patients: a scoping review. *Annals of Medicine & Surgery*, 87(4), 2204–2211. <https://doi.org/10.1097/ms9.0000000000000317>.

⁹⁴ King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation

their status changes from inactive to active in addition to whenever their waitlist status changes from active to inactive. We believe this alternative considered would ensure that IOTA waitlist patients who are Medicare beneficiaries are immediately informed when they regain eligibility to receive organ offers, which is critical for their potential access to life-saving transplantation, while enhancing beneficiary engagement through transparency about significant changes in transplant eligibility status and guaranteeing consistent, timely information across all IOTA participants. However, we recognize that requiring such notifications could impose significant administrative burden on IOTA participants, particularly IOTA participants with limited resources, requiring substantial investments in new systems and staff time that could divert resources from direct patient care. Additionally, frequent status change notifications might create patient anxiety and unrealistic expectations about organ offer immediacy, potentially overwhelming clinical teams and undermining transparency goals, while standardized requirements may fail to account for diverse patient populations with varying literacy levels and communication needs. While we are not proposing to also require IOTA participants to notify their IOTA waitlist patients who are Medicare beneficiaries whenever their status from inactive to active, we are seeking public comment regarding whether the inclusion of a notification whenever their waitlist status changes from inactive to active in addition to whenever their waitlist status changes from active to inactive would be preferable and would not impose additional administrative burden upon IOTA participants.

We propose at § 512.442(d)(1)(ii) that IOTA participants must include all of the following in this notification to IOTA waitlist patients who are Medicare beneficiaries:

The most recent date the IOTA waitlist patient who is a Medicare beneficiary became inactive.

- The reason for the change in waitlist status.
- That the IOTA waitlist patient who is a Medicare beneficiary cannot receive organ offers while inactive.
- Information on how the IOTA waitlist patient who is a Medicare beneficiary may become active on its waitlist again (for example, updating personal information, providing new clinical data, addressing insurance issues or other factors such as medical, psychosocial, and socioeconomic).

- How the IOTA waitlist patient who is a Medicare beneficiary may contact the IOTA participant for more information or with any questions.

We seek public comment on our proposed change in waitlist status notification requirements at proposed § 512.442(d)(1)(ii). In addition, we are also interested in comments on whether the proposed information to include in the change in waitlist status notification should include additional information.

We propose at § 512.442(d)(1)(iii) that IOTA participants must provide this notification to the IOTA waitlist patient who is a Medicare beneficiary—

- Electronically or by mail;
- Within 10 days of the IOTA waitlist patient who is a Medicare beneficiary's change in waitlist status—consistent with the patient records requirements at § 482.94(c)(2); and
- Annually, thereafter, for as long as the Medicare beneficiary remains inactive (that is; 365 consecutive days).

We considered alternative methodologies for implementing this provision. For example, we considered delaying the implementation of this provision until PYs 3 or 4, in conjunction with the proposed transparency into kidney transplant organ offers requirement to share information about declined kidney transplant organ offers, as described in section II.B.4.a(3) of this proposed rule. However, we believe that this proposed requirement would impose less administrative burden on IOTA participants than the proposed transparency into kidney transplant organ offers requirement to share information about declined kidney transplant organ offers, as described in section II.B.4.a(3) of this proposed rule, and could be implemented at an earlier stage.

We also considered alternative timelines for continued notification that an IOTA waitlist patient who is a Medicare beneficiary remains inactive on an IOTA participants waitlist, such as every 60 days, 90 days, or 180 days, but proposed an annual update based on an attempt to balance utility to the beneficiary with burden on the IOTA participants. We further considered alternative timelines not predicated on consecutive days but instead based on inactive status for at least 75 percent or 90 percent of days during a specified timeline, rather than reaching 365 consecutive days. We additionally considered an alternative timeline structured around the point at which an IOTA waitlist patient who is a Medicare beneficiary is ultimately discharged from a hospital. We also considered requiring IOTA participants to inform

IOTA waitlist patients who are Medicare beneficiaries about internal holds; however, we were uncertain regarding the implementation methodology for this provision.

We seek public comment on our proposed change in waitlist status delivery method and timeline requirements at proposed § 512.442(d)(1)(iii). We also seek comment on the alternatives considered.

We also propose at § 512.442(d)(2) that the IOTA participant must record in the IOTA waitlist patient who is a Medicare beneficiary medical record all of the following:

- A copy of the notification.
- The method by which the notification was delivered.
- The date in which the notification was sent.

Additionally, we propose at § 512.442(d)(3) that for IOTA waitlist patients who are Medicare beneficiaries and—

- For ESRD patients, the IOTA participant must also notify the dialysis facility (as defined at 42 CFR 494.10) and managing clinician (as defined at 42 CFR 512.310) or nephrologist; or
- For Non-ESRD patients,¹⁰¹ the IOTA participant must also notify the referring provider or practitioner providing care to the IOTA waitlist patient who is a Medicare beneficiary.

This notification timeframe conforms with the current timeframe at § 482.94, however, we solicit public comment on alternative timeframes that may be appropriate. We expect that IOTA participants would be expeditious and deliberate in determining an IOTA waitlist patient who is a Medicare beneficiary's waitlist status and communicating that information to them, the OPTN, and others as appropriate. We propose to finalize these requirements only if they are not redundant with other HHS guidance.

We seek public comment on these proposed documentation requirements at proposed § 512.442(d)(2) through (3).

We understand that a kidney transplant waitlist patient's condition or situation may change over time and warrant kidney transplant hospitals reassessing the kidney transplant waitlist patient to determine if their waitlist status should be updated.

¹⁰¹ A Non-ESRD patient is someone who has healthy kidneys or chronic kidney disease (CKD) in a less severe form that does not constitute irreversible kidney failure. These patients do not require life-sustaining dialysis treatment or an immediate kidney transplant, and their condition is managed through other medical treatments. However, non-ESRD patients may still be eligible to get wait listed for a preemptive kidney transplant before their kidney function deteriorates to the point of requiring dialysis.

However, we believe kidney transplant waitlist patients should be aware of these situations and the impact it has on their ability to receive an offer. Additionally, we also believe that “internal holds,” which are a process used by the kidney transplant hospital to temporarily not consider offers for a kidney transplant waitlist patient, despite the kidney transplant waitlist patient being listed as active with the OPTN are detrimental to the efficiency of the organ allocation system and could lead to increased organ discards by slowing down the allocation process. At present, there are no national policies mandating that kidney transplant waitlist patients be notified when they are designated as inactive, whether due to patient-specific reasons or after an extended period of inactivity. We believe that this proposed requirement would establish consistency across all IOTA participants in informing IOTA waitlist patients who are Medicare beneficiaries about their inactive waitlist status and are unable to receive organ offers. As such, we believe that these IOTA waitlist patients who are Medicare beneficiaries would gain greater awareness of their listing status and the necessary steps to become eligible to receive an organ for transplant.

Furthermore, we believe that the proposals in this section would improve communication between IOTA participants and their IOTA waitlist patients who are Medicare beneficiaries regarding their waitlist status and the implications of being inactive on a waitlist. Although these proposed requirements could create additional work for transplant coordinators in particular, we believe that they would promote effective and safe care for persons with organ failure by increasing IOTA waitlist patients who are Medicare beneficiaries’ awareness of their inactive waitlist status and provide them with the information required to be proactive in their reactivation. We note that the intent of these notifications is to prevent IOTA waitlist patients who are Medicare beneficiaries from being inactive on a waitlist for unnecessarily extended period of times.

b. Health Equity Plans

In the 2024 Final Rule (89 FR 96407), in response to comments,¹⁰² we

¹⁰² Commenters provided mixed opinions to the proposed health equity plan provisions, with approximately 70 percent expressing concern that it would be an unfunded administrative burden and would have unintended consequences. Approximately 10–15 percent of commenters expressed clear support and 15–20 percent of

commenters neither clearly supported nor opposed but offered suggestions for improvement. finalized at § 512.446(a) that an IOTA participant may voluntarily submit a health equity plan for all performance years (PY 1 through PY 6) and in a form and manner and by the date(s) specified by CMS. We also finalized that a health equity plan voluntarily submitted by an IOTA participant must include all elements at § 512.446(a)(1) through (7). We direct readers to the 2024 Final Rule for a full discussion of this policy, our rationale for this approach, and alternatives considered (89 FR 96405 through 96407). Lastly, we proposed and finalized the definitions for “Health equity goal”, “Health equity plan”, “Health equity plan intervention strategy”, and “Health equity plan performance measure” at § 512.402.

We continue to maintain that understanding and addressing the health needs of all IOTA waitlist patients and IOTA transplant patients remains essential to ensuring their benefit through improved access to the transplantation ecosystem. However, in consideration of the current Administration’s priorities and concerns regarding the imposition of additional burden on IOTA participants within a mandatory model, we propose removing the voluntary health equity plan provisions from the IOTA Model. We recognize that requesting IOTA participants to submit health equity plans, even on a voluntary basis, could impose an additional burden on IOTA participants. As such, we believe removing the voluntary health equity plan provisions from the IOTA Model would reduce burden on IOTA participants and constitute a more effective utilization of IOTA participant resources to focus on increasing access to kidney transplants, which would enhance their performance within the model and improve the quality of care.

Therefore, in this proposed rule we are proposing to remove the health equity plan provisions from § 512.446 (a)(1) through (7). Though currently there is no replacement for these policies, CMS may consider adding elements that are consistent with the current Administration’s focus on Making America Healthy Again (MAHA) through future notice and comment rule making. We believe there is an opportunity through IOTA Model to drive improvements in overall health by increasing access to kidney transplants. Lastly, given that we are proposing to remove all healthy equity provisions at § 512.446, we propose removing the definitions for health equity goal, health equity plan, health

commenters neither clearly supported nor opposed but offered suggestions for improvement.

equity plan intervention strategy, and health equity plan performance measure at § 512.402. We are proposing to remove all health equity plan provisions at § 512.446 to reduce burdensome requirements on IOTA participants to allow IOTA participants to focus their resources on the core objective of the model, increasing access to kidney transplants, as well as to comply with Executive Order 14151 Ending Radical and Wasteful Government DEI Programs and Preferencing (90 FR 8339)¹⁰³ issued January 20, 2025. CMS also wants to reiterate that allocation and transplantation decisions should be made based on objective and measurable medical criteria through the framework set up by the OPTN under 42 CFR 121.8 and should not be made on the basis of race or other criteria not laid out by the goals described in this section of the CFR.

We seek comment on our proposal to remove health equity plans from the IOTA Model and remove the corresponding regulations at § 512.446. We also seek comment on our proposal at § 512.402 to remove the definitions of health equity goals, health equity plan intervention, health equity plan performance measure(s), health equity project plan, resource gap analysis, target health disparities, and underserved communities.

5. Beneficiary Protections

a. Background

In the 2024 Final Rule (89 FR 96413), we finalized that IOTA participants must provide notice to attributed patients that they are participating in the IOTA Model as described in § 512.450(a)(1). However, CMS only has the authority to place requirements upon notifications to Medicare beneficiaries. As such, this notice should have been limited to Medicare beneficiaries. Therefore, we propose to update the policy at § 512.450(a)(1) to limit these notification requirements to Medicare beneficiaries only.

We seek comment on our proposal at proposed § 512.450(a)(1) to limit the notification requirement to Medicare beneficiaries.

b. Beneficiary Notifications

In the 2024 Final Rule (89 FR 96413), we finalized that in order to notify attributed patients of their rights and protections, and that the IOTA participant is participating in the IOTA

¹⁰³ Ending Radical And Wasteful Government DEI Programs And Preferencing: <https://www.whitehouse.gov/presidential-actions/2025/01/ending-radical-and-wasteful-government-dei-programs-and-preferencing/>.

Model, the IOTA participant needed to provide an approved beneficiary notification template to each attributed patient in a paper format as described in § 512.450(a)(3)(iii).

Since then, we have received feedback from IOTA participants that the main form of communication with their patients is through electronic means, often a patient portal where the patients receive all communication from the IOTA participant. We propose at § 512.450(a)(3)(iii)(A) and (B) allowing IOTA participants to distribute the paper copy of this notification to applicable attributed patients at their first office visit or other outpatient visit with the attributed patient after the start of the Model or, if the attributed patient has affirmatively opted out of receiving paper communication and has chosen to receive communication through electronic methods, this notification can be distributed through that agreed upon electronic method.

We seek comment on our proposal at proposed § 512.450(a)(3)(iii)(A) and (B) to allow IOTA participants to distribute this paper notification at the first in office or outpatient visit, or to distribute the notification in an electronic format in cases where the attributed patient has affirmatively opted out of receiving paper communications.

6. Monitoring

In the 2024 Final Rule (89 FR 96430), we finalized a list of monitoring activities to ensure compliance and promote the safety of attributed patients and the integrity of the IOTA Model as described in § 512.462(b)(2). Monitoring activities include documentation requests including surveys and questionnaires, audits of claims data, quality measures, medical records, interviews, site visits, monitoring attributed patient engagement incentives, monitoring out of sequence allocation, etc. However, we inadvertently omitted monitoring of the transparency requirements specified in § 512.442. These include:

- Publicly posting selection criteria in accordance with § 512.442(a);
- Informing eligible IOTA waitlist beneficiaries, as defined in section II.B.4.a(3) of this proposed rule, of the number of times an organ is declined on the Medicare beneficiary's behalf in accordance with proposed § 512.442(b);
- Reviewing selection criteria with IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist as specified in § 512.442(c); and,
- Notifying IOTA waitlist patients who are Medicare beneficiaries when

their waitlist status has changed from active to inactive in accordance with proposed § 512.442(d). Therefore, we propose at § 512.462(b)(2)(xi), (xii), (xiii) and (xiv) to include that CMS may monitor the review of acceptance criteria provision in accordance with § 512.442.

We seek comment on these proposed requirements at proposed § 512.462(b)(2)(xi), (xii), (xiii), and (xiv).

7. Remedial Action and Termination

In the 2024 Final Rule (89 FR 96433), we finalized a list of reasons why CMS may immediately or with advance notice terminate an IOTA participant from the IOTA Model as described in § 512.466. For example, CMS may immediately or with advance notice terminate an IOTA participant from participation in the model if due to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency, or if an IOTA participant is subject to investigation or action by HHS (including Office of Inspector General (OIG) and CMS) or the Department of Justice (DOJ) due to an allegation of fraud or significant misconduct.

However, we unintentionally omitted HHS and the OPTN as sources of vital information regarding possible events by IOTA participants identified as presenting a risk to patient safety, public health, etc., that may lead CMS to terminate IOTA participants. Therefore, we propose at § 512.466(a)(3)(ix)(C) to include a provision that states CMS can terminate an IOTA participant from the IOTA Model if HHS or the OPTN has determined that an IOTA participant has violated the OPTN's policies,¹⁰⁴ OPTN's Management and Membership policies,¹⁰⁵ or HHS's regulation (42 CFR 121) upon a review conducted pursuant to 42 CFR 121.10. We also propose the following minor technical changes to account for our proposal at § 512.466(a)(3)(ix)(C):

- Remove the following verbiage from § 512.466(a)(3)(ix)(A): or
- Add the following punctuation and verbiage at the end of § 512.466(a)(3)(ix)(B): or

We seek comment on our proposal at proposed § 512.466(a)(3)(ix)(C) to include OPTN as a source of information that may lead to CMS terminating an IOTA participant from the IOTA Model. We also seek comment

on our minor technical corrections at proposed § 512.466(a)(3)(ix)(A) and (B).

C. Request for Information (RFIs) on Topics Relevant to the IOTA Model

This section includes several requests for information (RFIs). In responding to the RFIs, the public is encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; RFIs do not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do 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 these RFIs and would not accept unsolicited proposals. Respondents are advised that the U.S. Government would not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to these RFIs would be solely at the respondent's expense. Failing to respond to any of the RFIs would not preclude participation in any future procurement, if conducted.

Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual respondents. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained because 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. All submissions become U.S. Government property and would not be returned. CMS may publicly post the comments received, or a summary thereof.

1. Pre-Transplantation Access Process Measure

In the 2024 Final Rule (89 FR 96346), we discussed that before a patient can be considered for, and placed on, the waiting list for a kidney transplant, they must first be referred by either a nephrologist or dialysis facility, at which point they undergo a comprehensive evaluation process by a transplant hospital. In the United States, kidney transplant waitlist candidates face considerable disparities in access to kidney transplant, such as in who is referred and placed on the waiting list, who remains "active" on the waiting

¹⁰⁴ For current OPTN policies please see <https://optn.transplant.hrsa.gov/policies-bylaws/policies/>.

¹⁰⁵ For current OPTN Membership and Management Policies please see <https://optn.transplant.hrsa.gov/policies-bylaws/optn-management-and-membership-policies/>.

list, and how waitlisted patients are managed by kidney transplant hospitals.¹⁰⁶ Studies have shown long-standing barriers and disparities to access to transplantation by patient demographics, such as socioeconomic and insurance factors. Disparities are driven by various factors, but we recognize that delays or lack of referrals for evaluation, evaluation criteria that may unintentionally deem a patient not eligible to be placed on a waitlist, and organ acceptance rate variations across kidney transplant hospitals, may exacerbate disparities.^{107 108 109 110}

Additionally, kidney transplant hospital performance is commonly measured by post-transplant outcomes.

The absence of standardized national criteria for transplant eligibility and post-transplant outcome regulations has led to inconsistent patient selection and waitlisting practices among transplant hospitals.^{111 112} All kidney transplant

waitlist patients, regardless of whether they receive organs from living or deceased donors, must be placed on the kidney transplant waitlist. While waitlisting metrics could effectively measure the total organ need at each transplant hospital and reduce dependency on regional organ availability, no standardized metrics currently exist to compare waitlisting rates between transplant programs.

An outcome or process measure for a transplant waitlist refers to a metric used to evaluate the efficiency and effectiveness of how a transplant hospital manages its waitlist, including factors like patient evaluation time, waitlist activation time, communication with patients, adherence to listing criteria, and timely organ offer acceptance, all aimed at optimizing the waitlist experience for transplant candidates and maximizing organ utilization. We recognize that including pre-transplant process measures could allow for a more thorough evaluation of transplant hospital performance and provide insight for patient decision-making.^{113 114} Implementation of a pre-transplant outcome or process measure in the IOTA Model would serve multiple strategic objectives: identification and remediation of process inconsistencies, reduction of waitlist mortality through optimization of referral-to-transplantation intervals, and quantification of clinical practice variations across kidney transplant hospitals.

We are seeking public comments on the following questions. We encourage commenters to provide empirical evidence to support their feedback whenever possible:

- For kidney transplant hospitals: What existing measures are being used to measure access to the waitlist or transplantation evaluation processes?
 - ++ What are the domains, strengths, and weaknesses of these measures?
 - ++ Are there factors that could make these measures more meaningful and practical?

++ Are there existing measures being used to measure time from referral to waitlist or waitlist to transplantation?

++ Would this type of measurement be useful for improving access to kidney transplantation?

++ How do these measures provide information that can be used to improve patient care and healthcare systems?

++ What unintended consequences could arise by measuring waitlist to referral and pre-transplant processes?

++ What data would be necessary to create measures of time from referral to waitlist and time from waitlist to transplant?

++ How could that data be transmitted to CMS in a way that minimizes burden to transplant hospitals?

++ What data would be necessary to create a measure on those specified components?

- For kidney transplant recipients and dialysis and ESRD patients: Why is a quality measure that looks at access to waitlist and pre-transplantation processes important to include?

++ What criteria would make this type of measure most useful for driving access to kidney transplantation?

- For all stakeholders: When measuring pre-transplantation processes, what specific components should be analyzed (for example, time from referral to waitlist, time from waitlist to transplant)?

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform any future quality measure efforts, as appropriate.

2. Allocation Out-of-Sequence (AOOS)

In the 2024 Final Rule (89 FR 96429), we discussed our concerns around the issue of AOOS transplants. As we stated in the 2024 Final Rule at 89 FR 96429: CMS is concerned about IOTA participants bypassing the match run, as defined in section III.C.5.d(1)(a) of [the] final rule, the OPTN policy-defined rank order list of transplant candidates to be offered an organ. This practice may undermine the mechanisms promoting equitable allocation in rationing this scarce resource. We proposed that CMS would monitor out of sequence allocation of kidneys by assessing how often an organ is offered or accepted for a transplant candidate or potential transplant recipient that deviates from the match sequence.

As a result, we finalized a provision at § 512.462(b)(2)(x) which states that monitoring activities may include monitoring AOOS of kidneys by assessing the frequency at which IOTA waitlist patients, top-ranked on an IOTA

¹⁰⁶ Whelan, A.M., Johansen, K.L., Copeland, T., McCulloch, C.E., Nallapothula, D., Lee, B.K., Roll, G.R., Weir, M.R., Adey, D.B., & Ku, E. (2022). Kidney transplant candidacy evaluation and waitlisting practices in the United States and their association with access to transplantation. *American Journal of Transplantation*, 22(6), 1624–1636. <https://doi.org/10.1111/ajt.17031>.

¹⁰⁷ Boerstra, B.A., Pippias, M., Kramer, A., Dirix, M., Daams, J., Jager, K.J., Hellemans, R., & Stel, V.S. (2024). The evaluation of kidney transplant candidates prior to waitlisting: a scoping review. *Clinical Kidney Journal*, 18(1). <https://doi.org/10.1093/ckj/sfae377>.

¹⁰⁸ Patzer, R.E., Perryman, J.P., Schragar, J.D., Pastan, S., Amaral, S., Gazmararian, J.A., Klein, M., Kutner, N., & McClellan, W.M. (2012). The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *American Journal of Transplantation*, 12(2), 358–368. <https://doi.org/10.1111/j.1600-6143.2011.03927.x>.

¹⁰⁹ Husain, S.A., Yu, M.E., King, K.L., Adler, J.T., Schold, J.D., & Mohan, S. (2023). Disparities in kidney transplant waitlisting among young patients without medical comorbidities. *JAMA Internal Medicine*, 183(11), 1238. <https://doi.org/10.1001/jamainternmed.2023.5013>.

¹¹⁰ Harding, J.L., Perez, A., Snow, K., Retzliff, S., Urbanski, M., White, M.S., & Patzer, R.E. (2021). Non-medical barriers in access to early steps of kidney transplantation in the United States—A scoping review. *Transplantation Reviews*, 35(4), 100654. <https://doi.org/10.1016/j.ttre.2021.100654>.

¹¹¹ Schold, J.D., Buccini, L.D., Poggio, E.D., Flechner, S.M., & Goldfarb, D.A. (2016). Association of Candidate Removals From the Kidney Transplant Waiting List and Center Performance Oversight. *American Journal of Transplantation*, 16(4), 1276–1284. <https://doi.org/10.1111/ajt.13594>; Schold, J.D., Arrigain, S., Flechner, S.M., Augustine, J.J., Sedor, J.R., Wee, A., Goldfarb, D.A., & Poggio, E.D. (2018). Dramatic secular changes in prognosis for kidney transplant candidates in the United States. *American Journal of Transplantation*, 19(2), 414–424. <https://doi.org/10.1111/ajt.15021>; Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, 21(1), 314–321. <https://doi.org/10.1111/ajt.16277>.

¹¹² Caldwell, J.S., Cheng, X.S., Chertow, G.M., & Goldhaber-Fiebert, J.D. (2025). Kidney transplant wait times under waiting list expansion scenarios. *JAMA Network Open*, 8(3), e251665. <https://doi.org/10.1001/jamanetworkopen.2025.1665>.

¹¹³ Nishio, A.G., Patel, A., Mehta, S., Yadav, A., Doshi, M., Urbanski, M.A., Concepcion, B.P., Singh, N., Sanders, M.L., Basu, A., Harding, J.L., Rossi, A., Adebisi, O.O., Samaniego-Picota, M., Woodside, K.J., & Parsons, R.F. (2024). Expanding the access to kidney transplantation: Strategies for kidney transplant programs. *Clinical Transplantation*, 38(5). <https://doi.org/10.1111/ctr.15315>.

¹¹⁴ Yeung, M.Y., Coates, P.T., & Li, P.K. (2022). Kidney Organ Allocation System: How to Be Fair. *Seminars in Nephrology*, 42(4), 151274. <https://doi.org/10.1016/j.semnephrol.2022.09.002>.

participant's kidney transplant waitlist, receive the organ that was initially offered to them; and determining the reasons behind cases where IOTA waitlist patients did not receive the kidney offered to them. CMS is working on implementing this provision as part of our monitoring efforts for the model.

Under the oversight of HRSA, the OPTN establishes allocation policies and is charged with investigating incidences of organs being allocated out of the OPTN-defined sequence. On August 30, 2024, HRSA provided a critical comment letter to the OPTN and OPTN contractor related to a complaint on this issue. In that letter,¹¹⁵ HRSA pointed out the OPTN bylaws requiring that each OPO must have a plan to equitably allocate donated organs among transplant patients that is consistent with the obligations of the OPTN. In June 2025, HRSA launched a dedicated AOOS web page to serve as a centralized resource, offering background on AOOS, ongoing updates, and opportunities for stakeholders and the public to submit questions and provide input.¹¹⁶

In response to the 2024 Proposed Rule, we received numerous comments from the public worried about the impact of the IOTA Model on further promoting AOOS. In the 2024 Final Rule (89 FR 96347), we saw comments around the efficiency metric where a commenter was concerned that out-of-sequence kidney offers are included in the measurement of success. Similarly, another commenter suggested CMS monitor the rate of AOOS that occurs. Another commenter was also worried that the IOTA Model, as proposed, could lead to an increase in AOOS to prioritize deceased donor kidney transplants (DDKTs) for its aligned population to increase scoring in the achievement domain.

While we did not make any changes in the 2024 Final Rule based on these comments, AOOS remains an issue of concern for CMS and HRSA. As a result, we are seeking public comments from all stakeholders on the following questions:

- How should CMS account for organs AOOS in the achievement domain? Should CMS adjust the counting of any deceased donor transplants performed on organs AOOS?
- How should CMS account for organs AOOS in the efficiency domain? Should CMS adjust scoring in the numerator or denominator of the metric to account for this?

- What de-identified data would be helpful for CMS and HRSA to share with the public about the use of AOOS in the IOTA Model and in the overall transplant system?

- Should kidney transplant waitlist patients be notified about a transplant hospital bypassing them on the match run for a patient who is lower on the match run? What is the right way to inform kidney transplant waitlist patients about this occurring and how does that align with the organ offer transparency provisions described elsewhere in this proposed rule or the IOTA Model? How should CMS monitor that this has occurred?

- Through our monitoring efforts laid out in § 512.462(b)(2)(x), we plan to monitor AOOS. What considerations or stratifications should CMS take into account when monitoring AOOS?"

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform any future quality measure or CMS policy efforts.

III. Collection of Information Requirements

CMS Innovation Center Models including the Increasing Organ Transplant Access (IOTA) Model are implemented and tested under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, *Chapter 35 of title 44, United States Code*, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule would need not to be reviewed by the Office of Management and Budget.

IV. Regulatory Impact Analysis

A. Statement of Need

The IOTA Model is a 6-year mandatory Medicare payment model operated by the CMS Innovation Center that tests whether upside and downside performance-based payments ("upside risk payments" and "downside risk payments") increase the number of kidney transplants performed by IOTA participants (that is, kidney transplant hospitals).

This proposed rule proposes to update the composite graft survival rate calculation and scoring methodology.

Under this proposed rule, model payments would be based on the number of transplant recipients who are beneficiaries with Medicare FFS coverage including beneficiaries with Medicare as a secondary payer.

Under the current specifications in the 2024 Final Rule, points earned in the quality domain are based on the IOTA participants' performance on the composite graft survival rate metric relative to national ranking, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. In response to public comment concerns about the proposed points allocation for the composite graft survival rate, arguing that it unfairly penalizes kidney transplant hospitals that accept higher-risk kidney transplant patients and suggesting modifications including lowering the threshold for maximum points over the lack of risk-adjustment on the composite graft survival rate, this proposed rule includes a modified points allocation. In this proposed rule, the modifications to the allocation of points awarded to IOTA participants for the composite graft survival rate would remove the possibility of getting free points for poor performance and provide a more even scoring distribution for participants.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, "Regulatory Planning and Review"; Executive Order 13132, "Federalism"; Executive Order 13563, "Improving Regulation and Regulatory Review"; Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts.). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or

¹¹⁶ <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/allocation-out-of-sequence-aos/>.

communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is not significant per section 3(f)(1) of E.O.

12866. Although we do not come close to the threshold to be considered significant under section 3(f)(1), we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

C. Detailed Economic Analysis

1. Revised Baseline

In this proposed rule, the baseline projection from the 2024 Final Rule was revised to include updated projections regarding the declining share of beneficiaries in Medicare FFS versus

MA currently expected over the course of the model. To isolate the impact of the updated projections of the share of beneficiaries in Medicare FFS versus MA, no changes in this proposed rule are included in the revised baseline impact displayed in Table 4. Reducing the share of transplants estimated to be eligible for the incentive reduces the baseline expected number of added transplants by nearly 10 percent, which is roughly offset by the expected associated decrease in incentive payments due to fewer overall transplants. As a result, the net impact is virtually unchanged at \$29 million over 6 years (see Table 4) from \$28 million estimated in the 2024 Final Rule.

TABLE 4: RESTATED BASELINE IMPACT ON UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING (PRESUMES NO CHANGES TO THE MODEL FROM 2024 FINAL RULE)

	7/1/25- 6/30/26	7/1/26- 6/30/27	7/1/27- 6/30/28	7/1/28- 6/30/29	7/1/29- 6/30/30	7/1/30- 6/30/31	6-Year Totals		
							Mean	10 th Percentile	90 th Percentile
Upside Risk Payments	13	15	17	19	19	20	104	81	127
Downside Risk Payments	0	0	0	0	0	0	-1	-2	-1
Total Net Payments	13	15	17	19	19	20	103	80	126
Added Transplants	149	316	503	702	842	884	3,396	1,242	5,846
Impact on Federal Spending	-5	-11	-18	-27	-34	-37	-132	-140	-36
Mean Net Savings	8	4	-1	-8	-15	-17	-29	-140	68

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions.

2. Modification of Scoring on Composite Graft Survival Rate

In the 2024 Final Rule, points earned in the quality domain are based on the

IOTA participants' performance on the composite graft survival rate metric relative to national ranking, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as

IOTA participants. Currently, points are awarded to the IOTA participant for their composite graft survival rate as described in Table 5.

TABLE 5: CURRENT COMPOSITE GRAFT SURVIVAL RATE SCORING: 2024 FINAL RULE

Performance Relative to National Ranking	Points Earned
80 th Percentile ≤	20
60 th ≤ and < 80 th Percentile	18
40 th ≤ and < 60 th Percentile	16
20 th ≤ and < 40 th Percentile	14
10 th ≤ and < 20 th Percentile	12
< 10 th Percentile	10

In response to public comment concerns about the proposed points allocation for the composite graft survival rate, arguing that it unfairly penalizes kidney transplant hospitals that accept higher-risk kidney transplant

patients and suggesting modifications including lowering the threshold for maximum points over the lack of risk adjustment on the composite graft survival rate, a modified points allocation is proposed in Table 6. This

proposed scoring would remove the possibility of getting free points for poor performance and provide a more even scoring distribution for participants.

TABLE 6: PROPOSED COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80 th Percentile relative to target OR for comparison	Equals 80 th percentile	Greater than 80 th percentile	20
60 th Percentile	Equals 60 th percentile	Less than 80 th percentile	15
40 th Percentile	Equals 40 th percentile	Less than 60 th percentile	10
20 th Percentile	Equals 20 th percentile	Less than 40 th percentile	5
20 th Percentile	N/A	Less than 20 th percentile	0

4. Projected Impact

Table 7 shows the projected impacts for upside and downside risk payments, transplants, and Federal spending. Although transplant recipients with any type of insurance may benefit from a kidney transplant hospital's participation in the model, model payments in this proposed rule are based on the number of transplant recipients who are beneficiaries with Medicare FFS coverage including

beneficiaries with Medicare as a secondary payer. Roughly 26 percent of IOTA participants are projected to receive upside risk payments in the first year, rising to about 32 percent over the succeeding 5 model years, with fewer than 26 percent of IOTA participants projected to owe downside risk payments in any of PYs 3 through 6. The magnitude of the average downside risk payment is relatively small, and the cumulative projected upside risk payments to IOTA participants,

amounting to \$76 million, are nearly 25 times the magnitude of a cumulative \$3 million in projected receipts from downside risk payments from IOTA participants to CMS. The amount of projected savings from new kidney transplants was greater than the net cost of payments in about 85 percent of simulation trials. Overall, mean net savings totaled \$50 million over 6 years, ranging from a savings of \$153 million to a cost of \$39 million at the 10th and 90th percentiles.

TABLE 7: PROJECTED IMPACT OF UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING

							6-Year Totals		
	7/1/25-6/30/26	7/1/26-6/30/27	7/1/27-6/30/28	7/1/28-6/30/29	7/1/29-6/30/30	7/1/30-6/30/31	Mean	10 th Percentile	90 th Percentile
Upside Risk Payments	9	11	13	15	13	14	76	57	95
Downside Risk Payments	0	-1	-1	-1	-1	-1	-3	-4	-2
Total Net Payments	9	11	13	14	12	14	73	54	92
Added Transplants	137	292	464	646	772	811	3,123	1,188	5,236
Impact on Federal Spending	-5	-10	-17	-25	-31	-34	-123	-153	-34
Mean Net Savings	5	1	-4	-11	-19	-21	-50	-153	39

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions.

In Table 7, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase in Medicare spending. The mean net savings results were generated from the average of 10,000 individual simulation trials and the results for the percentiles are from the top 10th and 90th percentiles of the 10,000 individual simulations. The outcomes in each row do not necessarily flow from the same trial in the model at the 10th and 90th

percentiles. For example, the 90th percentile for added transplants more likely corresponds to the trial that produced the 10th percentile in impact on Federal spending from those kidney transplants (because spending is reduced when kidney transplants grow).

5. Net Impact of Proposed Changes (Proposed Model Impacts Less Revised Baseline)

In Table 8, we show the impact of the proposed changes on projected model

outcomes, given by taking the proposed impacts in Table 7 less the revised baseline impacts in Table 4. The increase in model spending related to the revisions to the incentive methodology are projected, on average, to result in marginally greater overall savings through additional growth in transplantation. The model's net impact is projected to save nearly \$20 million more in total over 6 years relative to the revised baseline.

TABLE 8: PROJECTED IMPACT OF PROPOSED RULE CHANGES: PROPOSED MODEL LESS REVISED BASELINE

	7/1/25- 6/30/26	7/1/26- 6/30/27	7/1/27- 6/30/28	7/1/28- 6/30/29	7/1/29- 6/30/30	7/1/30- 6/30/31	6-Year Totals		
							Mean	10 th Percentile	90 th Percentile
Upside Risk Payments	-4	-4	-4	-4	-6	-6	-28		
Downside Risk Payments	0	0	0	0	0	0	-2		
Total Net Payments	-4	-4	-4	-5	-6	-6	-30		
Added Transplants	-11	-24	-39	-56	-70	-73	-273		
Impact on Federal Spending	0	1	1	2	2	3	9		
Mean Net Savings	-3	-4	-3	-3	-4	-3	-21	-13	-29

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions.

6. Estimated Burden on Kidney Transplant Hospitals

While the model is focused on transplant outcome measures that would be calculated by CMS, there would likely be some additional burden for compliance for the IOTA participants (that is, kidney transplant hospitals). To estimate the compliance cost we focused on § 512.442(c) that requires IOTA participants to review organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries at least every 6 months that the Medicare beneficiary is on their waitlist. For this estimate, we assume that the IOTA participant will take a total of 15 minutes per patient per year to review the criteria at least twice a year with each patient. This assumption likely yields an upper estimate since the method (for example, patient visit, phone, email, or mail) of how the IOTA participant communicates the review with the IOTA waitlist patient who is a Medicare beneficiary is up to the IOTA participant and will likely vary by IOTA participant, potentially reducing the time to conduct the review. In addition, the IOTA waitlist patient who is a Medicare beneficiary may decline the review, resulting in the IOTA participant having fewer Medicare waitlist patients than what is used in our estimate.

We estimate that the average IOTA participant would have 200 waitlist patients who are Medicare primary payer or Medicare secondary payer beneficiaries per year and that it would take a clinician 15 minutes to review organ offer acceptance criteria with each patient each year. Using base wage information from the Bureau Labor of Statistics (BLS) for a nurse practitioner (series 29–1171), we estimate the cost of completing these reviews to be \$63.46 per hour.¹¹⁷ The base wage is then

doubled [$\$63.46 \times 2$] to account for fringe benefits and overhead to equal an estimated cost of \$126.92 per hour.¹¹⁸ The cost of completing these reviews would then be \$6,346.00 per kidney transplant hospital per year [200 Medicare IOTA waitlist patients $\times$ 0.25 hour per review each year $\times$ \$126.92 hourly wage]. We also estimate that 25 percent of beneficiaries would need to be notified of a declined offer, and a further 25 percent would need to be notified of a change in waitlist status. Using the same wage assumption noted previously, this would add \$3,173 in cost per hospital [100 Medicare IOTA waitlist patients requiring either type of notification $\times$ 0.25 hour per notification $\times$ \$126.92 hourly wage]. Total estimated hospital cost per year is \$9,519 per year [$\$6,346 + \$3,173$]. Therefore, the total cost would come out to \$980,457.00 to complete the review of organ offer acceptance criteria for the 103 kidney transplant hospitals selected as IOTA participants [$\$9,519.00 \times 103$ IOTA participants = \$980,457.00]. The average total revenue for IOTA participants was calculated from inpatient claims with DRGs 008, 019, 650, 651, or 652 submitted for adult Medicare FFS or MA beneficiaries with Medicare as their primary or secondary payer was estimated to be \$2 million in calendar year (CY) 2024. Therefore, the \$9,519.00 cost per IOTA participant to review the organ offer acceptance criteria would represent 0.5 percent [$\$9,519.00 / \$2,000,000 = 0.5\%$] of their estimated total annual revenue from kidney transplants for Medicare beneficiaries.

Accessed on June 9, 2025. https://www.bls.gov/oes/current/oes_nat.htm.

¹¹⁸ Guidelines for the adjustment in base wages is based on the following report: Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2017. “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.” <https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework>.

7. Alternatives Considered

We considered an alternative policy that would both (a) include Medicare Advantage (MA) beneficiaries in the definition of Medicare kidney transplant recipients so that upside risk payments and downside risk payments are based on kidney transplants for beneficiaries with Medicare FFS or MA as a primary or secondary payer, and (b) reduce the maximum incentive payment from \$15,000 to \$10,000 per transplant. At baseline, the growth of MA enrollment in the ESRD population presents a risk that counterproductive incentives could effectively increase barriers to transplantation in the CKD population. Transplant-eligible beneficiaries represent the healthiest (and potentially most profitable) ESRD enrollment subset for the average MA plan, particularly as the marginal increase in premium from each additional diagnosis code submitted by the plan is significantly higher when the payment is calculated relative to the base ESRD rate (roughly \$10,000 PBPM) as opposed to the aged/disabled base rate (currently about \$1,200 PBPM) which would otherwise become effective in months following transplant with a functioning graft. In addition to the reducing monthly premium to MA plans (including their returns on coding intensity initiatives), transplantation for the non-aged ESRD population could be further disincentivized in MA because it generally leads to the end of Medicare eligibility, and as noted before, plans would financially benefit from keeping healthier transplant-eligible beneficiaries enrolled for as long as possible at the higher base payment rate.

MA now enrolls more than half of ESRD beneficiaries and is projected to eclipse 60 percent penetration during the model testing period. We also estimate that federal savings would be marginally greater for the average additional transplant under MA because risk scores tend to over-project ESRD spending for beneficiaries meeting the

¹¹⁷ Bureau of Labor Statistics (BLS). May 2024. “Occupational Employment and Wage Statistics.”

clinical criteria for transplantation. An analysis of Hierarchical Condition Category (HCC) risk score and Medicare Part A and B spending data for a cohort of 1,450 transplanted Medicare FFS primary payer beneficiaries from the first quarter of 2023 indicated actual

spending of only \$4,782 PBPM compared to \$6,935 in average estimated monthly MA premium had the beneficiary been enrolled in Medicare Part C during the 9-month period preceding transplant. Table 7 shows the total beneficiary months, total

actual spending, and total predicted MA payment from this sample, where MA payment was estimated by multiplying average monthly HCC risk scores by the corresponding 2023 FFS USPPC from the 2025 Announcement.¹¹⁹

TABLE 9: COMPARISON OF PRE-TRANSPLANT COHORT ACTUAL SPENDING (9-MONTH PERIOD PRIOR TO TRANSPLANT) TO PROJECTED MA PREMIUM BASED ON ACTUAL HCC RISK SCORES

	Months in Sample	Actual Spending	Predicted MA Payment
Cohort Totals	11,453	\$54,772,787	\$79,432,166
Per Beneficiary Per Month (PBPM)		\$4,782	\$6,935

On the other hand, after about 2 years post-transplant, cumulative post-graft spending appeared virtually identical to what the premium spending would have projected to be according to actual post-graft HCC scores. Assuming 45 percent of new transplants generated by the model are for MA beneficiaries, and these marginally added savings of \$2,000 PBPM accrue for what would have been on average 6-months of obviated MA ESRD enrollment, mean savings per added transplant would be assumed to grow by about \$5,000 relative to the \$40,000 average savings assumed under the policies in this rule which exclude MA beneficiaries from triggering model incentives.

Table 10 shows the projected impacts for upside and downside risk payments, transplants, and Federal spending under the alternative considered where the model would include beneficiaries with Medicare FFS or MA coverage including beneficiaries with Medicare as a secondary payer. Under this alternative, roughly 27 percent of IOTA participants would be projected to receive upside risk payments in the first year, rising to about 34 percent over the succeeding 5 model years, with fewer than 25 percent of IOTA participants projected to owe downside risk payments in any of PYs 3 through 6. The magnitude of the average downside risk payment would be relatively small, and the cumulative

projected upside risk payments to IOTA participants, amounting to \$79 million, would be nearly 20 times the magnitude of a cumulative \$4 million in projected receipts from downside risk payments from IOTA participants to CMS. The amount of projected savings from new kidney transplants was greater than the net cost of payments in about 85 percent of simulation trials. Overall under this alternative, mean net savings would be expected to total \$98 million over 6 years (\$48 million greater than the proposed model estimated in Table 7), ranging from a savings of \$228 million to a cost of \$14 million at the 10th and 90th percentiles.

TABLE 10: PROJECTED IMPACT OF PROPOSED RULE ALTERNATIVE CHANGES: ALTERNATIVE POLICY UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING

	7/1/25-6/30/26	7/1/26-6/30/27	7/1/27-6/30/28	7/1/28-6/30/29	7/1/29-6/30/30	7/1/30-6/30/31	6-Year Totals		
							Mean	10 th Percentile	90 th Percentile
Upside Risk Payments	10	12	14	15	14	15	79	60	98
Downside Risk Payments	0	-1	-1	-1	-1	-1	-4	-5	-3
Total Net Payments	10	11	13	14	13	14	74	55	94
Added Transplants	165	351	558	780	933	980	3,767	1,415	6,352
Impact on Federal Spending	-6	-14	-24	-35	-44	-48	-172	-228	-59
Mean Net Savings	3	-4	-11	-21	-31	-34	-98	-228	14

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions. Whereas this alternative includes savings for MA beneficiary transplants, the proposed policy estimates in tables 7 and 8 do not presume any impact on the MA population.

In Table 10, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase in Medicare spending. The mean net savings results were generated from the average of 10,000 individual simulation trials and the results for the percentiles

are from the top 10th and 90th percentiles of the 10,000 individual simulations. The outcomes in each row do not necessarily flow from the same trial in the model at the 10th and 90th percentiles. For example, the 90th percentile for added transplants more

likely corresponds to the trial that produced the 10th percentile in impact on Federal spending from those kidney transplants (because spending is reduced when kidney transplants grow).

In Table 11, we show the impact of the proposed changes on projected

¹¹⁹ See pages 15 and 16 in the announcement accessible at <http://www.cms.gov/files/document/2025-announcement.pdf>.

model outcomes, given by taking the proposed impacts in Table 10 less the revised baseline impacts in Table 4. Despite including MA transplants in this alternative policy, overall incentive payments would still decline marginally because of other changes to the methodology and a reduction in the

maximum incentive amount to \$10,000. However, total new transplants are anticipated to grow marginally because of a broader and more uniform deployment of the incentive over the overall Medicare population. Net savings are also marginally improved by the marginal added savings per

transplant assumed for MA transplants. Under the alternative policy, the model's net impact would have been projected to save nearly \$70 million more in total over 6 years relative to the revised baseline (a \$48 million greater increase than the proposed policy is estimated to produce in table 8).

**TABLE 11: PROJECTED IMPACT OF PROPOSED RULE ALTERNATIVE
CHANGES: ALTERNATIVE POLICY LESS REVISED BASELINE**

	7/1/25- 6/30/26	7/1/26- 6/30/27	7/1/27- 6/30/28	7/1/28- 6/30/29	7/1/29- 6/30/30	7/1/30- 6/30/31	6-Year Totals		
							Mean	10 th Percentile	90 th Percentile
Upside Risk Payments	-3	-4	-4	-4	-5	-5	-25		
Downside Risk Payments	0	-1	-1	-1	-1	-1	-3		
Total Net Payments	-3	-4	-4	-5	-6	-6	-28		
Added Transplants	16	34	55	78	91	96	371		
Impact on Federal Spending	-2	-3	-6	-8	-10	-11	-40		
Mean Net Savings	-5	-8	-10	-13	-16	-17	-69	-89	-54

Totals may not sum due to rounding. Projected savings allocated to year of transplant; dollars in millions. Whereas this alternative includes savings for MA beneficiary transplants, the proposed policy estimates in tables 7 and 8 do not presume any impact on the MA population.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the 160 total unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

We estimate the time it will take for a medical and health services manager

to review the proposed rule to be 1 hour [30,000 words $\times$ 50 percent read through $\div$ 250 words per minute $\div$ 60 minutes = 1 hour]. Using the wage information from BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$132.44 per hour, including overhead and fringe benefits [\$66.22 mean hourly wage $\times$ 2 = \$132.44].¹²⁰ The cost of reviewing the rule for each commenter would be \$132.44 [1 hour to review the rule $\times$ \$132.44 per hour = \$132.44] or a total cost of \$21,190.40 [\$132.44 $\times$ 160 unique commenters = \$21,190.40].

Assuming that not all commenters will be IOTA participants and to put the cost of the regulatory review for kidney transplant hospitals in context, we calculate the cost of reviewing the rule separately for the IOTA participants. The cost of reviewing the rule for each IOTA participant would be \$132.44 [1 hour to review the rule $\times$ \$132.44 per hour = \$132.44] or a total cost of \$13,641.32 [\$132.44 $\times$ 103 IOTA participants = \$13,641.32]. Therefore, the \$132.44 cost per IOTA participant to complete the regulatory review would represent approximately 0.007 percent [\$132.44/\$2,000,000 = 0.3%] of their estimated total annual revenue from

kidney transplants for Medicare beneficiaries.

E. Accounting Statement and Table

Consistent with OMB Circular A-4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), we have prepared an accounting statement in Table 12 showing the classification of the impact associated with the provisions of this proposed rule. Annualized estimates were determined from Table 8 Mean Net Savings, and the 10th and 90th percentiles from the same table for determining the minimum and maximum estimates. Not reported in Table 12 is the estimated total cost of the regulatory review which is a one-time total cost of \$34,831.72. This includes the cost of reviewing the proposed rule for all commenters (\$21,190.40) plus the cost of reviewing the rule for the IOTA participants (\$13,641.32). These costs were not included in Table 8 because the total amount is so small that if we were to annualize it over the projection period then the result would be too small to report.

¹²⁰ Bureau of Labor Statistics (BLS). May 2024. "Occupational Employment and Wage Statistics." Accessed on June 9, 2025. https://www.bls.gov/oes/current/oes_nat.htm.

¹²¹ Estimated annualized monetized transfers round to the same values shown in the table regardless of choosing a discount rate of 3 percent or 7 percent.

TABLE 12: ACCOUNTING STATEMENT

<i>Category</i>	<i>Primary Estimate</i>	<i>Minimum Estimate</i>	<i>Maximum Estimate</i>	<i>Source Citation (RIA, preamble, etc.)</i>
BENEFITS				
Annualized monetized benefits				
Annualized quantified, but unmonetized, benefits				
Qualitative (unquantified) benefits				
COSTS				
Annualized monetized costs	See comment in Section E. Accounting Statement and Table			Section D. Regulatory Review Cost Estimation
Annualized quantified, but unmonetized, costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: “on budget” ¹²¹	-\$3 million	-\$5 million	-\$2 million	RIA Table 8
From whom to whom?	From CMS to IOTA participants			
Annualized monetized transfers: “on budget”				
From whom to whom?				

G. Regulatory Flexibility Act (RFA)

Effects on IOTA participants in the model include the potential for additional upside risk payments from CMS to the IOTA participant of up to \$15,000 per eligible kidney transplant or downside risk payments from the IOTA participant to CMS of up to \$2,000 per eligible kidney transplant (refer to section IV.C. (Detailed Economic Analysis) of the 2024 Final Rule for a description of how upside and downside risk payments are calculated in the model). We project that payouts will far exceed the relatively small sum of downside risk payments expected over the 6-year model performance period. Only about \$3 million in total downside risk payments are expected over the 6 years, with fewer than 26 percent of IOTA participants projected to owe downside risk payments in any of years 3 through 6. By contrast, we project that \$76 million in total upside risk payments would be made over 6 years to roughly 26 percent of IOTA participants in the first year, rising to about 33 percent over the succeeding 5 model years.

Under the RFA, agencies are to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$9.0 million to \$47.0 million in any 1

year). Although many IOTA participants (that is, kidney transplant hospitals with NAICS 622110 General Medical and Surgical Hospitals) may be small entities as that term is used in the RFA, kidney transplants only represent a small fraction of the revenue such hospitals generate, and even the largest per transplant downside risk payment of \$2,000 (which is not expected to apply to any hospitals at the median projection and only about 1 percent of hospitals at the 90th percentile projection) would not represent a significant economic impact. Additional sources of financial burden on IOTA participants to consider include the estimated cost of \$6,346.00 per IOTA participant per year to review the organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries, \$1,587 to notify patients about offers declined on their behalf, \$1,587 to notify patients about changes in their waitlist status, and the one-time cost of \$132.44 per IOTA participant to have their medical and health services manager review this rule. Refer to the sections titled, “Estimated Burden on Participant Hospitals” and “Regulatory Review Cost Estimation” in this proposed rule for an explanation of how these burden estimates were determined.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. The \$6,346.00 cost per IOTA participant to review the organ offer

acceptance criteria, the \$1,587 for notifying patients about offers declined on their behalf, \$1,587 for notifying patients about a change in status, and the \$132.44 cost per IOTA participant to complete the regulatory review would represent 0.3 percent, 0.1 percent, 0.1 percent, and 0.007 percent, respectively, of the estimated total annual revenue per IOTA participant from inpatient claims with DRGs 008, 019, 650, 651, or 652 submitted for adult Medicare FFS or MA beneficiaries with Medicare as their primary or secondary payer. Based on these estimates, we do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, under section 1102(b) of the Act, a regulatory impact analysis should be prepared if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe this proposed rule would not have a significant impact on small rural hospitals. Currently, no small rural hospitals are IOTA participants and no additional IOTA participants are being proposed. Therefore, the Secretary has certified that this proposed rule will not

have a significant impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately \$187 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule will not have a substantial direct effect on state or local governments, preempt states, or otherwise have a Federalism implication.

J. E.O. 14192, “Unleashing Prosperity Through Deregulation”

Executive Order 14192, titled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” For *E.O. 14192* accounting purposes, savings to the Federal government that are classified as transfers in regulatory impact analyses do not count as cost savings.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the “**DATES**” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 5, 2025.

List of Subjects in 42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Recordkeeping requirements.

For the reasons set forth in the preamble the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 512 as set forth below:

■ 1. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 2. Section 512.402 is amended by:

■ a. Adding the definition for “Eligible IOTA waitlist beneficiary”;

■ b. Removing the definitions for “Health equity goals,” “Health equity plan intervention,” “Health equity plan performance measure(s),” and “Health equity project plan”;

■ c. Adding the definitions for “Military medical treatment facility,” “MPSC,” and PRA;

■ d. Removing the definition for “Resource gap analysis”;

■ e. Adding the definition for “Single-organ kidney transplant”;

■ f. Removing the definition for “Target health disparities”;

■ g. Adding the definition for “Transplant organ offer acceptance criteria”;

■ h. Removing the definition for “Underserved communities”; and

■ i. Adding definition for “VA medical facility”.

The additions and revisions read as follows:

§ 512.402 Definitions.

* * * * *

Eligible IOTA waitlist beneficiary means an IOTA waitlist patient, as defined at § 512.402, who is a Medicare beneficiary and meets all of the following criteria:

(1) Is active on the IOTA participant’s waitlist.

(2) Has accrued a minimum of 3 years of waiting time on the IOTA participant’s waitlist.

* * * * *

Military medical treatment facility (MTF) means both of the following:

(1) Any fixed facility of the Department of Defense that is outside of a deployed environment and used primarily for health care.

(2) Any other location used for purposes of providing health care services as designated by the Secretary of Defense as defined in 10 U.S.C. 1073c(j)(3).

* * * * *

MPSC stands for Membership and Professional Standards Committee.

* * * * *

PRA stands for panel-reactive antibody.

* * * * *

Single-organ kidney transplant means the procedure in which a kidney alone is surgically transplanted from a living or deceased donor to a transplant recipient alone.

* * * * *

Transplant organ offer acceptance criteria means individualized patient acceptance parameters that kidney waitlist patients, as defined at § 512.402, may elect regarding the categories of organ offers they are prepared to accept for transplantation.

* * * * *

VA medical facility means a VA hospital, a VA community-based outpatient clinic, or a VA health care center, any of which must have at least one full-time primary care physician as defined in 38 CFR 17.1505. A Vet Center, or Readjustment Counseling Service Center, is not a VA medical facility.

* * * * *

■ 3. Section 512.412 is amended by—

■ a. In paragraph (a) introductory text, removing the phrase “meets both of the following” and adding in its place the phrase “meets all of the following”.

■ b. In paragraph (a)(1), removing the figure “11” and adding in its place the figure “15”.

■ c. Adding paragraph (a)(3).

The addition reads as follows:

§ 512.412 Participant eligibility and selection.

(a) * * *

(3) The kidney transplant hospital is not a MTF or VA medical facility as defined at § 512.402.

* * * * *

■ 4. Section 512.428 is amended by—

■ a. Revising paragraphs (b)(1)(iii)(E) and (b)(1)(iv)(A);

■ b. Adding paragraph (b)(2) and reserving paragraph (b)(3);

■ c. Revising Table 1 to paragraph (d); and

■ d. Revising paragraphs (d)(1) and (2).

The revisions and additions read as follows:

§ 512.428 Quality Domain.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(E) Multi-organ transplants (except for kidney/pancreas transplants).

(iv)(A) When calculating the composite graft survival rate, CMS only includes single-organ kidney transplants, as defined at § 512.402, and kidney/pancreas transplants for

transplant recipients who are 18 years of age and older in the number of kidney transplants performed by the IOTA participant during each PY in the denominator.

* * * * *

(2) *Risk-adjustment.*

(i) *Risk-adjustment transplant recipient and donor characteristics.* In accordance with paragraphs (b)(1) through (3) of this section, CMS risk-adjusts the composite graft survival rate based on, at minimum, the following:

(A) Transplant recipient characteristics.

(1) Age.

(2) Sex.

(3) Kidney function (eGFR/creatinine).

(4) Diabetes status.

(5) Hypertension with or without cardiovascular disease.

(6) Human leukocyte antigen (HLA) mismatch.

(7) Plasma renin activity (PRA) levels.

(B) Donor characteristics.

(1) Age.

(2) Sex.

(3) Kidney function (eGFR/creatinine).

(4) Diabetes status.

(5) Hypertension history with or without cardiovascular disease.

(6) Cardiovascular disease.

(7) Human leukocyte antigen (HLA) mismatch.

(8) Plasma renin activity (PRA) levels.

(9) Cause of death.

(10) Donation after cardiac death.

(ii) *Risk-adjustment methodology.*

(A) *Risk analysis.* CMS analyzes the transplant recipient and donor characteristics as specified in paragraphs (b)(2)(i)(A) through (D) of this section.

(B) *Risk scoring.* CMS applies a risk score to each individual IOTA kidney transplant patient, as defined at § 512.402, based on the analysis of the transplant recipient and donor characteristics in paragraph (ii)(A) of this section.

(C) *Adjustment and comparison.* CMS uses the calculated composite graft survival rate risk scores identified in paragraph (2)(ii)(B) of this section to—

(1) Normalize the composite graft survival rate outcome to control for differences in transplant recipient risk.

(2) Adjust the composite graft survival rate, based on the normalized composite graft survival rate outcome.

* * * * *

(3) Reserved.

(d) * * *

TABLE 1 TO PARAGRAPH (d)—IOTA MODEL COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance relative to national ranking	Lower bound condition	Upper bound condition	Points earned
80th Percentile	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	5
20th Percentile	N/A	Less than 20th percentile	0

■ 5. Section 512.430 is amended by—

■ a. In paragraph (b)(1) introductory text, removing the phrase “is 60 points or above,” and adding in its place the phrase “is above 60 points,”;

■ b. In paragraph (b)(2)(ii), removing the phrase “between 41 to 59 points (inclusive),” and adding in its place the phrase “between 40 to 60 points (inclusive)”;

■ c. In paragraph (b)(3) introductory text, removing the phrase “is at or below 40 points” and adding in its place the phrase “is below 40 points”; and

■ d. Revising paragraph (d)(6)(ii).

The revision and addition read as follows:

§ 512.430 Upside risk payment, downside risk payment, and neutral zone.

* * * * *

(d) * * *

(6) * * *

(i) * * *

(ii) The IOTA participant must pay the downside risk payment to CMS in a single payment within 60 days after the date on which the demand letter is issued. If full payment is not received by CMS within 60 days after demand is made, CMS will invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, in accordance with 31 U.S.C. 3711(g).

■ 6. Section 512.436 is amended by revising paragraphs (a)(1) and (b) introductory text to read as follows:

§ 512.436 Extreme and uncontrollable circumstances.

(a) * * *

(1) May at its sole discretion provide flexibilities to an IOTA participant if the IOTA participant is located in—

(i) An emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and

(ii) A county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

(2) Has sole discretion to determine the period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas.

(b) *Impact on payments.* In the event of an extreme and uncontrollable circumstance, as described in paragraph (a) of this section, CMS may adjust the magnitude and direction of the IOTA participant's upside or downside risk payment, if applicable, prior to recoupment or payment, if the IOTA participant is participating in the IOTA Model when CMS has declared such an emergency period. CMS may determine

any adjustment made based in part on the following:

* * * * *

■ 7. Section 512.442 is amended by—

■ a. Revising paragraphs (a) and (b);

■ b. In paragraph (c) introductory text, removing the phrase “acceptance criteria with” and adding in its place the phrase “acceptance criteria (as defined at § 512.402) with”;

■ c. Revising paragraphs (c)(1) and (2);

■ d. Adding paragraph (d).

The revisions and addition read as follows:

§ 512.442 Transparency requirements.

(a) *Publication of selection criteria.* (1) The IOTA participant must publicly post on its website the criteria used by the IOTA participant for evaluating and selecting patients for addition to their kidney transplant waitlist by the end of PY 1.

(2) For all subsequent PYs, the IOTA participant must review its publicly posted criteria used for evaluating and selecting patients for addition to its kidney transplant waitlist and ensure that the information is up on its website to date by the end of each relevant PY.

(3) IOTA participants performing living donor kidney transplants must—

(i) Publicly post on its website its living donor selection criteria for evaluating potential living donors for

kidney transplant waitlist patients by the end of PY 2; and

(ii) For all subsequent PYs, review its living donor selection criteria for evaluating potential living donors for kidney transplant waitlist patients and ensure that the information on its website is correct by the end of each relevant PY.

(b) *Transparency into kidney transplant organ offers.* For PYs 3 through 6, the IOTA participant must do the following for all eligible IOTA waitlist beneficiaries, as defined at § 512.402:

(1) Inform eligible IOTA waitlist beneficiaries of the number of times an organ is declined on the eligible IOTA waitlist beneficiary's behalf, unless the eligible IOTA waitlist beneficiary opts out of receiving this notification.

(i) For each 6-month period in which an organ offer is received and declined, provide notifications to each eligible IOTA waitlist beneficiary that include all of the following:

(A) How much wait-time the eligible IOTA waitlist beneficiary is currently listed with and their percent PRA value.

(B) In each 6-month period, how many match-runs, as defined at § 512.402, the eligible IOTA waitlist beneficiary came up on and how many donors they received kidney organ offers from.

(C) Unique patient-specific considerations for that eligible IOTA waitlist beneficiary for which deceased donor kidneys the IOTA participant would consider for that eligible IOTA waitlist patient.

(D) The refusal reason(s) why offers were declined based off OPTN refusal codes in plain language.

(E) Of the deceased donor kidney organ offers declined for that eligible IOTA waitlist beneficiary, how many of those declined offers were transplanted into another kidney transplant patient.

(F) Potential avenues to accelerate access to transplant.

(ii) [Reserved]

(2) The IOTA participant must provide the notification described in paragraph (b)(1) of this section via patient visit, email, electronically, or mail on an individual basis, unless the eligible IOTA waitlist beneficiary opts out of receiving this notification.

(i) IOTA participants must give eligible IOTA waitlist beneficiaries the opportunity to opt out of receiving the notification described in paragraph (b)(1) of this section.

(ii) If an eligible IOTA waitlist beneficiary opts out of receiving this notification, the IOTA participant must do both of the following:

(A) Record in the eligible IOTA waitlist beneficiary's medical record all of the following:

(1) The date on which this notification was declined.

(2) The method by which this notification was declined.

(B) Offer to provide this notification once every 6 months at which time the eligible IOTA waitlist beneficiary will have the opportunity to opt out of receiving this notification again.

(3) Record all of the following in the eligible IOTA waitlist beneficiary's medical record:

(i) That the eligible IOTA waitlist beneficiary received the information specified in paragraph (b)(1) of this section.

(ii) The method by which this notification was delivered.

(iii) The date by which this notification was delivered.

(4) Provide the information specified in paragraph (b)(1) of this section to the eligible IOTA waitlist beneficiary's nephrologist or nephrology professional.

(c) * * *

(1) * * *

(i) Prior to reviewing transplant organ offer acceptance criteria, as defined at § 512.402, with IOTA waitlist patients who are Medicare beneficiaries, IOTA participants must give these beneficiaries an opportunity to decline this review.

(ii) If an IOTA waitlist patient who is a Medicare beneficiary declines this review, the IOTA participant must do both of the following:

(A) Record in the IOTA waitlist patient who is a Medicare beneficiary's medical record all of the following:

(1) The date on which this review was declined.

(2) The method by which this review was declined.

(B) Offer the IOTA waitlist patient who is a Medicare beneficiary the opportunity to review transplant organ offer acceptance criteria once every 6 months at which time the IOTA waitlist patient who is a Medicare beneficiary will have the opportunity to decline this review again.

(2) The IOTA participant must record in the IOTA waitlist patient who is a Medicare beneficiary's medical record all of the following:

(i) The information specified in paragraph (c) of this section was reviewed with the IOTA waitlist patient who is a Medicare beneficiary.

(ii) The date in which this review took place.

(iii) The method by which this review was delivered.

(d) *Change in waitlist status notification.* (1) The IOTA participant

must do the following for all IOTA waitlist patients who are Medicare beneficiaries during the model performance period:

(i) Inform IOTA waitlist patients who are Medicare beneficiaries any time their status on the waitlist is changed that would impact their ability to receive an organ offer.

(ii) When there is a change in waitlist status, provide notifications to each IOTA waitlist patient who is a Medicare beneficiary that includes all of the following:

(A) The most recent date the IOTA waitlist patient who is a Medicare beneficiary became inactive.

(B) The reason for the change in waitlist status.

(C) That the IOTA waitlist patient who is a Medicare beneficiary cannot receive organ offers while inactive.

(D) Information on how the IOTA waitlist patient who is a Medicare beneficiary may become active on its waitlist again.

(E) How the IOTA waitlist patient who is a Medicare beneficiary may contact the IOTA participant for more information or with any questions.

(iii) The IOTA participant must provide this notification (as described in paragraph (d)(1)(i) of this section), and the information specified in paragraph (d)(1)(ii) of this section as follows:

(A) Electronically or by mail on an individual basis.

(B) Within 10 days of the IOTA waitlist patient who is a Medicare beneficiary's change in waitlist status.

(C) Annually, thereafter, for as long as the IOTA waitlist patient who is a Medicare beneficiary remains inactive (that is, 365 consecutive days).

(2) Record in the IOTA waitlist patient who is a Medicare beneficiary's medical record a copy of the notification that includes all of the following:

(i) The method by which the notification was delivered.

(ii) The date of when the notification was delivered.

(3) For IOTA waitlist patients who are Medicare beneficiaries and—

(i) ESRD patients, the IOTA participant must also notify the dialysis facility (as defined at 42 CFR 494.10) and managing clinician (as defined at § 512.310) or nephrologist.

(ii) Non-ESRD patients, the IOTA participant must also notify the referring provider or practitioner providing care to the IOTA waitlist patient who is a Medicare beneficiary.

§ 512.446 [Removed]

■ 8. Subpart D is amended by removing § 512.446.

■ 9. Section 512.450 is amended by—

■ a. In paragraph (a)(1), removing the phrase “attributed patients that” and adding in its place the phrase “attributed patients who are Medicare beneficiaries that”; and

■ b. Revising paragraph (a)(3)(iii).
The revision reads as follows:

§ 512.450 Required beneficiary notifications.

(a) * * *

(2) * * *

(3) * * *

(iii)(A) Provide the notification described in paragraph (a) of this section to each applicable attributed patient in a paper format at their first office visit or other outpatient visit after the start of the Model; or

(B) If the attributed patient has affirmatively opted out of receiving paper communication and has chosen to receive communication through electronic methods, the notification described in paragraph (a) of this section may be distributed through that agreed upon electronic method.

* * * * *

■ 10. Section 512.462 is amended by adding paragraph (b)(2)(xi) to read as follows:

§ 512.462 Compliance and monitoring.

* * * * *

(b) * * *

(2) * * *

(xi) Monitoring the publication of selection criteria provision in accordance with § 512.442(a).

(xii) Monitoring the transparency into kidney transplant organ offers provision in accordance with § 512.442(b).

(xiii) Monitoring the review of acceptance criteria provision in accordance with § 512.442(c).

(xiv) Monitoring the change in waitlist status provision in accordance with § 512.442(d).

* * * * *

■ 11. Section 512.466 is amended by revising and republishing paragraph (a)(3)(ix) to read as follows:

§ 512.466 Termination.

(a) * * *

(3) * * *

(ix) Poses significant program integrity risks, including but not limited to any of the following:

(A) Is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency.

(B) Is subject to investigation or action by HHS (including OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:

(1) Being subject to the filing of a complaint or, filing of a criminal charge.

(2) Being subject to an indictment.

(3) Being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

(C) If HHS or the OPTN has determined that an IOTA participant has violated the OPTN's policies, OPTN's Management and Membership policies, or HHS's regulation (42 *CFR* 121) upon a review conducted pursuant to 42 *CFR* 121.10.

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–22543 Filed 12–9–25; 4:15 pm]

BILLING CODE 4120–01–P



FEDERAL REGISTER

Vol. 90

Thursday,

No. 236

December 11, 2025

Part V

Environmental Protection Agency

40 CFR Part 52

Air Plan Approval; South Carolina; Second Planning Period Regional Haze Plan; Final Rule

ENVIRONMENTAL PROTECTION AGENCY**National Oceanic and Atmospheric Administration****40 CFR Part 52****[EPA–R04–OAR–2022–0367; FRL–10406–02–R4]****Air Plan Approval; South Carolina; Second Planning Period Regional Haze Plan****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a regional haze State Implementation Plan (SIP) revision submitted by the State of South Carolina on March 3, 2022 (hereinafter referred to as “Haze Plan”), as satisfying applicable requirements under the Clean Air Act (“CAA” or “Act”) and EPA’s Regional Haze Rule (RHR) for the regional haze program’s second planning period. South Carolina’s SIP submission was submitted to address the requirement that states must periodically revise their long-term strategies (LTSs) for making reasonable progress toward the national goal of preventing any future, and remedying any existing, anthropogenic impairment of visibility, including regional haze, in mandatory Class I Federal areas (hereinafter referred to as “Class I areas”). This SIP submission also addresses other applicable requirements for the second planning period of the regional haze program. EPA is taking this action pursuant to sections 110 and 169A of the Act.

DATES: This rule is effective January 12, 2026.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2022–0367. All documents in the docket are listed on the *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:

Matthew Bloemer, Multi-Air Pollutant Coordination Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9653. Mr. Bloemer can also be reached via electronic mail at *bloemer.matthew@epa.gov*.

SUPPLEMENTARY INFORMATION:**I. Background**

On March 3, 2022, the South Carolina Department of Health and Environmental Control (DHEC) ¹ submitted a revision to its SIP to address regional haze for the second planning period.² South Carolina made this SIP submission to satisfy the requirements of the CAA’s regional haze program pursuant to CAA sections 169A and 169B and 40 Code of Federal Regulations (CFR) 51.308. EPA has determined that the regional haze SIP revision for the second planning period meets the applicable statutory and regulatory requirements and is thus approving South Carolina’s submission.

Through a notice of proposed rulemaking (NPRM) published on July 31, 2025 (90 FR 36005), EPA proposed to approve South Carolina’s Haze Plan as satisfying the regional haze requirements for the second planning period contained in the CAA and 40 CFR 51.308. EPA described its rationale for proposing to approve the Haze Plan in the July 31, 2025, NPRM. Comments on the July 31, 2025, NPRM were due on or before September 29, 2025.

¹ On July 1, 2024, DHEC was restructured into a health agency, the Department of Public Health, and an environmental agency, the Department of Environmental Services (DES). In a letter dated June 20, 2024, South Carolina represented to EPA that all the functions, powers, and duties of the environmental divisions, offices, and programs of DHEC, including the authority to administer and enforce state implementation plans, are retained and continued in full force and effect under DES. The letter is in the docket for this rulemaking. The state agency will simply be referred to as “the State” or “South Carolina” for the remainder of this document.

² The March 3, 2022, SIP submission, with exception of the supporting modeling files and Confidential Business Information, is included in the docket for this rulemaking.

II. Response to Comments

In response to the NPRM, EPA received one set of comments from the National Parks Conservation Association (NPCA), Sierra Club, and the Coalition to Protect America’s National Parks (hereinafter “Conservation Groups”); one set of comments from the Mid-Atlantic/Northeast Visibility Union (MANE–VU); and one set of comments from the Augusta Aiken Audubon Society, Coalition to Protect America’s National Parks, NPCA, South Carolina Environmental Law Project, and Waccamaw Audubon Society. Additionally, EPA received a comment letter from an anonymous commenter about greenhouse gases ³ that is not relevant to this action, and two identical comments in support of this action from one individual. All comments received are available in the docket for this rulemaking. Summaries of the significant comments received and EPA’s responses to these comments are below.

Comment 1: The Conservation Groups claim that EPA’s new uniform rate of progress (URP) policy violates the CAA. These comments are discussed in more detail in Comments 1.a through 1.d. A response to these comments follows after Comment 1.d.

First, the Conservation Groups assert that EPA recently announced a new policy whereby if “visibility conditions for a Class I area impacted by a State are below the URP and the State has evaluated potential control measures and considered the four statutory factors, the State will have presumptively demonstrated reasonable progress for the second planning period.” However, they state EPA’s description of the new policy in its proposal to approve South Carolina’s 2022 SIP Revision differs from earlier descriptions of the policy as originally announced in the Agency’s proposal to

³ Specifically, the commenter asks EPA to “account for the economic costs of carbon dioxide” in this action. However, greenhouse gases are non-haze forming and are therefore beyond the scope of this action, which is focused solely on visibility impairing pollutants and specifically the approvability of South Carolina’s regional haze SIP for the second planning period. Nor does the commenter identify any legal duty for EPA to calculate such costs. The commenter cites to Executive Order 13990 as authority, but that executive order was revoked on January 20, 2025. The commenter also cites generally to the National Environmental Policy Act (“NEPA”), but it is long-settled that NEPA does not apply to EPA’s actions approving SIPs. See *Appalachian Power Co. v. EPA*, 477 F.2d 495, 508 (4th Cir. 1973) (quoting the holding in *Getty Oil Co. (Eastern Operations), Inc. v. Ruckelshaus*, 467 F.2d 349, 359 (3d Cir. 1972) that “[it] is apparent that the Clean Air Act itself contains sufficient provisions for the achievement of those goals sought to be attained by NEPA”).

approve West Virginia's SIP. They state that in the West Virginia proposal, EPA explained that, if visibility conditions at affected Class I areas⁴ are projected to be below the URP, and the state considered the four factors, the state presumptively demonstrates reasonable progress and that absent from EPA's description of the new URP policy in the West Virginia proposal is a need for states to have "evaluate[d] potential control measures." The Conservation Groups assert that in EPA's proposal here, EPA incorporates this additional phrase into its description of the new URP policy for the first time, without explaining the significance of that purported change. Additionally, they state that EPA explicitly states that the new policy reflects only "a change in policy from *current guidance* as to how the URP should be used in the evaluation of regional haze second planning period SIPs."

Response 1: EPA disagrees with the Conservation Groups. EPA has not substantively changed the URP policy since it was announced in the West Virginia regional haze NPRM,⁵ including in the South Carolina regional haze NPRM. In the South Carolina regional haze NPRM, EPA noted that "it is the Agency's policy, as announced in the recent proposed action for West Virginia's Regional Haze SIP for the second planning period, that, where visibility conditions for a Class I area impacted by a State are below the URP and the State has evaluated potential control measures and considered the four statutory factors, the State will have presumptively demonstrated reasonable progress for the second planning period for that area." Although the Conservation Groups are correct that EPA included the phrase "has evaluated potential control measures" within this sentence and that EPA did not include this phrase in the West Virginia NPRM when discussing the URP Policy, the inclusion of this phrase was merely descriptive and was not intended to announce any substantive deviation from EPA's URP policy. This is because evaluation of potential control measures for regional haze SIPs is conducted pursuant to the four factors. Specifically, the RHR text at 40 CFR 308(f)(2)(i) requires states to evaluate

and determine the emission reduction measures that are necessary to make reasonable progress by considering the four statutory factors. Additionally, the full sentence quoted by the Conservation Groups in the South Carolina regional haze NPRM clearly indicates that it was merely summarizing the "Agency's policy, as announced in the recent proposed action for West Virginia's Regional Haze SIP." EPA confirms that the URP policy is as follows: where visibility conditions for a Class I area impacted by a State are below the URP and the State has considered the four statutory factors, the State will have presumptively demonstrated reasonable progress for the second planning period for that area.

Comment 1.a: The Conservation Groups state that EPA's URP policy violates the plain language of the CAA. They quote *Loper-Bright Enterprises v. Raimondo* for the proposition that "a statutory provision is interpreted 'using the traditional tools of statutory construction' to arrive at the provision's 'best reading.'"⁶ They state that the starting point for that inquiry is the text of the Act and then assert that the plain language of 42 U.S.C. 7491 bars EPA's proposed new policy.

The Conservation Groups note that section 7491(b)(2) requires states to develop plans that "make reasonable progress toward meeting the national goal" and that section 7491(g)(1) defines "reasonable progress," providing that, "in determining reasonable progress there shall be taken into consideration the costs of compliance, the time necessary for compliance, and the energy and non-air quality environmental impacts of compliance, and the remaining useful life of any existing source subject to such requirements." They assert that "the dependent clause 'in determining reasonable progress' must be joined with the independent clause of that section—i.e., the four reasonable progress factors—to make sense." Thus, they suggest that "accurately reading those clauses together, the Act requires that states and EPA must determine what constitutes 'reasonable progress' based on the four statutory factors listed in Section 7491(g)(1)" and that "absent from the statutory text is any reference to the URP."

The Conservation Groups state that "EPA misreads this provision when, in its new URP policy, it changes the phrase 'taken into consideration' into 'considers.'" They maintain that "[t]he word 'consideration' means 'something that is considered as a ground of

opinion or action' or 'the act of regarding or weighing carefully.'" The Conservation Groups state that "the things that states and EPA must 'take into consideration' are the four statutory factors listed in (g)(1)." Furthermore, they assert that "States and EPA must not merely 'consider' the four statutory factors, but must use them 'in determining reasonable progress,' confirming that the best reading of this statutory provision requires states to determine reasonable progress based on the four statutory factors, and not other unlisted factors." They state that "[h]ad Congress intended states to consider other factors, such as the URP, in determining what constitutes reasonable progress, it would have listed those factors in the statutory definition for 'reasonable progress.'"

The Conservation Groups also assert that "[t]he new URP policy also would only require states and EPA to apply the Act's text in certain scenarios" and that "[u]nder the new policy, even if a state conducted control analyses that show new or existing controls are reasonable based on the four statutory factors, states and EPA can ignore the results of those analyses and not require any emission reduction measures to make reasonable progress if they show all affected Class I areas are projected to be below the URP glidepath at the end of the planning period." They state that this would result in EPA and states "disregard[ing] the text that Congress set forth in section 7491(g)(1) requiring states to determine reasonable progress based on the four statutory factors. A policy that makes the statutory text superfluous in some cases, but not in others, is absurd."

The Conservation Groups claim that EPA's proposal for South Carolina approval is a prime example. They note that "South Carolina requested that EPA approve the 2022 SIP Revision without incorporating into the SIP any of the permit provisions the State determined were necessary to make reasonable progress—a request EPA proposes to grant." However, they assert that "EPA ignores that, in the 2022 SIP Revision, South Carolina determined that installation of wet flue gas desulfurization (wet FGD) on [International Paper—Georgetown's (IP-Georgetown)] No. 1 Recovery Boiler would cost just \$3,100/ton of [sulfur dioxide (SO₂)] reduce," which the Conservation Groups suggest is a cost-effective control. South Carolina stated that the \$3,100/ton value was no longer applicable, and rejected this potential control measure, because IP Georgetown had requested a federally enforceable limit on the Boiler's potential to emit of

⁴ Areas statutorily designated as mandatory Federal Class I areas consist of national parks exceeding 6,000 acres, wilderness areas and national memorial parks exceeding 5,000 acres, and all international parks that were in existence on August 7, 1977. CAA section 162(a). There are 156 mandatory Class I areas. The list of areas to which the requirements of the visibility protection program apply is in 40 CFR part 81, subpart D.

⁵ See 90 FR 16478 (April 18, 2025).

⁶ 603 U.S. 369, 400, 403 (2024).

330 [tons per year (tpy)] of SO₂ to be incorporated into the SIP. Thus, they state that “[b]ecause EPA proposes to grant South Carolina’s request to exclude this limit from the SIP, the State’s reason for rejecting wet FGD for the No. 1 Recovery Boiler is no longer valid. Yet, South Carolina and EPA still exclude wet FGD for the No. 1 Recovery Boiler despite the fact that South Carolina’s own Four-Factor Analysis for IP Georgetown shows that this control is reasonable and cost-effective, and so, necessary to make reasonable progress for the facility, because they allege that all Class I areas affected by South Carolina pollution are projected to be below the URP glidepath.” The Conservation Groups then claim that “[a]s a result, the new URP policy allows EPA and states to disregard the text that Congress set forth in section 7491(g)(1) requiring states to determine reasonable progress based on the four statutory factors. A policy that makes the statutory text superfluous in some cases, but not in others, is absurd.”

The Conservation Groups then note that “[m]ultiple courts, including the Supreme Court, have held that the Clean Air Act’s plain text requires that EPA engage in rigorous and substantive review of SIPs.” They quote section 7491(b)(2)(B), which requires states to develop plans “that mak[e] reasonable progress toward meeting the national goal” and assert that this “inherently requires EPA to assess whether SIP submissions provide adequate measures to achieve that goal.” They also quote section 7410(k)(3), which requires EPA to determine if SIPs “meet all of the applicable requirements of this chapter,” and argue that this provision requires EPA to “assess the adequacy, effectiveness, and reasonableness of SIPs to ensure they comply with the Act and its implementing regulations.”

The Conservation Groups assert that “EPA’s new URP policy would render these Clean Air Act requirements superfluous. In pointing to the new policy, EPA tries to evade its duty to review Four-Factor Analyses or control determinations to ensure that the technical bases for those analyses are adequately documented and the determinations are based on reasoned decision-making.” They assert that the South Carolina proposal here is an apt example and note that “EPA’s entire evaluation of South Carolina’s Four-Factor Analyses spans just two pages of the proposal, one of which is devoted just to describing its new URP policy.” They maintain that “[i]n its purported ‘evaluation,’ EPA merely makes conclusory statements that what South Carolina did in the 2022 SIP Revision

was ‘reasonable’ without providing any explanations or analyses to support those statements.” The Conservation Groups state that “EPA states that South Carolina ‘reasonably’ concluded that no new controls are necessary for [Century Aluminum of South Carolina Inc. (Century)].” But they assert that “[t]he only support EPA provides for that assertion is a bare claim that South Carolina evaluated the cost of controls consistent with the Control Cost Manual, but nowhere in the proposal does EPA explain how South Carolina’s analyses complied with that Manual or whether the cost information used in the analyses was reliable or adequately documented.” On the other hand, the Conservation Groups state that “readily available record evidence, including the Conservation Groups comments to the State on its draft 2022 SIP Revision, show that South Carolina neither followed the Control Cost Manual nor provided necessary documentation to support its analyses.” They allege that “[r]ather than provide any rationale to support its assertions or grapple with the record before it, EPA points to its new URP policy to claim that South Carolina’s control determinations for Century are reasonable and the 2022 SIP Revision presumptively demonstrated reasonable progress for the second planning period.”

In addition, the Conservation Groups state that “EPA’s claim that the Act requires only reasonable progress and not maximal progress is a red herring” and “[t]he plain text of the Clean Air Act embodies Congress’s determination that the rate of progress achieved by the emission reduction measures found to be reasonable based on the four statutory factors ‘is, by definition, a reasonable rate of progress.’” They argue that “EPA tries to sever the word ‘reasonable’ from ‘progress’ in justifying its new URP policy to make a free-floating determination, unmoored from the four statutory factors, as to what is ‘reasonable.’” On the contrary, the Conservation Groups maintain that “in severing ‘reasonable’ from ‘progress’ here, EPA must also recognize the ordinary meaning of the word ‘progress,’ which is defined as ‘gradual betterment’ or ‘a forward or onward movement.’” Thus, they assert that the “Agency cannot use its attempt to break this term apart to justify approving SIPs that improperly adopt the status quo instead of requiring facilities to adopt emission reduction measures that are reasonable based on a review of the four factors, and therefore, necessary to make reasonable progress toward the goal of remedying existing and preventing

future impairment. In any event, the Agency cannot change the fact that Congress deliberately placed ‘reasonable progress’ under section 7491(g)’s heading of ‘Definitions,’ making it a statutorily defined term.”

The Conservation Groups allege that “EPA’s own interpretation of the Act’s text in its 2017 RHR revision preamble demonstrates that the new URP policy violates the statute.” From the preamble, they state that “EPA explained that the terms ‘compliance’ and ‘subject to such requirements’ in section 7491(g)(1) showed that ‘Congress intended the relevant determination to be the requirements with which sources would have to comply in order to satisfy the [Clean Air Act’s] reasonable progress mandate.’” Thus, they argue that “the Four-Factor Analyses must be the basis on which states determine the requirements that represent reasonable progress.”

The Conservation Groups state that EPA cannot point to any asserted ambiguity or lack of explicit direction in 7491(g)(1) to claim it can interpret the statutory text to allow consideration of visibility conditions or the URP in determining what constitutes reasonable progress. Instead, they claim, “every tool” available must be used “to determine the best reading of the statute and resolve the ambiguity.”

The Conservation Groups assert that “EPA also cannot escape *Loper-Bright*’s mandate to find the ‘best reading’ of the provision by citing Congress’ instruction for EPA in section 7491(a)(4) to issue regulations as some indication of intent to delegate authority to EPA to undercut the Regional Haze Program” and “nothing in section 7491(a)(4) authorizes EPA to create a ‘presumption’ that a haze plan demonstrates reasonable progress, thereby excusing the state from implementing reasonable emission reductions based on a consideration of the statutory factors for a source, where affected Class I areas are on or below the URP.” They further argue that “section 7491(a)(4) authorizes EPA only to ‘promulgate regulations’ ‘after notice and public hearing.’” Therefore, they allege that “in a transparent attempt to avoid actually issuing any uniform, national ‘regulation’ under sections 7491(a)(4) and 7607(d)(1)(j) articulating the Agency’s interpretation of the Clean Air Act’s visibility provisions, EPA is instead attempting to amend the RHR on a piecemeal, state-by-state basis.” Moreover, they maintain that “EPA has failed to comply with section 7491(a)(4)’s mandate to issue any such regulation ‘after notice and public hearing.’”

The Conservation Groups also assert that “nothing in section 7491 suggests, let alone clearly states, that EPA has authority to create a presumption that, where a Class I area is on the so-called URP, states need not implement further emission reductions based on a consideration of the four statutory reasonable factors.” Finally, the Conservation Groups state that “under section 7491(a)(4), EPA must ‘promulgate regulations to assure reasonable progress toward meeting the national goal.’ The national goal is ‘the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory class I Federal areas which impairment results from manmade air pollution.’”

The Conservation Groups claim that Congress directed states to make reasonable progress in each successive planning period. They point to section 7491(b)(2)(B), which provides that states’ plans must set forth long-term strategies “for making reasonable progress toward meeting the national goal” covering “ten to fifteen year” periods. They assert that the Act “does not contemplate prolonging progress toward attaining natural visibility conditions.” The Conservation Groups argue that Congress “set a framework for EPA to establish iterative planning periods during which states must build on emission reductions achieved in each successive planning period.” The Conservation Groups then state that “EPA claims in the proposal that it ‘believe[s] this policy also recognizes the considerable improvements in visibility impairment that have been made by a wide variety of state and federal programs in recent decades.’” They contend that “[m]erely relying on past reductions, or expected ongoing reductions from the implementation of already existing air quality programs, again absurdly makes this statutory text superfluous by allowing states and EPA to evade the directive to continue making progress toward the natural visibility goal in each planning period if the states show that all affected Class I areas are projected to be below the URP at the end of the planning period.” They conclude that “EPA relies on a factor that Congress could not have intended that it or states consider.”

The Conservation Groups continue by stating “[c]ontinued delay in achieving the natural visibility goal is something Congress explicitly addressed in the 1990 Clean Air Act amendments. Although the reasonable progress provisions were enacted in the 1977 Amendments, EPA ignored them. In response, Congress forced EPA to act with its 1990 Amendments to the Act.”

Based on legislative history, the Conservation Groups further assert that states and EPA must make reasonable progress toward the natural visibility goal in each successive planning period.

Comment 1.b: The Conservation Groups assert that EPA’s contemporaneous understanding of the Act reflects the best reading of the statute. The Conservation Groups cite *Loper-Bright* for the proposition that “an agency’s contemporaneous understanding of a statutory provision may warrant respect in interpreting that provision.” They assert that the RHR, as originally promulgated in 1999 “is the best evidence of EPA’s ‘contemporaneous’ understanding of the Clean Air Act’s requirements.” Quoting a provision of the 1999 RHR, they state that it “required states and EPA to establish reasonable progress goals (RPGs) based on the four statutory factors.” The Conservation Groups acknowledge that the 1999 RHR also required states to consider the URP in establishing RPGs but assert that “nothing in the 1999 RHR regulatory text allows states or EPA to ignore the requirement to determine the emission reduction measures necessary to make reasonable progress based on the four statutory factors.”

The Conservation Groups also note that “[t]he 1999 RHR required that, ‘[i]n determining whether the State’s goal for visibility improvement provides for reasonable progress towards natural visibility conditions, the Administrator will evaluate the demonstrations developed by the State pursuant to paragraphs (d)(1)(i) and (d)(1)(ii) of this section.’ The cross-referenced paragraphs pertain to the state’s demonstration of how the four factors were taken into consideration in establishing the RPGs. Thus, neither EPA nor states could treat the Four-Factor Analysis [(FFA)] required by the Act and the RHR as an ungraded, make-work exercise.”

The Conservation Groups then quote that the 1999 RHR preamble and assert that it “made clear that states and EPA could not use the URP to avoid complying with the statutory and regulatory requirements of the haze program.” The Conservation Groups also state that, “in the 1999 RHR, EPA had originally proposed ‘presumptive ‘reasonable progress targets,’ similar to its new URP policy, which treats the URP as the target states should aim for but not exceed in their SIPs. But EPA ultimately rejected that approach in the final Rule.” They conclude that “EPA rejected the notion that the URP itself necessarily represented reasonable progress.” The Conservation Groups cite

to the 2017 RHR preamble, the 2019 Guidance,⁷ and the 2021 Clarifications Memorandum⁸ to make similar arguments as stated above.

The Conservation Groups state that “[a]t every opportunity since promulgating the original 1999 RHR, EPA has reaffirmed, reiterated, and repeated that relying on the URP to avoid adopting otherwise reasonable controls based on an analysis of the four statutory factors violates the Clean Air Act. EPA’s new URP policy allows states and EPA to do exactly that, and so, cannot be the best reading of the statute. Rather, EPA’s contemporaneous interpretation of the Act embodied by the 1999 RHR constitutes the best reading of the Act’s haze requirements.”

Comment 1.c: The Conservation Groups state that the context of the Act’s visibility provisions confirms the best reading of the statute. Citing *United States Sugar Corp. v. EPA*, the Conservation Groups assert that “[t]he context of section 7491(g)(1) supports that EPA’s contemporaneous interpretation of the Act is the best reading of the statute.” They state that “section 7491(g)(1) does not list visibility conditions or the URP as factors that can be considered in determining what constitutes reasonable progress” whereas section 7491(g)(2), which defines Best Available Retrofit Technology (BART) “explicitly includes visibility as one of its five factors.” They then quote *Intel Corp. Inv. Pol’y Comm. v. Sulyma*, for the proposition that “Congress acts intentionally and purposely when it includes particular language in one section of a statute but omits it in another.” They assert that, “[b]ecause Congress intentionally omitted any reference to visibility in the definition of reasonable progress, it is clear that states may not reject controls based on assertions about visibility conditions at Class I areas.” They then quote section 7491(b)(2) and assert that “states and EPA account for visibility impacts in determining which Class I areas are affected by in-state pollution sources and in selecting the sources that contribute to impairment at those Class

⁷ In reference to EPA’s August 20, 2019, guidance titled: “Guidance on Regional Haze State Implementation Plans for the Second Implementation Period” (“2019 Guidance”) which is available at: https://www.epa.gov/sites/default/files/2019-08/documents/8-20-2019_-_regional_haze_guidance_final_guidance.pdf.

⁸ In reference to EPA’s July 8, 2021, Clarification Memorandum titled: “Clarifications Regarding Regional Haze State Implementation Plans for the Second Implementation Period” (“2021 Clarification Memo”) which is available at: <https://www.epa.gov/system/files/documents/2021-07/clarifications-regarding-regional-haze-state-implementation-plans-for-the-second-implementation-period.pdf>.

I areas to be addressed in the long-term strategy, but not in determining what emission reduction measures are necessary to make reasonable progress for those selected sources.”

The Conservation Groups next state that section 7491 “does not contain any exemptions from the Act’s reasonable progress requirements, including in cases where affected Class I areas are projected to be below the glidepath.” They assert that “[t]his is again in stark contrast to section 7491(c), which contains explicit exemptions from BART that are based on visibility conditions. That Congress did not provide for similar, or any, exemptions from reasonable progress shows that Congress did not intend any exemptions such as EPA proposes here.” They further assert that “EPA cannot create the exemption it proposes by invoking the de minimis principle, as courts have explained that ‘an agency can’t use [that principle] to create an exception where application of the literal terms would provide benefits, in the sense of furthering the regulatory objectives.’”

Finally, the Conservation Groups quote the 2017 RHR revision preamble regarding the collective significance of small amounts of pollutants to regional haze and conclude that “under EPA’s new URP policy, states could evade the Act’s reasonable progress requirements even for large sources of visibility impairing pollution, for which controls would likely result in large benefits.”

Comment 1.d: The Conservation Groups state that the purpose of the Act’s visibility provisions further confirms the best reading of the statute. They cite *Lissack v. Comm’r of Internal Revenue*, and quoting section 7491(a), the Conservation Groups assert that the purpose of the Act’s visibility provisions “is the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory class I Federal areas which impairment results from manmade air pollution.” The Conservation Groups also quote the 2017 RHR revision preamble, in which they assert “EPA rejected the idea that states could use the URP as a safe harbor, pointing to the Act’s natural visibility goal.” They conclude that, “[c]ontrary to Congress’s stated goal in establishing the Regional Haze Program, the new URP policy would allow states to adopt SIPs that do not include *any* additional measures to remediate anthropogenic visibility impairment during a given planning period.”

Response to Comments 1.a through 1.d: EPA disagrees with the Conservation Groups’ position that the URP policy articulated in our proposed

approval of South Carolina’s submission is inconsistent with the CAA. The Conservation Groups’ reading of the statute is not the best, and they misconstrue the recently adopted policy in several ways. As noted by the Conservation Groups, under *Loper Bright*, courts seek to determine the “best reading” of a statute. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024).

First, EPA’s recently adopted policy is consistent with the statute. Pursuant to CAA section 169A(a)(4), Congress explicitly delegated to EPA authority to promulgate regulations regarding reasonable progress towards meeting the national goal. As the Conservation Groups suggest, in determining the measures necessary to make reasonable progress towards the national visibility goal under CAA section 169A(a)(1), Congress mandated “tak[ing] into consideration the cost of compliance, the time necessary for compliance, and the energy and nonair quality environmental impacts of compliance, and the remaining useful life of any existing source subject to such requirement.” See CAA section 169A(g)(1).

But this does not mean, as the Conservation Groups incorrectly state, that the recently adopted policy ignores the results of a state’s FFA if a Class I area is below the URP. Rather, consistent with our discussion under the preamble of the 2017 RHR, the URP continues to serve as a regulatory planning metric to inform states’ decision making when considering the four statutory factors. EPA disagrees with Conservation Groups’ view that the recently adopted URP policy is an exemption to the statutory mandate; the policy continues to require states to take into consideration the four statutory factors. Being below the URP does not relieve a State of its obligations under the CAA and the RHR to make reasonable progress. Also, EPA still reviews a state’s determination of whether additional control measures are necessary for reasonable progress, whether the state submitted those measures for incorporation into the SIP, and whether the measures are consistent with other provisions in the CAA.

As required by the statute, South Carolina took into consideration the four statutory factors in CAA section 169A(g)(1) and determined that no additional controls were necessary to make reasonable progress. CAA section 169A(b)(2) requires SIPs to include “such emission limits, schedules of compliance and other measures as may be necessary to make reasonable progress.” Congress explicitly stated its

intent for states to only include mechanisms as may be necessary for Class I areas to achieve reasonable progress. South Carolina concluded that it was not necessary to incorporate any new emission limitations, schedules of compliance or other measures into its SIP. Thus, contrary to the Conservation Groups’ statements, South Carolina did not ignore the results of its consideration of the four statutory factors.

Second, EPA disagrees with the Conservation Groups’ statements that EPA’s recently adopted policy allows states and EPA to entirely ignore the statutory directive to make reasonable progress toward the national visibility goal in the second planning period. Due to the iterative nature of the regional haze planning process, reasonable progress is not measured solely through the accomplishments in any one, discreet planning period. CAA section 169A(b)(2) requires SIPs to “contain such emission limits, schedules of compliance and other measures as may be necessary to make reasonable progress” toward the national visibility goal and 169A(g)(1) requires that “in determining reasonable progress there shall be taken into consideration the cost of compliance, the time necessary for compliance, and the remaining useful life of any existing source subject to such requirements.” Not only has the State considered the four statutory factors and concluded that no additional control measures would be appropriate considering the outcome of its analysis, but the Class I areas affected by emissions from South Carolina remain below their respective URPs. In doing so, the State has adequately demonstrated that its current measures are all that are necessary to make reasonable progress in the second planning period.

Third, regarding the Conservation Groups’ statements that “Congress set a framework for EPA to establish iterative planning periods during which states must build on emission reductions achieved in each successive planning period,” there is no statutory or regulatory requirement that this process must include a new set of additional control measures each and every planning period. Not only is the statute clear on its face, but the legislative history supports EPA’s reading of the CAA. The reconciliation report for the 1977 CAA amendments indicates that the term “maximum feasible progress” in CAA section 169A was changed to “reasonable progress” in the final version of the legislation passed by both chambers. Therefore, a State is required to determine only what constitutes

reasonable progress toward the national visibility goal under CAA section 169A(a)(1), not achieve the maximal amount of visibility improvement each iterative planning period. Under the 2017 RHR, a state determines this by weighing and considering the four statutory factors under CAA section 169A(g)(1) against potential additional control measures to determine if any control measures are necessary for reasonable progress. It is therefore reasonable that, after considering the four statutory factors, South Carolina concluded that no additional measures are necessary to make reasonable progress in this planning period since the state's existing LTS is still making reasonable progress at the Class I areas impacted by a state's anthropogenic emissions and those Class I areas where South Carolina may be reasonably anticipated to cause or contribute to any impairment.

Fourth, EPA's change in policy does not create an exemption, de minimis or otherwise, from the statutory requirements. CAA Section 169A requires any state that contains a Class I area, or "which may reasonably be anticipated to cause or contribute to any impairment of visibility in any such area" to have an implementation plan that contains "such emission limits, schedules of compliance and other measures as may be necessary to make reasonable progress toward the national goal" of "the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory class I Federal areas which impairment results from manmade air pollution." See CAA sections 169A(a), (b).

EPA's recently adopted policy does not create an exemption to these statutory provisions. Under the policy, states are still required to identify measures necessary to make reasonable progress by "tak[ing] into consideration" the four statutory factors set forth in CAA section 169A(g)(1), and to submit measures necessary for reasonable progress to EPA to be reviewed for approvability into the SIP. A state is not exempted from this requirement simply because a particular Class I area is below the URP.

Both the CAA and the RHR then require the state to include those measures in its SIP. CAA section 169A(b)(2); 40 CFR 51.308(f)(2). However, regardless of whether the state identified additional measures for inclusion in its SIP, if the state takes into consideration the four factors, and the Class I areas the state contributes to are below the URP, the state will be presumed to be achieving reasonable progress towards the national goal for

the second planning period with respect to that area. At no point in the process of identifying measures necessary to make reasonable progress toward the national goal does this new policy exempt a state from its statutory and regulatory obligations to identify measures necessary for reasonable progress by taking into consideration the four statutory factors and including any such measures in its SIP.

Fifth, the Conservation Groups incorrectly state that EPA's recently adopted policy is contrary to the purpose of the statute. EPA disagrees with that statement. The Conservation Groups failed to consider the plain language of the statute in their assertion that "[b]ecause Congress intentionally omitted any reference to visibility in the definition of reasonable progress, it is clear that states may not reject controls based on assertions about visibility conditions at Class I areas." The Conservation Groups misconstrue why Congress included in CAA section 169A(g)(2) an explicit requirement to consider "improvement of visibility" when determining BART but did not include a parallel explicit requirement for the determination of reasonable progress under CAA section 169A(g)(1).

CAA sections 169A(b)(2)(A) and (g)(7) make BART applicable to a "major stationary source," with the potential to emit 250 tons of any pollutant, that was in existence on August 7, 1977, but not "in operation" before August 7, 1962, and whether or not the type or quantity of that pollutant impacts visibility at any Class I area. The BART provision outlined in CAA section 169A(b)(2)(A) thus demonstrates Congressional intent for states to, first and foremost, focus attention directly on the presumed sources of visibility impairment. Because Congress directs states to look at specifically-identified ("BART eligible")⁹ sources, it was reasonable for Congress to also specify that only those existing BART sources impacting visibility needed to be subject to the five BART statutory factors in section 169A(g)(2) ("Subject to BART"). See 70 FR 39104 at 39106–7 (July 6, 2005).

However, while the BART provisions mandate consideration of visibility in determining which sources are subject to BART and in selecting controls, the reasonable progress provisions make it optional for non-BART sources.^{10 11}

⁹ See 40 CFR 51.301; 64 FR 35714 at 35738 (July 1, 1999); 70 FR 39104 at 39105 (July 6, 2005).

¹⁰ See, e.g., 2019 Guidance at 36–37 ("EPA interprets the CAA and the Regional Haze Rule to allow a state reasonable discretion to consider the anticipated visibility benefits of an emission control measure along with the other factors when

Specifically, there was no need to insert a "improvement in visibility" provision with respect to CAA section 169A(g)(1) since reasonable progress by definition includes improvement in visibility. See CAA section 169A(a)(1). CAA section 169A only ever speaks of reasonable progress in terms of making "reasonable progress toward meeting the national goal" of CAA section 169A(a)(1) of "the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory class I Federal areas which impairment results from manmade air pollution." See CAA sections 169A(a)(1), 169A(b)(2), and 169A(b)(2)(B). The only time the full phrase "reasonable progress toward meeting the national goal" is omitted is in CAA section 169A(g)(1), but it is clear from the three other instances of the use of the term in CAA section 169A that the best reading of that provision is that it is consistent with the three other times Congress used the term "reasonable progress" in CAA section 169A. Therefore, because visibility improvement is inherent in determining what is necessary for reasonable progress, it was not necessary for Congress to specifically add it to the reasonable progress considerations in CAA section 169A(g)(1). The Conservation Groups are therefore incorrect that EPA has attempted to "escape" *Loper Bright*'s mandate to find the best reading of the statute; we simply disagree with the Conservation Groups as to that best reading. EPA has interpreted "reasonable progress" in section 169A(g)(1) in light of the fact that that phrase clearly refers back to the three other times it is used in full, that is, "reasonable progress toward meeting the national goal." Considering a phrase in light of its whole statutory context, with a presumption that a phrase will be used consistently throughout a statutory provision, is one of the canonical, "traditional tools of statutory construction" that *Loper Bright* establishes as the judiciary's first stop in determining the best reading of the statute. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 399–401 (2024).

Lastly, the Conservation Groups incorrectly state that EPA's application of the new policy is inconsistent with EPA's role under CAA section 110(k)(3). Congress delegated EPA authority to

determining whether a measure is necessary to make reasonable progress.").

¹¹ EPA also notes that even in the first planning period, States could consider visibility in their reasonable progress determinations, so long as it was done in a reasonable way in accordance with the CAA. See *North Dakota v. U.S. E.P.A.*, 730 F.3d 750, 766 (8th Cir. 2013).

determine whether a SIP meets the requirements in CAA sections 169A and 169B. *See* CAA section 110(k)(3). The Conservation Groups assert that EPA lacks “authority” to create a presumption because nothing in CAA section 169A(a)(4) directs the Agency to create a presumption, and furthermore, even if it did, the Agency did not follow the 169A(a)(4)’s procedural requirements. The Conservation Groups misconstrue the role of the Agency’s URP Policy and the articulated presumption. The Policy is not a regulation that states are required to follow. Rather, the presumption discussed in the proposal explains the Agency’s thinking in reviewing states’ second planning period SIPs. EPA is not only authorized to review such SIPs but is in fact obligated to do so under CAA section 110(k)(3). As such, the role of the Agency is not ministerial, and the recently adopted policy does not exempt EPA from meeting its statutory requirement. Thus, because South Carolina’s SIP meets the statutory and regulatory requirements, EPA concluded that approval of South Carolina’s SIP is reasonable.

Comment 2: The Conservation Groups state that “[u]sing the ‘traditional tools’ of construction, EPA cannot square its new URP policy with the RHR, just as it cannot square that policy with the Clean Air Act.” They further state that “[t]he RHR’s long-term strategy requirements track those of the Clean Air Act, requiring that such strategies ‘must include the enforceable emissions limitations, compliance schedules, and other measures that are necessary to make reasonable progress pursuant to [40 CFR 51.308(f)(2)(i) through (iv)].’” They assert that 40 CFR 51.308(f)(2)(i) requires states to evaluate and determine the emission reduction measures that are necessary to make reasonable progress by considering the four factors (costs of compliance, the time necessary for compliance, the energy and non-air quality environmental impacts of compliance, and the remaining useful life of any potentially affected anthropogenic source of visibility impairment) and suggest that 40 CFR 51.308(f)(2)(i) contains a dependent clause (“the State must evaluate and determine . . . the measures that are necessary to make reasonable progress”) to make sense. Based on this grammatical argument, they state that “accurately reading these clauses together requires that states and EPA determine the measures that must be included in a state’s long-term strategy *based on* the four factors” (emphasis in original comments) and

that “[n]othing in sections 51.308(f)(2)(ii)–(iv) changes this requirement or allows states to reject otherwise reasonable measures that satisfy the four factors by pointing to the URP.”

The Conservation Groups claim that “[t]he RHR’s RPG provisions further make clear that the URP cannot supplant the requirement to conduct thorough and reasonable Four-Factor Analyses to identify necessary measures in the long-term strategy. Section 51.308(f)(3)’s requirement that states establish RPGs for their in-state Class I areas refers back to (f)(2)’s requirement to establish emission limits and other measures necessary to make reasonable progress.” They further state that “section 51.308(f)(2) is directly linked to the four factors, as the emission limits and measures necessary to make reasonable progress must be based on the four factors.”

The Conservation Groups proceed to claim that “[t]he purpose and history of the 2017 RHR revision confirm these requirements. As EPA explained in the 2017 RHR revision preamble, one purpose of the revised Rule was to clarify misunderstandings in the interpretation and application of the 1999 RHR.” Citing to the 2017 RHR, they state that EPA clarified that the URP is not and was never intended to be a “safe harbor.”¹² Furthermore, they claim that EPA declined to explicitly state in the RHR itself that the URP is not a safe harbor because it believed that point was already clear. Quoting the 1999 RHR, the Conservation Groups likewise cite to language in which EPA stated that “[t]he URP was never intended to be a safe harbor.”¹³

The Conservation Groups state that EPA has “explained that the Four-Factor Analysis is not a box checking exercise; rather, states must engage in thorough and reasoned analyses to satisfy the requirements of the RHR” and that “[c]ontrary to EPA’s new URP policy, a state’s mere mention or reference to the four statutory factors is not sufficient to demonstrate that the state conducted those analyses in compliance with the RHR.” They further assert that “EPA has time and time again explained that treating the URP as a safe harbor, as the Agency proposes to do with its new URP policy, violates the RHR.”

The Conservation Groups conclude by stating that “the text of the RHR specifically requires EPA to engage in rigorous and substantive reviews of state SIP submissions” and suggest that “EPA

relies on the new URP policy to evade its substantive review duties.”

Response 2: EPA disagrees with the Conservation Groups’ position that the URP policy is inconsistent with the RHR. This comment tracks many of the issues the Conservation Groups raised with respect to their allegations that EPA’s recently adopted URP policy is inconsistent with the CAA. For example, they assert that EPA’s policy is inconsistent with the regulatory requirement that the LTS “must include the enforceable emissions limitations, compliance schedules, and other measures that are necessary to make reasonable progress” and that this policy allows states or EPA to reject otherwise reasonable emission reduction measures that satisfy the four statutory factors based on the URP. Just as the URP policy does not create an exemption to the CAA’s statutory provisions, it also does not create exemptions to the RHR. Under the policy, and consistent with 40 CFR 51.308(f)(2), states are still required to identify measures necessary to make reasonable progress by considering the four statutory factors set forth in CAA section 169A(g)(1), and to submit measures necessary for reasonable progress to EPA to be reviewed for approvability into the SIP. A state is not exempted from this requirement simply because a particular Class I area is below the URP.

Both the CAA and the RHR then require the state to include those measures in its SIP. CAA section 169A(b)(2); 40 CFR 51.308(f)(2). However, regardless of whether the state identified additional measures for inclusion in its SIP, if the state takes into consideration the four factors, and the Class I areas the state contributes to are below the URP, the state will be presumed to be achieving reasonable progress towards the national goal for the second planning period with respect to that area. At no point in the process of identifying measures necessary to make reasonable progress toward the national goal does this new policy exempt a state from its statutory and regulatory obligations to identify measures necessary for reasonable progress by taking into consideration the four statutory factors and including any such measures in its SIP. We do not agree with the Conservation Groups that the RHR’s use of “by considering” with regard to the four factors in 51.308(f)(2) means that the national goal of visibility and a state’s progress towards that goal is wholly excluded from a state and EPA’s consideration.

Because EPA’s recently adopted policy is that there is a presumption that

¹² *See* 82 FR 3093.

¹³ *See* 82 FR 3093–94.

the state's second planning period SIP is making reasonable progress for a Class I area, if the state has taken into consideration the four statutory factors and that area is below the 2028 URP, EPA has concluded that this SIP is fully approvable. To meet the RPG requirements under 40 CFR 51.308(f)(3), the RPGs established by a state must reflect the measures it deemed to be necessary to make reasonable progress within the applicable implementation period and must be projected to be achieved by the end of the applicable implementation period. Therefore, it is sufficient under 40 CFR 51.308(f)(3) that this SIP establishes RPGs that reflect visibility conditions that are projected to be achieved by the end of the second planning period.

Comment 3: The Conservation Groups claim that “[b]eyond violating the plain language, intent, context, and purpose of both the Clean Air Act and the RHR, EPA’s application of its new URP policy in the proposal here is both internally inconsistent and inadequately explained. As a result, EPA fails to provide a ‘satisfactory explanation’ for its proposal to approve the 2022 SIP Revision, making the proposal arbitrary and capricious in violation of both the CAA and the APA.” This comment, along with individual points raised by the Conservation Groups, are summarized and responded to in Comments 3.a and 3.b below.

Comment 3.a: The Conservation Groups state that EPA’s proposal to approve South Carolina’s 2022 SIP Revision is internally inconsistent in at least three ways. First, the Conservation Groups state that “EPA claims that its new URP policy does not treat the URP as a safe harbor; yet EPA’s statements explaining its new policy underscore that it does.” They state that this is contrary to the 1999 RHR, 2017 RHR revision, 2019 Guidance, and 2021 Clarification Memo which all state that the URP is not a safe harbor. Furthermore, they state that “if EPA’s new URP does not treat the URP as a safe harbor,” then the “Agency’s explanation and application of its new policy in the proposal is inconsistent and not adequately explained, all of which also violates the Clean Air Act and fundamental principles of reasoned agency decisionmaking.”

Second, the Conservation Groups state that “EPA notes in the proposal that states’ source selection methods must be ‘reasonable’ and ‘reasonably explained’ but fails to explain or address anywhere in the proposal whether the new URP policy requires that states’ Four-Factor Analyses be based on reliable, reasonable, and well-

documented information.” They claim that EPA’s new URP policy therefore allows the Agency and states to treat the FFAs as an “ungraded box checking exercise,” in violation of the CAA and RHR. They state that this further makes EPA’s proposal here internally inconsistent, arbitrary, and capricious, because states are required to conduct reasonable source selection processes but then permitted to conduct unreasonable and unsupported FFAs. They claim also that this makes EPA’s new policy irrational, as states are still required to select sources, consider a “meaningful set” of control measures, and conduct FFAs “without any requirement that this process affect the ultimate outcome of the SIP.”

Third, the Conservation Groups assert that “EPA explains that all measures that the State determines are necessary to make reasonable progress must be included in the SIP but also states in the proposal that permit measures that South Carolina determined are necessary are now ‘moot’ and do not need to be included in the SIP.” The Conservation Groups say that the proposal “repeatedly states that measures, new or existing, that are found to be necessary must be included as federally enforceable SIP measures as required by 42 U.S.C. 7491(b)(2) and 40 CFR 51.308(f)(2).” Despite this, they claim that “[i]n the 2022 SIP Revision, South Carolina determined that existing measures contained in permit provisions for Century, [Santee Cooper Cross Generating Station (Cross), Santee Cooper Winyah Generating Station (Winyah)], and IP Georgetown are necessary to make reasonable progress and prevent future impairment in this second planning period, and so, proposed to incorporate those permit provisions into the SIP. Similarly, South Carolina again determined in the 2025 SIP Supplement that updated permit provisions for Cross, Winyah, and IP Georgetown are necessary to make reasonable progress, and so, proposed to incorporate those permit provisions into the SIP. Yet, buried in a footnote in the proposal, EPA now asserts that these permit provisions are ‘moot’ and that the Agency is not incorporating any permit provisions into the SIP.”

The Conservation Groups conclude by saying that “[n]othing in the proposal or letters EPA cites from the State analyzes, let alone demonstrates, that these permit provisions are no longer necessary to make reasonable progress or prevent future impairment.” They state in the December 2024 letter EPA cites in which South Carolina withdrew the permit provisions for Century from the SIP, that South Carolina “explicitly

explained that it was in the process of updating a ‘standalone regional haze construction permit’ for Century and that the State would ‘submit the final construction permit in a supplement to the final SIP as part of the request for materials proposed for adopting into the regulatory portion of the South Carolina SIP.’” The Conservation Groups note that “EPA points only to its new URP policy and South Carolina’s request to approve the 2022 SIP Revision without any permit provisions based on that new policy to support its refusal to incorporate these measures into the SIP. Therefore, they state that “EPA’s application of its new URP policy here is both internally inconsistent with its own explanations of the Clean Air Act’s and RHR’s requirements and in violation of those same requirements.”

Response 3.a: As discussed in more detail in response to Comments 1.a through 1.d, EPA disagrees with the comment that the URP policy is a “safe harbor” or an exemption to the RHR requirements. Being below the URP does not relieve a state of its obligations under the RHR to make reasonable progress.

Regarding the comment that EPA fails to explain or address anywhere in the proposal whether the new URP policy requires that states’ FFAs be based on reliable, reasonable, and well-documented information, EPA disagrees. The NPRM explained that “40 CFR 51.308(f)(2)(iii) plays an important function in requiring a state to document the technical basis for its decision making so that the public and EPA can comprehend and evaluate the information and analysis the state relied upon to determine what emission reduction measures must be in place to make reasonable progress.” In the NPRM, EPA also explained that “[r]egarding cost and engineering information, the State provided the underlying cost calculations associated with the cost summaries in Section 7.8 of the plan for Century, Cross, IP-Georgetown, and [WestRock Charleston Kraft, LLC (WestRock-Charleston)], and the proposed FFAs in Appendix G provide engineering analyses evaluating potential new control measures.” This technical data is also discussed in more detail in Responses 11.b, 11.c, and 11.d.

EPA also disagrees with the Conservation Groups’ assertion that approval of the Haze Plan under the new URP policy without any of the permit provisions is arbitrary, capricious, and an abuse of authority and does not comply with the substantive requirements of the CAA and RHR. EPA proposed to approve the Haze Plan without the permit

conditions, as requested by South Carolina in its June 4, 2025, letter, based on the new URP policy.¹⁴ South Carolina considered the four statutory factors for Century, IP-Georgetown, Cross, and Winyah in technical analyses. Subsequently, South Carolina clarified in its June 4, 2025, letter that it is not necessary to include in the SIP any final permit conditions for these evaluated facilities and that statements appearing in South Carolina's submittal concerning existing or additional measures are no longer applicable. In addition, South Carolina never submitted its 2025 SIP Supplement, and it confirmed in its June 4, 2025, letter that it does not intend to submit or include final permit conditions for these facilities for incorporation into the regulatory portion of the South Carolina SIP. As discussed in the NPRM, because South Carolina considered the four statutory factors for these facilities and visibility conditions at all Class I areas to which South Carolina contributes are below the URP, South Carolina has demonstrated that it has made reasonable progress for the second planning period without any measures in the regulatory portion of the SIP for these facilities.

Comment 3.b: The Conservation Groups claim that EPA fails to adequately explain how the new URP policy creates only a "Presumption" that a SIP is approvable. They state the "EPA asserts in the proposal that its new URP policy does not create a safe harbor but creates only a 'presumption' that a SIP demonstrates reasonable progress and is approvable." In general, they state "a presumption establishes a 'legal inference or assumption that a fact exists,' 'unless the adversely affected party overcomes' the presumption with other evidence." They claim that "even

if the new URP policy created only a presumption that a SIP is approvable, the new policy still violates the plain text of the Clean Air Act and the RHR, as well as EPA's interpretations of the Act and Rule." Additionally, they claim that "EPA cannot point to any 'clear congressional authorization' for the authority to create a presumption that, where a Class I area is on the so-called URP, states need not implement further emission reductions based on a consideration of the four statutory reasonable factors." They conclude by saying that "[i]n any case, EPA cannot cure the legal errors in the new policy by claiming the policy creates only a presumption, and so, is somehow different than treating the URP as a safe harbor."

The Conservation Groups further claim that "EPA does not explain the operation of the purported presumption created by its new policy anywhere in the proposal. As noted, the presumption appears to relieve EPA of its duty to substantively review a State's control determinations and Four-Factor Analyses where the Agency concludes that the State has triggered that presumption. Otherwise, it is entirely unclear what role the 'presumption' serves in EPA's review of SIPs." Thus, the Conservation Groups maintain that "the presumption created by the new policy also relieves states of the obligation to demonstrate reasonable progress in a manner that is reasonable and adequately documented." They state that EPA proposes to relieve South Carolina of those obligations here, and "even though South Carolina determined that existing measures are necessary to make reasonable progress and prevent future impairment for Century, Cross, Winyah, and IP Georgetown, EPA proposes to grant the State's request to exclude all of those measures from the SIP based on its new URP policy. Treating the new URP policy as a presumption is contrary to the burdens set forth in the Clean Air Act and the RHR." They assert that "[n]othing in the statute or the RHR allows EPA to shift that burden off the states or the Agency."

The Conservation Groups continue by saying that "if the new URP policy does, in fact, create only a presumption that a SIP is approvable, then there must be circumstances in which the presumption can be overcome." They state that "[n]owhere in the proposal, however, does EPA articulate what those circumstances would be or whether or not they are present for South Carolina's 2022 SIP Revision." They assert that "EPA's proposal here fails to provide adequate notice of the

Agency's rationales in support of its proposed action."

The Conservation Groups go on to describe three circumstances that "potentially could overcome the new URP policy's presumption that a SIP is approvable." The first circumstance raised by the Conservation Groups "is that all Class I areas affected by pollution from the state—here, South Carolina—are not projected to be below the URP glidepath at the end of the planning period. As discussed in detail below, however, that circumstance *is* present here." The second circumstance raised by the Conservation Groups is that a state "entirely fails to evaluate potential control measures or consider the four statutory factors for any sources or group of sources." The third circumstance raised by the Conservation Groups is that "although states evaluated potential control measures and considered the four statutory factors, they failed to do so reasonably or in compliance with the requirements of the Clean Air Act and the RHR."

Response 3.b: Initially, EPA disagrees with the Conservation Groups' assertion that the URP policy creates a presumption that the SIP is approvable. Rather, the new policy creates a presumption that Class I areas are making reasonable progress. Furthermore, EPA disagrees with the assertion that EPA has not clearly explained how its new policy creates a presumption that Class I areas are making reasonable progress. As first articulated in West Virginia's April 18, 2025, notice and reiterated in other actions, including this action, where projected 2028 visibility conditions for a Class I area impacted by a state are below the URP and the state has considered the four statutory factors, the state will have presumptively demonstrated that its LTS is adequate to make reasonable progress for the second planning period for that area. Thus, EPA has articulated two requirements that must be met for the presumption to be applicable. Furthermore, EPA notes that just because a Class I area is below the URP does not mean that a state is relieved of its obligations under the CAA and the RHR to make reasonable progress, as well as a multitude of other rule requirements that must be satisfied. In other words, the URP is not a "safe harbor," as that phrase has sometimes been used, because EPA still must review a state's determination whether additional control measures are necessary to make reasonable progress, if control measures are necessary, determine whether the state submitted those measures for incorporation into the SIP, and evaluate whether the

¹⁴ South Carolina's letter states: "The South Carolina Department of Environmental Services (Department) is requesting a full approval of the Regional Haze State Implementation Plan (SIP) for South Carolina Class I Federal Areas for Second Planning Period (2019–2028) submittal dated March 3, 2022 (SC–132) pursuant to the policy announced in the Environmental Protection Agency's (EPA) April 18, 2025, proposed approval of West Virginia's (90 FR 16478) Regional Haze SIP and reaffirmed in the proposed approval of South Dakota's Regional Haze SIP (90 FR 20425) on May 14, 2025. . . . per the presently applicable EPA policy, South Carolina's SIP submittal meets the requirements of the Clean Air Act (CAA) for demonstrating reasonable progress towards the visibility goal; therefore, no additional or existing measures need to be adopted into the SIP as part of the long-term strategy for this planning period. As a result, it is not necessary to include in the SIP any final permit conditions for any of the evaluated facilities, and according to the policy, Section 7.9 of the SIP, Appendix G–3 of the SIP, and statements appearing in Section 7.8 of the SIP concerning existing or additional measures are no longer applicable."

measures are consistent with other provisions in the CAA, as EPA did here in approving South Carolina's SIP. EPA is not required, in acting on the state's submission, to speculate about what facts or circumstances would necessitate a disapproval.

Comment 4: The Conservation Groups state that “[t]he new URP policy violates the Clean Air Act’s procedural requirements, as it is inconsistent with both national policy and actions taken on second planning period SIPs by nearly every EPA region” and that “[t]he new policy also effectively revises the RHR without complying with the Act’s rulemaking requirements and is intended to have national scope and effect.” This comment, along with individual points raised by the Conservation Groups, are summarized and responded to in Comments 4.a through 4.d below.

Comment 4.a: The Conservation Groups assert the while “EPA acknowledges that its new policy reflects ‘a change in policy’ regarding the URP,” it “ignores that its announcement of this change in a regional SIP action, and continued application of that policy in other regional SIP actions, including this one, violates the Clean Air Act’s requirements that SIP actions be consistent with national policy.”

Citing the 1999 RHR and 2017 RHR, as well as its 2019 Guidance and 2021 Clarification Memo, the Conservation Groups state that “EPA’s new URP policy is incompatible with its own longstanding policy that the URP is not a safe harbor, and the mere fact that a Class I area is projected to be on or below the URP glidepath does not allow states to conduct unreasonable Four-Factor Analyses or ignore reasonable emission reduction measures. Not only is this EPA’s longstanding policy, it is also the Agency’s national policy.”

The Conservation Groups then quote CAA section 7601(a)(2)(A), which requires EPA to “assure fairness and uniformity in the criteria, procedures, and policies applied” in acting on SIPs and EPA’s consistency regulations at 40 CFR part 56. They allege that “[b]ecause EPA’s proposed approval of the South Carolina 2022 SIP Revision is based on an interpretation of the Clean Air Act that ‘varies from national policy,’ the Agency is required under 40 CFR 56.5(b) to obtain the concurrence of the relevant EPA Headquarters Office before finalizing the proposed approval. Yet, nothing in the record indicates that the regional office obtained that concurrence.”

The Conservation Groups then cite 40 CFR 56.5(c) and EPA’s 1975 “State

Implementation Plans—Procedures for Approval/Disapproval Actions, OAQPS No. 1.2–005A” and state that “the record includes no reference to the Agency’s SIP Review Guidelines, let alone indicates that EPA complied with them.” Additionally, they assert that “[b]ecause EPA’s proposal ‘would significantly affect emission control regulations’ or ‘have significant national policy implications,’ a full interagency review and concurrence is required.” With respect to this interagency review, the Conservation Groups state that “Executive Order 12,866 requires review by the Office of Management and Budget of any ‘significant regulatory actions,’ which includes actions that ‘[r]aise novel legal or policy issues arising out of legal mandates.’” They state that “the record shows no attempt at compliance,” but rather “that EPA’s proposal incorrectly states that compliance is not required.

The Conservation Groups conclude that “EPA cannot take action or approve a SIP that violates applicable Clean Air Act requirements.” They state that “by applying the new URP policy that sharply departs from national policy, EPA proposes to do just that. EPA’s proposed piecemeal approach to rewriting its national URP policy arbitrarily and impermissibly ‘institutionalize[s] the kind of inconsistencies that prompted Congress to enact’ § 7601(a)(2) in the first place.” They further note that “[b]ecause EPA has failed to demonstrate that it complied with the Agency’s own consistency regulations, as required by 40 CFR 56.5, the Agency’s proposed action is contrary to law.”

Citing 40 CFR 56.5(a), the Conservation Groups assert that along with requiring consistency with national policy, EPA’s regulations require that EPA regional office SIP actions “[a]re as consistent as reasonably possible with the activities of” [sic] other EPA regions” in accordance with 42 U.S.C. 7601(a)(2)(A) in order to “assure fairness and uniformity in the criteria, procedures, and policies applied by the various [EPA] regions in implementing and enforcing” the Act. The Conservation Groups state that “EPA’s current proposal to approve the 2022 SIP Revision based on its new URP policy is inconsistent with SIP actions taken by nearly every other EPA region, as well other EPA Region 4 actions, stating that ‘the URP . . . is not a ‘safe harbor.’” Due to this alleged inconsistency, the Conservation Groups assert that EPA’s proposed approval “violates the Clean Air Act’s and its implementing regulations’ requirements.”

Response 4.a: Under *FCC v. Fox*, an agency’s change in policy is not arbitrary and capricious if the agency acknowledges the change, believes the new policy to be better than the one it replaces, and “show[s] that there are good reasons for the new policy.” See 556 U.S. 502, 515. EPA did not change the policy *sub silentio*, as it stated its reasons for implementing this recently adopted policy. EPA announced this change in the proposed approval of West Virginia’s regional haze SIP on April 18, 2025. See 90 FR 16478. In Section I, *What action is the EPA proposing?* of that notice, EPA states that “[b]ased on our change in policy discussed in section V of this document, EPA proposes that West Virginia’s regional haze SIP meets the statutory and regulatory requirements for the regional haze second planning period.” EPA more fully articulated the substance of the change in policy in Section V, *The EPA’s Rationale for Proposing Approval*, of that notice. *Id.* at 16482–84. As EPA explained in the proposal for this action, the changed policy is prospective, which addresses the primary concern in *FCC v. Fox*.

Additionally, EPA notes that the legislative history of CAA section 169A is consistent with the Agency’s change in policy. The Agency has articulated its rationale for this change, including that this change “aligns with the purpose of the statute and RHR, which is achieving ‘reasonable’ progress, not maximal progress, toward Congress’ natural visibility goal.” See 90 FR 36005, 36017 (July 31, 2025). The reconciliation report for the 1977 CAA amendments, indicates that the term “maximum feasible progress” in 169A was changed to “reasonable progress” in the final version of the legislation passed by both chambers. See Legislative History of the CAA Amendments of 1977 P.L. 95–95 (1977), *H.R. Rep. No. 95–564*, at 535. This change in the final version of the statute indicates that Congress did not require SIPs to contain measures to make the maximal possible progress towards the national goal in each Haze SIP. Instead, Congress intended for Class I areas to achieve a rate of progress that was reasonable, taking into consideration the four statutory factors under CAA section 169A(g)(1). Therefore, EPA’s recently implemented policy is consistent with the Congressional intent behind the original framing of CAA sections 169A.

EPA disagrees that its change in policy means that all its actions on second planning period regional haze SIPs that pre-date its proposed approval of the West Virginia second planning period submittal are inconsistent with

the new policy. On April 18, 2025, EPA announced its policy regarding the use of the URP in the context of determining reasonable progress. On July 7, 2025, in EPA's final action approving the West Virginia regional haze SIP for the second planning period articulated the policy. *See* 90 FR 29737 (July 7, 2025). The recently adopted policy is consistent with EPA's long-standing position that the URP is not a "safe harbor." As stated in Responses 1 and 1.a through 1.d, EPA's new policy establishes a presumption that the reasonable progress requirements of the CAA and the RHR are met if the state has taken into consideration the four statutory factors and the visibility impairment for each Class I area is projected to be below the URP (*i.e.*, the "glidepath") at the end of the applicable planning period. Unlike treating the URP as a "safe harbor," the policy does not exempt or allow a state to evade the requirements of the CAA or the RHR. Treating the URP as a "safe harbor" would exempt states from considering the four statutory factors and would allow states to exclude measures necessary for reasonable progress from the SIP. Simply stated, final actions predating the recent URP policy weighed the URP differently in evaluating whether regional haze plans met the requirements of the CAA and the RHR.

EPA acknowledges that under this policy, the URP informs EPA actions on SIPs differently than previous actions, which may result in a different conclusion. Under 40 CFR 51.308(f)(3)(i), RPGs are to be established by a state that contains a Class I area to "reflect the visibility conditions that are projected to be achieved by the end of the applicable implementation period as a result of those enforceable emissions limitations, compliance schedules, and other measures required under paragraph (f)(2) of this section that can be fully implemented by the end of the applicable implementation period, as well as the implementation of other requirements of the CAA." The change in policy leaves this process intact. As before our change in policy, a state must still identify "enforceable emissions limitations, compliance schedules, and other measures" [40 CFR 51.308(f)(2)], by taking into consideration the four statutory factors, and EPA will approve any such measures that are submitted by the State as measures necessary for reasonable progress as long as they are consistent with other provisions of the CAA. States' only other obligation under 40 CFR 51.308(f)(3) applies only when the RPG for a Class I area affected by

emissions from the state is above the URP. In that case, states must provide a robust demonstration "that there are no additional emission reduction measures for anthropogenic sources or groups of sources in the State that may reasonably be anticipated to contribute to visibility impairment in the Class I area that would be reasonable to include in the long-term strategy." Because EPA's URP policy only applies when a Class I area is below its URP, the new policy does not impact this obligation either.

EPA's Regional Consistency regulations at 40 CFR part 56, and in particular 40 CFR 56.5(a) and (b), are not relevant to this action. 40 CFR 56.5(a) requires, in relevant part, that "[e]ach responsible official in a Regional Office, including the Regional Administrator, shall assure that actions taken under the act . . . [a]re as consistent as reasonably possible with the activities of other Regional Offices." 40 CFR 56.5(b) requires that a "responsible official in a Regional office shall seek concurrence from the appropriate EPA Headquarters office on any interpretation of the Act, or rule, regulation, or program directive when such interpretation may result in application of the act or rule, regulation, or program directive that *is inconsistent* with Agency policy" (emphasis added). As EPA expressly indicated in the proposal for this action the approval is *consistent* with the change in Agency policy, first announced in *Air Plan Approval; West Virginia; Regional Haze State Implementation Plan for the Second Implementation Period*. 90 FR 16478 (April 18, 2025). Therefore, there is no obligation under EPA's Regional Consistency regulations for anyone in the Region to seek concurrence from EPA Headquarters to take action consistent with EPA policy. For the same reason, this action is also consistent with the actions of other EPA Regional Offices. The lack of relevance of these regulations to this action accounts for the lack of materials related to compliance with the Regional Consistency process in the docket for this rulemaking. Finally, as noted below, this action is not subject to E.O. 12866.

Comment 4.b: The Conservation Groups cite the preamble to the 2017 RHR, and they assert that there are two ways EPA's new URP policy effectively revises the national RHR. First, the Conservation Groups maintain that the new URP policy "creates an exception to the national RHR's categorical prohibition against relying on the URP as a safe harbor from reasonable control measures." They further note that "EPA claims that the Clean Air Act and the

RHR allow states to avoid control measures that are reasonable under the four statutory factors, and so, necessary to make reasonable progress where the state demonstrates that affected Class I areas are meeting the URP." Thus, they allege that "EPA has revised a rule that, as a matter of law, allows no exceptions, into a rule that allows exceptions when (or where) EPA decides that all affected Class I areas are meeting the URP." Second, the Conservation Groups maintain that "the proposed action changes the applicability of the RHR's URP policy, making that national policy inapplicable to South Carolina." They further argue that "[t]he proposed action thus amends the national, categorical URP policy to no longer be national or categorical."

The Conservation Groups cite CAA section 7491(a)(4) and claim that EPA cannot support its attempt to effectively amend the RHR through regional SIP actions. They state that "this section requires EPA to undergo a rulemaking process to promulgate regulations."

The Conservation Groups further cite 7607(d)(1), as requiring "the 'promulgation or *revision* of regulations under part C of subchapter I of [the Act] (relating to prevention of significant deterioration of air quality and protection of visibility)' to be carried out using the procedures in Section 7607(d)." They also state that "[t]he [Clean Air] Act's rulemaking procedures require that EPA include in the docket all data, information, and documents related to the methodology for the proposed revision, as well as an explanation of the major legal interpretations underlying the rule." The Conservation Groups further note that "this action is subject to the requirement in Executive Order 12,866 for interagency review by the Office of Management and Budget; and in turn, the procedures in Section 7607(d) require EPA to provide the results of such review in the docket prior to the date of proposal and finalization." The Conservation Groups assert that EPA has not followed these procedures.

Response 4.b: EPA does not agree that the new policy effectively revises the RHR. Rather, as described in Response 2, the policy is consistent with the existing RHR. Moreover, the requirements of CAA section 307(d) apply only to specific enumerated types of actions under the CAA and to "such other actions as the Administrator may determine."¹⁵ Actions on SIPs are not one of the enumerated actions, and the Administrator has not determined that this action is subject to 307(d) pursuant

¹⁵ See CAA section 307(d)(1).

to section 307(d)(1)(V). Therefore, the procedures in 307(d) do not apply to this action.

Comment 4.c: The Conservation Groups cite the preamble to the 2017 RHR revision, in which “EPA concluded that judicial review of the Rule—including EPA’s national policy position that the URP is not a safe harbor against implementing reasonable control measures—should be centralized in the D.C. Circuit.” They then assert that, “[e]ven if the proposed action does not amend the nationally applicable RHR (it does), EPA must publish a finding that the revisions to the Agency’s national Rule, which embodies its national URP policy are ‘based on a determination of nationwide scope [and] effect.’”¹⁶

The Conservation Groups discuss two recent U.S. Supreme Court decisions that pertain to the effect of a “determination of nationwide scope and effect” on venue, *EPA v. Calumet Shreveport Refining, LLC et al.* (“*Calumet*”), No. 23–1229 (June 18, 2025) and *Oklahoma et al. v. EPA et al.* (“*Oklahoma*”), No. 23–1067 (June 18, 2025). Citing to *Calumet*, they assert that “Here, the key driver of EPA’s action is its new URP policy. EPA gives no other ‘intensely factual’ consideration for proposing to approve South Carolina’s 2022 SIP Revision despite ample evidence that additional emission reduction measures are necessary to make reasonable progress.” They continue to state that “[w]here EPA does purport to draw a conclusion regarding the State’s Four-Factor Analyses, EPA does so in a conclusory fashion without any substantive review.” Furthermore, they argue that “EPA’s new URP policy allows EPA to evade fact-intensive review of a state’s Four-Factor Analyses, instead substituting a purely ministerial determination as to whether the SIP submittal contains Four-Factor Analyses, regardless of whether they are rational or supported by the record.”

Again citing *Calumet*, the Conservation Groups state that “‘EPA relies on determinations of nationwide scope or effect to reach a *presumptive resolution*, those determinations qualify as the primary driver of its decision,’ and EPA’s action is therefore based on a determination of nationwide scope or effect. That is precisely what has happened here: EPA has made a presumptive resolution of the issue of whether South Carolina’s 2022 SIP Revision makes reasonable progress.” They maintain that “the Agency’s resolution of that central issue is

indisputably based on the Agency’s new URP policy that purportedly allows EPA to determine that the 2022 SIP Revision presumptively demonstrates reasonable progress.” The Conservation Groups continue to state “[t]hat there are particular facts that might cause EPA to depart from this presumption (and which facts EPA does not even specify) would be merely ‘peripheral.’ Indeed, EPA has now proposed to apply its new URP policy to approve multiple SIPs across EPA Regions without any hint that any of those SIPs might fail the ‘presumption.’” They further state that EPA’s new policy is “based on the same determinations of nationwide scope and effect” that it made in the 2017 RHR revision.

The Conservation Groups acknowledge that the Supreme Court held that “EPA still has a role in deciding whether a regional action is based on a determination of nationwide scope or effect. While in dicta the Supreme Court theorized that it would be rare for EPA to fail to make the determination of nationwide scope and effect despite it being appropriate to do so, the Court only mentioned issue preservation as a potential obstacle to reviewability of such a failure.” They further state that “[t]he Act gives EPA discretion to make the determination of nationwide scope and effect; in such a circumstance, it is arbitrary and capricious for EPA to fail to explain why it is or is not exercising that discretion.”

Response 4.c: The Conservation Groups’ claim that EPA “must” publish a finding that this action is “based on a determination of nationwide scope [or] effect” is unsupported and incorrect. Under CAA section 307(b)(1),¹⁷ a petition for review of an action that is “locally or regionally applicable may be filed only in the United States Court of Appeals for the appropriate circuit,” with one exception: if (i) the action “is based on a determination of nationwide scope or effect” and (ii) “if in taking such action the Administrator finds and publishes that such action is based on such a determination,” then any petition for review must be filed in the D.C. Circuit. Thus, if a locally or regionally applicable action is “based on a determination of nationwide scope or effect,” the CAA’s venue provision expressly grants the EPA Administrator complete discretion to invoke, or decline to invoke, the exception to the general rule that challenges be heard in the appropriate regional circuits. The Supreme Court has recognized that

“[b]ecause the ‘nationwide scope or effect’ exception can apply only when ‘EPA so finds and publishes’ that it does, EPA can decide whether the exception is even potentially relevant.” As the D.C. Circuit has also stated, the “EPA’s decision whether to make and publish a finding of nationwide scope or effect is committed to the agency’s discretion and thus is unreviewable.” Although a court may review “whether a locally or regionally applicable action is based on a determination of nationwide scope or effect *when EPA so finds and publishes*. . . . a court may not ‘second-guess’ the agency’s discretionary decision to make and publish (or not) a finding of nationwide scope or effect.”

The Administrator has not made and published a finding that this action is based on a determination of nationwide scope or effect. Accordingly, any petition for review of this action must be filed in the United States Court of Appeals for the appropriate regional circuit.

Comment 5: The Conservation Groups state that “[e]ven if EPA’s new URP policy does not violate the Clean Air Act and RHR (it does), EPA cannot approve South Carolina’s 2022 SIP Revision based on that policy.” They further note that “[a]s EPA explains in its proposal here, to qualify for presumptive approval under the new policy, all Class I areas, both in-state and out-of-state, that may be affected by pollution from the state must be projected to be below their respective URP glidepaths at the end of the planning period.” The Conservation Groups assert that “[n]either EPA nor South Carolina demonstrate that all Class I areas affected by South Carolina pollution will be below their respective glidepaths in 2028.”

The Conservation Groups raise three individual reasons to justify their assertion above. First, they claim all states rely on the Interagency Monitoring of Protected Visual Environments (IMPROVE) monitoring network to develop their URP glidepaths, but recent threats raise significant concerns about the continued operation of the network. Second, they claim neither EPA nor South Carolina clearly states whether they relied on adjusted URP glidepaths, but to the extent they do, those adjustments do not comply with the requirements of the RHR. Third, they claim neither EPA nor South Carolina clearly identifies the Class I areas that may be affected by pollution from South Carolina, but to the extent they do, EPA and South Carolina both ignore additional out-of-state Class I areas that

¹⁶ Citing 42 U.S.C. 7607(b)(1).

¹⁷ See 42 U.S.C. 7607(b)(1).

are affected by South Carolina pollution. Each of these points raised are summarized and responded to in more detail in Comments 5.a through 5.c below.

Comment 5.a: The Conservation Groups note “the importance of the IMPROVE network to the Regional Haze Program (and other Clean Air Act programs)” and point out that “the Trump Administration issued a stop-work order on multiple contracts to maintain the IMPROVE network earlier this year.” They state that, “[a]lthough those contracts appear to have been reinstated, funding cuts for air quality monitoring remains an issue, threatening the continued operation of the IMPROVE network.” The Conservation Groups conclude that “[w]ithout the IMPROVE network, not only would states be unable to meet the RHR’s monitoring requirements, but they also could not show that their SIPs qualify for approval under EPA’s new URP policy.”

Response 5.a: EPA disagrees that there are any issues with the IMPROVE network that are relevant to our action on the Plan. From the time that South Carolina worked on the Haze Plan up until it submitted the Plan to EPA, the IMPROVE network was in operation. Additionally, as stated in the Haze Plan, and required by the rule, South Carolina continues to support and participate in the IMPROVE network. Concerns about the future funding of the IMPROVE network are speculative, out of the control of South Carolina, and beyond the scope of the basis for our action on the Haze Plan.

Comment 5.b: The Conservation Groups cite the provisions of the RHR concerning the URP and RPGs and note that “neither EPA nor South Carolina state whether they rely on adjusted or unadjusted glidepaths.” They provide further context by stating that “[i]t appears that [Visibility Improvement State and Tribal Association of the Southeast (VISTAS)] relied on EPA’s glidepath adjustments from the Agency’s September 2019 Modeling Technical Support Document (2019 Modeling TSD). In the VISTAS final Regional Haze Air Quality Report (Final VISTAS Modeling Report), VISTAS explains that the URP can be adjusted to account for the contribution of international anthropogenic emissions on visibility impairment at Class I areas to derive a ‘default adjusted’ glidepath, citing EPA’s 2018 Technical Guidance on Tracking Visibility Projects for the Second Implementation Period of the Regional Haze Program (2018 Visibility Tracking Guidance).”

The Conservation Groups assert that the “VISTAS and EPA glidepath adjustments fail to satisfy the requirements of the RHR” because “[i]n its 2019 Modeling TSD, EPA highlighted substantial problems with available data and methods for adjusting Class I area glidepaths based on both international and prescribed wildland fire emissions.” Additionally, they state that “EPA also noted that the science on which modeling contributions from international emissions rests is questionable, stating that ‘[d]ue to the uncertainty in many of the calculations and modeling and ambient data, additional scrutiny of the initial glidepath adjustments are warranted.’” The Conservation Groups note several data and modeling limitation for prescribed fires, which include: limited existing emissions data and that data does not “accurately” capture the year-to-year variability with these emissions; the categorization of fires between wildfires (considered natural emissions) and prescribed fires (considered anthropogenic emissions) is uncertain; and the impacts of prescribed fires are likely double counted since they are already accounted for when estimating conditions on 20 percent most impaired days. They state that EPA did not include contributions from prescribed fire in its proposed adjustments to the glidepath in the 2019 Modeling Technical Support Document. Finally, they state that “these adjustments allow EPA and states to ‘flatten out’ the glidepaths for the relevant Class I areas to make it *appear* that these Class I areas are on track to meet the Clean Air Act’s goal of achieving natural visibility conditions when that is not the case.”

Therefore, the Conservation Groups claim that “[t]o the extent EPA and South Carolina rely on VISTAS or EPA URP glidepath adjustments, those adjustments do not satisfy the requirements of the RHR.” They conclude by saying that “[n]either South Carolina nor EPA can properly rely on URP adjustments that do not comply with the RHR” and that “EPA also cannot show that the South Carolina 2022 SIP Revision satisfies the new URP policy for presumptive approval.”

Response 5.b: EPA disagrees with this comment. South Carolina used an unadjusted value for “natural visibility conditions on the most impaired days.” For example, at Cape Romain Wilderness Area (Cape Romain), this value is 9.78 deciview (dv), as shown in Figure 3–1 of South Carolina’s Haze Plan. This value corresponds to the unadjusted value for natural conditions at Cape Romain (9.78 dv) found in Appendix A of EPA’s June 3, 2020,

“Recommendation for the Use of Patched and Substituted Data and Clarification of Data Completeness for Tracking Visibility Progress for the Second Implementation Period of the Regional Haze Program,”¹⁸ which provides updates to EPA’s December 20, 2018, “Technical Guidance on Tracking Visibility Progress for the Second Implementation Period of the Regional Haze Program,”¹⁹ This is further supported by information contained in Table 4–1 of the “VISTAS Future Year Model Projections Report Task 9a” found in Appendix E–6 in South Carolina’s Haze Plan. In this report, the unadjusted value for natural conditions at Cape Romain is 9.79 dv,²⁰ whereas the calculated adjusted value is 11.89 dv. Additionally, for the nearby Class I areas outside of South Carolina, Okefenokee National Wilderness Area (Okefenokee) and Wolf Island National Wilderness Area (Wolf Island), which are impacted by emissions from sources in South Carolina, Georgia also used unadjusted values for natural visibility conditions in their glidepath analysis. Therefore, neither South Carolina nor Georgia made adjustments to the glidepath for the Class I areas impacted by sources in South Carolina, so the Conservation Groups’ concerns about hypothetical adjustments to the glidepath are not relevant to the URP analysis being relied upon by EPA in this action.

Comment 5.c: The Conservation Groups cite CAA section 169A(b)(2), and assert that “[t]he Act requires states in which a Class I area is located or ‘the emissions from which may reasonably be anticipated to cause or contribute to any impairment of visibility in any such area’ to develop a SIP that makes reasonable progress toward the natural visibility goal.” They also state that similar language is found in 40 CFR 51.308(f), which says that states must address regional haze at all in-state Class I areas “and in each mandatory Class I Federal area located outside the State that may be affected by emissions from within the State.” And finally, they cite the 2019 Guidance for the

¹⁸ See https://www.epa.gov/sites/default/files/2020-06/documents/memo_data_for_regional_haze_0.pdf.

¹⁹ See https://www.epa.gov/sites/default/files/2018-12/documents/technical_guidance_tracking_visibility_progress.pdf.

²⁰ The 9.79 dv value corresponds to the value in Appendix A of EPA’s 2018 “Technical Guidance on Tracking Visibility Progress for the Second Implementation Period of the Regional Haze Program,” which was the guidance that was available at the time the VISTAS Report in Appendix E–6 was developed. This value was revised to 9.78 in the updated 2020 EPA memorandum referenced above.

same assertion. They state that “[n]either South Carolina in the 2022 SIP Revision nor EPA in its proposal here clearly specify which out of state Class I areas the State identified as being impacted by South Carolina pollution.” Therefore, the Conservation Groups claim that South Carolina failed to satisfy the CAA requirement that the State identify affected Class I areas, and EPA failed to adequately explain the basis for its proposal to approve the states identification of Class I areas.

The Conservation Groups further state that Table 10–3 and Figure 10–1 of South Carolina’s submittal identifies the top 10 Class I areas outside of South Carolina impacted by the State’s projected 2028 emissions but that “[n]either EPA nor South Carolina clearly state whether any of the Class I areas listed in Table 10–3 or Figure 10–1 of the 2022 SIP Revision are the Class I areas that South Carolina identifies as being affected by in-state pollution.” The Conservation Groups thus contend that South Carolina did not “satisfy the Clean Air Act’s requirement that it identify affected Class I areas” and cite to CAA section 169A(b)(2) and 40 CFR 51.308(f)(2) in support of this statement.

The Conservation Groups also assert that “even assuming South Carolina identified the 10 Class I areas listed above, the State still failed to properly identify all out-of-state Class I areas affected by South Carolina pollution, and so, neither South Carolina nor EPA can show that all affected Class I areas are projected to be below their respective URP glidepaths at the end of the planning period.” They state that “South Carolina relied on VISTAS modeling to identify affected out-of-state Class I areas. However, the VISTAS modeling, and South Carolina’s identification of Class I areas based on that modeling, is highly flawed.” The Conservation Groups identify two specific concerns with the VISTAS modeling and claim that the modeling did not meet the Clean Air Act’s requirements.

First, the Conservation Groups state that “South Carolina identified the Class I areas noted above based on its statewide emissions of only SO₂ and [nitrogen oxides (NO_x)] and did not consider direct emissions of [particulate matter (PM)]” and the State also did not “consider other haze-forming pollutants, like NH₃ and VOCs.” On that account, they argue that “South Carolina failed to consider all emissions of visibility impairing pollutants in identifying affected Class I areas.” They further highlight that “South Carolina identified only the ‘top 10 Class I areas outside of South Carolina’ that are

affected by pollution from the State.” However, the Conservation Groups argue that “neither the Clean Air Act nor the RHR allow states to identify only the most or top impacted Class I areas, or otherwise set a cutoff for the identification of affected Class I areas” and that “[b]oth the statute and the regulation require states to identify *any* Class I area to which a state contributes to any impairment.” They maintain that the “[c]ontrolling precedent mandates that words like ‘any’ must be given their literal, ‘capacious’ meanings” and that “[t]he plain language of the Act mandates that EPA and the states broadly identify all Class I areas to which in-state pollution may contribute to visibility impairment, and not some subset of those states.” On that account, the Conservation Groups assert that “EPA’s own summary of South Carolina’s identification of affected Class I areas shows that the State’s process did not meet requirements of the Clean Air Act.”

Second, the Conservation Groups claim that “the VISTAS modeling was riddled with errors and inaccuracies, rendering that modeling highly unreliable.” They state that the VISTAS modeling significantly underpredicted the contribution of sulfate to visibility impairment on the 20 percent most impaired days, that it relied on data that “did not reflect the dramatic shift in nitrate contribution to visibility impairment over the five-year period representing current conditions from 2014 to 2018.” The Conservation Groups continue by claiming that VISTAS’ Particulate Matter Source Apportionment Technology (PSAT) tagging process was flawed and that VISTAS applied PSAT tagging to sulfate and nitrate separately, even though those pollutants act in combination with other haze pollutants to cause visibility impairment. They conclude that “[a]s a result, the VISTAS modeling arbitrarily and incorrectly excluded large sources of SO₂ and NO_x, thereby likely ignoring out-of-state Class I areas that are affected by South Carolina pollution sources.”

The Conservation Groups claim that “even the flawed VISTAS modeling on which South Carolina relied to identify affected Class I areas shows that South Carolina pollution contributes to impairment at numerous Class I areas that the State and EPA ignore.” Furthermore, they state that “VISTAS PSAT modeling results in the 2022 SIP Revision appendices show that South Carolina sulfate and nitrate pollution contributes to impairment at even more Class I areas beyond the 10 listed above,” including 29 other Class I areas in the US and one International Park in

Canada. They claim that neither South Carolina nor EPA demonstrate, or can demonstrate, that these additional Class I areas are projected to be below their respective URP glidepaths at the end of this planning period. They additionally assert that the same VISTAS modeling shows that many of these 30 areas are projected to be above their unadjusted and adjusted glidepaths at the end of this planning period. Finally, the Conservation Groups assert that “South Carolina and EPA cannot rely on glidepath adjustments for these Class I areas to claim that they will be below their glidepaths in 2028, as the methods for glidepath adjustments on which South Carolina and EPA potentially rely did not meet the requirements of the RHR.”

In conclusion, the Conservation Groups claim that South Carolina and EPA “do not and cannot show that all Class I areas affected by South Carolina pollution will be below their respective URP glidepaths at the end of the planning period, EPA’s proposal to approve the 2022 SIP Revision based on its new URP policy is arbitrary, capricious, and contrary to the law.”

Response 5.c: EPA disagrees with these comments. The RHR requires states to submit a LTS that addresses regional haze visibility impairment for each mandatory Class I area within the State and for each mandatory Class I area located outside the State that may be affected by emissions from the State.²¹ However, while the statute says “for a State the emissions from which may reasonably be anticipated to cause or contribute to any impairment of visibility in any such area,”²² there is no specific statutory or regulatory requirement to identify the precise set of Class I areas that may be affected by emissions from the state, and there is no requirement to establish a source contribution threshold in identifying those areas.

The Conservation Groups also reference additional Class I areas that they claim are potentially affected by emissions from South Carolina and may potentially be above the 2028 URP for those areas. EPA does not agree that emissions from South Carolina cause or contribute to visibility impairment at all of those areas or that any or all of those areas are above the 2028 URP.²³ The VISTAS modeling results cited by the Conservation Groups do not support the claim that all of those additional areas

²¹ See 40 CFR 51.308(f)(2).

²² See CAA section 169A(b)(2).

²³ The RPGs for the areas identified by the Conservation Groups are below the adjusted 2028 URP. See Haze Plan Appendix F–3.

“may be affected” by emissions from South Carolina (or that emissions from South Carolina are “reasonably anticipated to cause or contribute any impairment in those areas”). While EPA has not identified a numerical “cause or contribute” threshold, EPA does not agree, in this instance, that *any* non-zero contribution can or should be considered to “cause or contribute” to visibility impairment to an out-of-state Class I area. Thus, states should merely reasonably document contributions from emissions in their state to out-of-state Class I areas and ensure that they meet the regulatory requirements, which South Carolina has done. As the Conservation Groups themselves note, South Carolina did so here in Table 10–3 and Figure 10–1 of its submittal, which contains highlights of even more detailed information contained in Appendix E–7.

EPA similarly disagrees with the Conservation Groups’ claims about VISTAS’ modeling. Detailed responses to the modeling comments discussed above and other related comments regarding the VISTAS modeling can be found in Responses 6.a, 7, and 8 below.

Comment 6: The Conservation Groups contend that EPA’s proposal to approve South Carolina’s reliance on the VISTAS’ visibility modeling is arbitrary, capricious, and contrary to law because the Agency ignored significant flaws in this modeling. They state that they informed VISTAS and EPA of significant errors in the visibility modeling through a 2021 letter and that EPA did not acknowledge these errors in the NPRM. They contend these errors affected the source selection process for all of the VISTAS states. Consequently, they assert that South Carolina improperly excluded major sources of haze-forming pollution from FFAs. These alleged errors are addressed in Comments 6.a through 6.c below.

Comment 6.a: The Conservation Groups contend that the VISTAS modeling significantly underpredicted the contribution of sulfates to visibility impairment at Class I areas on the 20 percent most impaired days and that this underprediction was largest during the summer months when sulfate extinction is known to be a major contributor to visibility impairment, and when visibility impairment is most problematic. They also assert that these errors resulted in the modeling not meeting VISTAS’ model performance goals and modeling acceptance criteria for a number of Class I areas. They provide examples of specific Class I areas in and around South Carolina where they contend the visibility modeling exceeded the acceptance

criteria for sulfate at Great Smoky Mountains National Park (Great Smoky Mountains) by – 6.92 percent and at Okefenokee by – 11.42 percent and that at Cape Romain the modeling “barely satisfies” the less than plus or minus 30 percent criteria at – 28.85 percent. They further assert that, although the State claims it corrected for these underpredictions through the use of relative response factors (RRFs) for its 2028 future year projections, neither South Carolina nor EPA assessed whether use of RRFs adequately corrected for errors in the modeling. They state that according to EPA’s 2018 Modeling Guidance, the effectiveness of RRFs is dependent on the type of data used to calculate them.²⁴

Response 6.a: EPA disagrees that there are significant flaws in South Carolina’s 2028 visibility modeling that resulted in excluding major sources of haze-forming pollution from evaluation via FFAs for the second planning period. As the Conservation Groups state, South Carolina relied upon the photochemical visibility modeling performed by VISTAS to project the impact of the State’s 2028 SO₂ and NO_x emissions on visibility in both in-state and out-of-state Class I areas. VISTAS performed the modeling in accordance with the principles described within EPA’s 2018 Modeling Guidance.²⁵ In 2018, EPA approved the Quality Assurance Project Plan²⁶ prepared by VISTAS for performing the modeling and reviewed and provided comments on the VISTAS Modeling Protocol. EPA also reviewed the VISTAS final modeling reports and data relied upon by South Carolina and found them acceptable.

Regarding sulfate predictions, Figure 6–7 of South Carolina’s Haze Plan shows the results of the normalized mean bias and normalized mean error statistical model performance tests for sulfates across the VISTAS region. Figure 6–7 does show that the modeled sulfate levels are biased low, with some values falling outside of the model performance criteria. However, as discussed below, these biases are not uncommon in photochemical modeling analyses and can be addressed with additional analyses. As noted by the Conservation Groups, the normalized

mean bias (NMB) statistic on the 20 percent most impaired days for Cape Romain in South Carolina shows model underprediction, but it is within the VISTAS performance criteria. Figure 6–27 in South Carolina’s Haze Plan graphically shows that the VISTAS Criteria for NMB (less than plus or minus 30 percent) and Normalized Mean Error (NME) (less than plus or minus 50 percent) are met for the Cape Romain Class I area in South Carolina.

Model bias and error, either high or low, is not uncommon in photochemical modeling analyses due to uncertainties in model inputs and the scientific model formulation, and the fact that all air quality models are simplified approximations of the complex phenomena of atmospheric chemistry, fate, and transport of pollutants. Section 6.0 of EPA’s 2018 Modeling Guidance discusses uncertainties that may affect model results and provides recommendations to mitigate modeling bias and uncertainty. South Carolina acknowledges that model performance generally underpredicted observed concentrations on the 20 percent most impaired days but stated that model performance was assessed at the “one atmosphere” level and was deemed acceptable for its regulatory determinations in the Haze Plan (which references the 2018 Modeling Guidance in several instances). The 2018 Modeling Guidance states that it is not appropriate to use a “bright-line test” for distinguishing between adequate and inadequate photochemical model performance for a single performance test statistic.²⁷ EPA’s 2018 Modeling Guidance instead recommends using a “weight of evidence” approach for evaluating model performance holistically.²⁸

As discussed in Section 5.2(d) of EPA’s “Guideline on Air Quality Models” contained in 40 CFR part 51, Appendix W, there are no specific levels of any model performance metric that indicate acceptable model performance. The decision regarding acceptability is heavily influenced by professional judgment of the reviewing authority, which is EPA in this case. Based upon the overall performance of the model for all pollutants affecting visibility, considered holistically, South Carolina’s conclusions that the modeling is

²⁴ EPA’s *Modeling Guidance for Demonstrating Air Quality Goals for Ozone, PM_{2.5} and Regional Haze* (November 29, 2018) (“2018 Modeling Guidance”) is in the docket for this rulemaking and is also available at: https://www.epa.gov/sites/default/files/2020-10/documents/o3-pm-rh-modeling_guidance-2018.pdf.

²⁵ *Id.*

²⁶ The April 3, 2018, Quality Assurance Project Plan for the VISTAS II Regional Haze Project is located in Appendix A–1 of the Haze Plan.

²⁷ See 2018 Modeling Guidance at 69 (“Further, even with a single performance test, it is not appropriate to assign “bright line” criteria that distinguish between adequate and inadequate model performance.”).

²⁸ *Id.* (“[T]he EPA recommends that a “weight of evidence” approach be used to determine whether a particular modeling application is valid for assessing the future attainment status of an area.”).

acceptable for use in the regional haze SIP analyses are reasonable, and South Carolina provided a reasonable explanation for the model bias.

Just as importantly, South Carolina took appropriate steps to correct for this model bias. The Haze Plan explains that the model is applied in a relative sense through the calculation of RRFs following the procedures in 2018 Modeling Guidance for calculating 2028 future year visibility impacts, which mitigates concerns about the low bias in the sulfate model predictions. As described in EPA's 2018 Modeling Guidance, RRFs are "the fractional change in air quality concentrations that is simulated due to emissions changes between a base and a future year emissions scenario."²⁹

Applying the model in a relative sense using the RRFs is an important tool in mitigating the impacts of the sulfate modeling underpredictions in the 2011 baseline year on the model projections for the 2028 future year. Section 4.1 of the 2018 Modeling Guidance provides a detailed explanation of why EPA recommends photochemical modeling be applied in a relative sense and explains that problems posed by model bias are expected to be reduced when using the relative approach. Section 7.2.6.1 of South Carolina's Haze Plan explains the calculation of 2028 visibility estimates using the RRF approaches contained in EPA's 2018 Modeling Guidance. Using the RRF approach with an average of five years of IMPROVE³⁰ data on the 20 percent most impaired days and 20 percent clearest days along with the relative percent modeled change in all the PM species between 2011 and 2028 reduces the influence of the bias in sulfate-modeled (and other PM species) values in the 2011 baseline year. The 2028 visibility impairment projection is derived primarily from the five-year average of actual IMPROVE monitoring data in 2009–2013 that was then scaled in a relative sense by the modeling results. If the model were being applied in an absolute sense, the low bias in the sulfate modeled values would have a larger impact on the 2028 visibility projections. For these reasons, South Carolina's use of the VISTAS model results to inform source selection was reasonable due to the use of RRFs to minimize the impacts of model bias. Additionally, regardless of the sulfate model performance, a specific source selection approach is not required by

the RHR. South Carolina reasonably selected the nine facilities (five of which are in-state) that have the highest impact on visibility at the State's Class I area, as well as out-of-state Class I areas, for emissions control analysis (see Response 7.a) and considered the four statutory factors. EPA finds that South Carolina's source selection methodology is consistent with the RHR because it was reasonable and resulted in the selection of a reasonable set of sources contributing to visibility impairment at Class I areas affected by South Carolina's sources.

Comment 6.b: The Conservation Groups state that VISTAS relied on an "outdated" 2011 baseline year for its 2028 future year emissions projections and assumed that electric generating units (EGUs) would operate in the exact same manner in 2028 as they did in 2011. Thus, they assert that the model assumptions and results are incorrect because EGUs are likely to have different load utilization in 2028 than in 2011.

Response 6.b: South Carolina's use of a 2011 base emissions inventory year to project emissions out to 2028 (the end of the second planning period) is reasonable in this instance. Although it is always preferable to use the most recent information available for modeling, the 2011 baseline year inventory used by VISTAS was the latest region-wide inventory available at the time that South Carolina's SIP submittal was being developed during the VISTAS technical work, which took place from December 2017 to February 26, 2021.³¹ In EPA's experience, coordination among states such as those in the VISTAS region takes time, and the modeling involved is time-consuming, highly technical, and resource intensive. The modeling generally requires hundreds of hours of time to gather the model input data (e.g., emissions, meteorology, land-use, etc.), prepare modeling protocols, perform the modeling, and analyze the results. The computational resources to run photochemical models are also very large. "Mainframe" clusters of a large number of computer processors are required to run the models, and even using these powerful computers, it takes weeks of computer run-time for a full-year model simulation. Additionally, EPA's newer 2016-based modeling platform only became available in September 2019,³² after VISTAS had

already invested a considerable amount of time and money into the regional haze modeling analysis, including the Comprehensive Air Quality Model with Extensions (CAMx) PSAT source apportionment modeling that was used to identify sources to evaluate or reasonable progress. EPA develops the National Emissions Inventory (NEI) suitable for use in such models every three years.³³ By design, the regional haze program requires states to spend significant time in the planning phase, and this generally necessitates the use of a baseline year that is substantially earlier than the date the state submits its SIP to EPA.

In addition, there is no RHR requirement regarding the baseline year for regional photochemical modeling (nor is photochemical modeling required). At the time VISTAS began their regional haze modeling, EPA did not have a more recent baseline emissions inventory year available for state use in the second period regional haze plans. Furthermore, South Carolina explains the use of this particular baseline year and states that the 2011 emissions inventory was the most recently available quality-assured statewide emissions inventory when the VISTAS project began for the second planning period.³⁴ Moreover, prior to using this data, South Carolina discussed the selection of this baseline year emissions inventory and received confirmation from EPA to use this emissions inventory.³⁵

www.epa.gov/visibility/technical-support-document-epas-updated-2028-regional-haze-modeling.

³³ For more information on the NEI, see <https://www.epa.gov/air-emissions-inventories/national-emissions-inventory-nei>.

³⁴ See Haze Plan at 22 ("The year 2011 was selected as the modeling base year because the VISTAS 2028 emissions inventory is based on the 2011 Version 6 EPA modeling platform. For the analyses in this SIP, this period consists of those years surrounding 2011 (i.e. 2009–2013)"). See also Haze plan at 47 ("Calendar year 2011 satisfies the criteria in EPA's modeling guidance episode selection discussion and is consistent with the base year modeling platform. Specifically, EPA's guidance recommends choosing a time period which reflects the variety of meteorological conditions that represent visibility impairment on the 20 percent clearest and 20 percent most-impaired days in the Class I areas being modeled (high and low concentrations). This is best accomplished by modeling a full calendar year. In addition, the 2011/2028 modeling platform was the most recent available platform when VISTAS started their modeling work. EPA's 2016-based platform became available at a later date after VISTAS had already invested a considerable amount of time and money into the modeling analysis. Using the 2016-based platform was not feasible from a monetary perspective, nor could such work be done in a timely manner.").

³⁵ See the January 29, 2018, email from EPA (Richard Wayland) regarding use of a 2011 base

Continued

²⁹ *Id.* at 103.

³⁰ IMPROVE visibility monitoring data is available at: <https://vista.cira.colostate.edu/Improve/>.

³¹ See "Timeline" for the VISTAS II Regional Haze Project at: <https://www.metro4-sesarm.org/content/vistas-regional-haze-project-intro>.

³² See "Technical Support Document for EPA's Updated 2028 Regional Haze Modeling" at: <https://>

The 2011 emissions inventory was used to estimate emissions of visibility impairing pollutants in 2028. VISTAS applied reductions expected from federal and state regulations to the visibility impairing pollutants NO_x, PM, and SO₂. South Carolina's 2028 emissions projections are based on the State's technical analysis of the anticipated emission rates and level of activity for EGUs, other point sources, non-point sources, on-road sources, and off-road sources based on their emissions in the 2011 base year, considering growth and additional emissions controls to be in place by 2028. In addition, the VISTAS emissions inventory for 2028 accounts for post-2011 emission reductions from promulgated federal, state, local, and site-specific control programs.

Although South Carolina used 2011 as its emissions inventory base year, as required by the RHR at 40 CFR 51.308(f)(2)(iii), South Carolina also examined more recent emissions inventory information for SO₂ and NO_x for the years 2017, 2018, and 2019 and compared these emissions to the 2028 emission projections that were used for modeling purposes in Section 7.6.5, Table 7–19 of its Haze Plan. This helped to ensure that the State adequately considered more recent emissions inventory information when developing LTS. The technical information provided in the docket demonstrates that the emissions inventory in the Haze Plan adequately reflects projected 2028 conditions. Given the aforementioned reasons, EPA finds the use of the 2011 baseline year by VISTAS (and thus South Carolina) reasonable. Additionally, regardless of the use of a 2011 baseline year, a specific source selection approach is not required by the RHR. South Carolina reasonably selected the nine facilities (five of which are in-state) that have the highest impact on visibility at the State's Class I area, as well as out-of-state Class I areas, for emissions control analysis (see Response 7.a) and considered the four statutory factors. EPA finds that South Carolina's source selection methodology is consistent with the RHR because it was reasonable and resulted in the selection of a reasonable set of sources contributing to visibility impairment at Class I areas affected by South Carolina's sources.

Comment 6.c: The Conservation Groups state that VISTAS used "outdated" monitoring data for its 2028 future year projections that did not reflect an observed shift in nitrate

contribution to visibility impairment in the southeastern United States in the recent past. They therefore contend that this resulted in the exclusion of major NO_x sources from the modeling results.

Response 6.c: Regarding the Conservation Groups' comment that the 2009–2013 modeling base period did not reflect more recent changes in nitrate contributions, EPA discussed its views on this issue in detail in the NPRM. Nitrates are also discussed in Response 8, below. EPA agrees that after the 2009–2013 timeframe, nitrate impacts have become more significant on some of the 20 percent most impaired days, especially considering the significant decrease in SO₂ emissions and measured sulfate concentrations as acknowledged in the NPRM. EPA nonetheless agrees with South Carolina's conclusion that for the second planning period, sulfates remain the dominant visibility-impairing pollutant at the Class I areas affected by South Carolina and that it is therefore reasonable for South Carolina to focus on SO₂-emitting sources during this period.

Comment 7: The Conservation Groups state that the purported errors in the VISTAS modeling discussed in Comment 6 were carried forward into the source selection process for VISTAS states, including South Carolina, and that those errors caused VISTAS, and the states that relied on the VISTAS process, to improperly exclude sources from FFAs. In addition to the modeling errors, they state that South Carolina adopted VISTAS' "unreasonable" source screening process that uses Area of Influence (AoI) and PSAT analyses and applied unreasonably high source selection thresholds. Based on these reasons, they conclude that EPA's proposal to approve the State's source selection method is arbitrary and capricious. The Conservation Groups' specific comments on this topic are addressed in Comments 7.a through 7.h, below.

Comment 7.a: The Conservation Groups claim that South Carolina employed unreasonably high source selection thresholds for the AoI analysis, which were too restrictive and resulted in the identification of only six South Carolina sources at the AoI step. Specifically, they assert that by using percentage-based source selection thresholds, the State's calculated threshold in absolute terms was higher for Class I areas with the most severe visibility impairment, meaning that fewer sources were identified at the AoI step for Class I areas with the worst impairment. The Conservation Groups state that for the areas with the worst

visibility impairment, more sources should be selected to make progress toward the natural visibility goal.

The Conservation Groups state that after performing the AoI analysis and creating initial lists of facilities for PSAT tagging, the VISTAS states then compared their lists and collaborated on the final list of facilities for which AoI impacts were significant enough to warrant further evaluation. They state that South Carolina failed to provide any information on how the VISTAS states went through this comparison process or any criteria used to determine whether an AoI impact is significant enough. They contend that EPA and the State therefore failed to adequately explain the AoI step in the selection process.

Response 7.a: EPA disagrees with this comment. The RHR does not require states to consider evaluating controls for all sources, all source categories, or any or all sources in a particular source category. Nor does the RHR expressly specify criteria for minimum source selection thresholds.

These flexibilities are, however, not unbounded. The RHR requires that "[t]he State should consider evaluating major and minor stationary sources or groups of sources, mobile sources, and area sources. The State must include in its implementation plan a description of the criteria it used to determine which sources or groups of sources it evaluated and how the four factors were taken into consideration in selecting the measures for inclusion in its long-term strategy."³⁶ In addition, the technical basis for source selection must also be documented, as required by 40 CFR 51.308(f)(2)(iii). Thus, states must utilize a reasonable source selection methodology, and whatever choices states make regarding source selection should be reasonably explained.³⁷ South Carolina met these requirements. Specifically, South Carolina discussed the criteria it used to determine which sources or groups of sources were evaluated by the State, including the use of AoI analysis, photochemical modeling (e.g., PSAT), and associated source selection thresholds for AoI and PSAT tagging in its Haze Plan. South Carolina documented its use of these approaches in extensive detail within Section 7.5 of the Haze Plan and Appendix D–1 of the Haze Plan (relating to AoI analysis) and Section 7.6 and Appendices E–1a, E–1b, E–2a, E–2b, E–2c, E–2d, E–2e, E–2f, E–3, E–4, E–5, E–

year by VISTAS for regional haze in the docket for this rulemaking.

³⁶ See 40 CFR 51.308(f)(2)(i).

³⁷ See 90 FR 36005, 36007.

6, E-7a, and E-8 of the Haze Plan (relating to PSAT analysis).

South Carolina's documentation adequately demonstrates why its source selection methodology—including the use of an AoI threshold contribution of nitrate of three percent or more or sulfate of two percent or more for in-state sources, and a threshold contribution of four percent sulfate plus nitrate out-of-state sources for follow-up PSAT tagging and a one percent PSAT threshold on a pollutant-by-pollutant basis for source selection—is reasonable. For the reasons stated herein and in the NPRM, EPA finds that South

Carolina's source selection methodology was reasonable and resulted in the selection of a reasonable set of sources contributing to visibility impairment at Class I areas affected by South Carolina's sources. The State's methods for selecting sources for a control analysis and the State's AoI and PSAT analyses identified sources in South Carolina having the highest impact on visibility at Class I areas at the end of the second planning period and identified sources outside of South Carolina having the largest impacts on visibility at Cape Romain. A specific

source selection approach is not required by the RHR.³⁸

The results of this methodology were reasonable as well. South Carolina selected for emissions control analysis the nine sources with the largest visibility impacts (accounting for both SO₂/sulfate and NO_x/nitrate³⁹) at Cape Romain and nearby Class I areas in neighboring states. On the whole, SO₂ emissions from the five in-state sources selected by South Carolina for further analysis are projected to impact visibility at Class I areas as described in Table 1, below.

TABLE 1—SULFATE PSAT CONTRIBUTIONS (PERCENT) FOR THE FIVE SOURCES SELECTED FOR FURTHER ANALYSIS IN NEARBY CLASS I AREAS ON THE 20 PERCENT MOST IMPAIRED DAYS *

Sources ** sulfate PSAT contributions to Class I areas	Cape Romain (SC)	Okefenokee (GA)	Wolf Island *** (GA)
WestRock-Charleston	3.88		
Century	2.43		1.30
Cross	2.34	1.22	1.34
Winyah	1.39		
IP-Georgetown	1.71		

* Note that fields with a “-” indicate that visibility impacts are below one percent.

** The Class I areas listed in Table 1, above, are included because the South Carolina facilities in this table have a sulfate PSAT contribution of one percent or more at one or more of these areas.

*** Wolf Island has no IMPROVE monitor. Visibility at Wolf Island is assumed to be the same as the nearest Class I area monitor located at Okefenokee.

Although these five sources are the largest contributors within South Carolina to visibility impairment at Class I areas, most anthropogenic impacts to visibility at Cape Romain come from outside of South Carolina.

This is illustrated in Figure 7–18 of the Haze Plan, which provides the contributions from 2028 SO₂ and NO_x emissions to visibility impairment from all source sectors for the 20 percent most impaired days in units of inverse

megameters (Mm⁻¹). The entries in Table 2, below, show the contributions from South Carolina, all other VISTAS states, and other Regional Planning Organizations (RPOs) to Cape Romain.

TABLE 2—CONTRIBUTIONS OF 2028 SO₂ AND NO_x EMISSIONS FROM ALL SOURCE SECTORS TO VISIBILITY IMPAIRMENT FOR THE 20 PERCENT MOST IMPAIRED DAYS FOR CAPE ROMAIN (Mm⁻¹) *

Class I area	Projected 2028 impairment on 20% most impaired days **	SC	All other VISTAS states	CENRAP region ***	LADCO region ***	MANE-VU region ***	All other regions ***
Cape Romain	52.82	4.20	6.46	1.87	3.74	1.57	2.36

* Reference “ATTACHMENT A PSAT TAG RESULTS adjusted 09–02–2020.xls” included in the docket. The columns to the right of “Projected 2028 Impairment on 20% Most Impaired Days” do not add up to the values in the “Projected 2028 Impairment on 20% Most Impaired Days” column due to international emissions and boundary emissions visibility impacts not shown in this table.

** Value represents visibility impairment from all anthropogenic and natural sources.

*** “CENRAP” refers to Central Regional Air Planning Association (which is associated with the Central States Air Resource Agencies (CENSARA)); “LADCO” refers to Lake Michigan Air Directors Consortium; MANE-VU; See also <https://www.epa.gov/visibility/visibility-regional-planning-organizations>.

Table 2 illustrates that South Carolina's in-state SO₂ and NO_x emissions account for a relatively small percentage (eight percent) of total

visibility impairment at Cape Romain impacted by South Carolina sources.⁴⁰

Likewise, the PSAT Tag Results spreadsheet referenced in Section 6.3 of Appendix E–7a of the Haze Plan shows

the visibility impacts on a facility-by-facility basis due to SO₂ emissions. Specifically, the spreadsheet referenced in Attachment A of Appendix E–7a shows the following SO₂ visibility

³⁸ Both of these approaches (AoI and PSAT) are example methods in the 2019 Guidance. See subsection “(b) Estimating baseline visibility impacts for source selection” on pages 12–15 of the 2019 Guidance. PSAT is a type of photochemical modeling which is item 4 on page 13 of the 2019

Guidance. VISTAS' AoI analyses involve items 1–3 on page 13 of the 2019 Guidance.

³⁹ South Carolina selected sources for PSAT modeling based on the combined impact of sulfate plus nitrate. Sulfates and nitrates were modeled together in the PSAT modeling with the other PM species that impact visibility (e.g., direct PM,

organic carbon, elemental carbon, etc.). There were no sources with a sulfate impact below the PSAT threshold(s), but a sulfate plus nitrate impact above the threshold(s).

⁴⁰ These percentages were calculated by dividing the “SC” column by the “Projected 2028 20% Most Impaired Days Column” and multiplying by 100.

impacts to Class I areas impacted by South Carolina sources on the 20 percent most impaired days in units of Mm^{-1} .

TABLE 3—2028 SO_2 VISIBILITY IMPACTS TO CAPE ROMAIN ON THE 20 PERCENT MOST IMPAIRED DAYS (Mm^{-1})

Source	Cape Romain
WestRock-Charleston	0.523
Century	0.327
Cross	0.316
Winyah	0.187
IP-Georgetown	0.230
Total of South Carolina Selected Sources	1.583
South Carolina Total Contribution	3.252
All Sources (including out-of-state contribution)	15.464

The above data in Table 3 further supports that South Carolina's source selection thresholds and source selection methodology were reasonable. Specifically, on the 20 percent most impaired days, South Carolina's in-state sources selected for further analysis are responsible for approximately 48.68 percent of South Carolina's total in-state SO_2 visibility impairment at Cape Romain.⁴¹ States are not required by the RHR to select every source in the state, and South Carolina selected the in-state sources with the largest visibility impacts on in-state and nearby Class I areas.

Table 3 also shows that most emissions of visibility-impairing sulfates that impact South Carolina's Class I area on the 20 percent most impaired days are emitted from outside of South Carolina. The same general pattern holds for the 20 percent least impaired days as well. South Carolina does not have jurisdiction through its SIP to regulate sources outside of state boundaries. South Carolina did, however, request FFAs from other states for an additional four facilities outside of South Carolina through the interstate consultation process.⁴² The "regional" nature of the regional haze program necessarily requires South Carolina to rely on reasonable progress made by other states, just as other states must rely on South Carolina to make reasonable progress.

Turning to the Conservation Groups' other source selection comments, they assert that by using a percentage threshold for AoI, the calculated threshold in absolute visibility impact terms was higher for Class I areas with the most severe visibility impairment, which resulted in fewer sources being evaluated for reasonable progress for the

most visibility-impaired Class I areas. Thus, the Conservation Groups assert that the use of a percentage threshold was unreasonable.

EPA disagrees with this comment. As noted above, states have flexibility to adopt any source selection methodology so long as the methodology is reasonable, and their choices are reasonably explained. A percentage threshold, rather than one using an absolute visibility threshold (Mm^{-1} or dv), allowed South Carolina—like every other VISTAS state—to select sources with the largest visibility contributions to each Class I area regardless of the magnitude of visibility impairment at a Class I area. This approach is reasonable. Use of a percentage-based threshold produced a relative ranking of visibility impairment to allow the State to focus on the sources contributing to the largest amount of visibility impact at each individual Class I area. Therefore, EPA finds that South Carolina's source selection method is reasonable and adequately explained for the reasons discussed above and within our proposal.

In addition, EPA disagrees with the Conservation Groups' assertion that EPA and South Carolina failed to adequately explain the AoI step of the source selection process. The AoI and PSAT tagging steps were described in sections 7.5 and 7.6 of the Haze Plan, and EPA evaluated the process in the NPRM. The two-step process of screening with the AoI analysis and then applying the more refined PSAT source apportionment modeling to sources that met the initial AoI screening criteria is a sound technical approach for identifying sources to evaluate for reasonable progress. Elements of South Carolina's AoI approach are discussed in EPA's 2019 Guidance as a viable method to assess sources' visibility impacts to Class I areas.⁴³ South Carolina, along

with many of the VISTAS states, also relied upon the AoI initial screening approach in its first planning period Haze Plan. VISTAS used the AoI analysis as an initial screening step because it is a much simpler and less resource intensive approach than using PSAT tagging to model hundreds to thousands of potential sources. The AoI screening approach identified a smaller subset of sources that could undergo refined analysis using PSAT modeling. EPA finds the two-step process of first screening with the AoI analysis followed by use of the more refined PSAT source apportionment modeling to sources is valid, reasonable, and adequately explained. Regarding the assertion that South Carolina failed to provide any information on how the VISTAS states went through its comparison process, this comment is not germane to South Carolina's selection of sources for PSAT analysis because all of the facilities above the State's AoI thresholds were selected for PSAT analysis. As discussed above, EPA finds South Carolina's source selection method reasonable and adequately explained.

Comment 7.b: The Conservation Groups state that VISTAS considered sulfate and nitrate separately in the PSAT model analyses, which the Conservation Groups allege does not align with how these pollutants act in combination in the atmosphere along with other haze precursors, to contribute to light extinction and visibility impairment. As a result, they argue that VISTAS likely underestimated the overall visibility impact of individual sources in its PSAT analysis.

Response 7.b: EPA disagrees with Conservation Groups' assertion that VISTAS' separate consideration of sulfate and nitrate undermines its

⁴¹ These percentages were calculated by dividing the "Total of Selected South Carolina Sources" row in Table 3 by the "South Carolina Total Contribution" row and multiplying by 100.

⁴² See Haze Plan at Section 7.6.

⁴³ EPA's 2019 Guidance at 12–14 discussing Q/d (emissions (Q) divided by distance to a Class I area

(d)), trajectory analyses, residence time analyses, and source apportionment photochemical modeling (e.g., CAMx PSAT).

analysis of visibility impacts. Sulfates and nitrates were modeled together in the PSAT modeling with the other PM species that impact visibility (e.g., direct PM, organic carbon, elemental carbon, etc.). Section 7.6.2 of the Haze Plan summarizes the results of the PSAT modeling. This section states: “[t]he adjusted PSAT results were used to calculate the percent contribution of each tagged facility to the total sulfate and nitrate point source (EGU + non-EGU) contribution at each Class I area.” Table 7–11 of the Haze Plan contains the specific PSAT results for Cape Romain. South Carolina considered the PSAT modeled results for sulfate and nitrate separately only to compare against its selected one percent PSAT threshold for each of these pollutants to identify a reasonable number of sources for further analyses. The State’s approach is reasonable for the reasons discussed above, and it was adequately justified in the Haze Plan and in EPA’s NPRM.

Comment 7.c: The Conservation Groups state that VISTAS used an outdated 2028 emissions projection to “tag” sources. They note that although VISTAS documented that the initial 2028 emission inventory projections were updated for the final modeling, the associated PSAT modeling did not use the final 2028 inventory. The Conservation Groups state that VISTAS scaled predicted sulfate and nitrate to the corresponding changes in SO₂ and NO_x emissions in the updated 2028 inventory using a linear relationship between sulfate and nitrate concentrations. They argue ample evidence shows that there is a non-linear relationship between emissions and sulfate/nitrate concentrations, and that this resulted in additional errors into the modeling.

Response 7.c: EPA disagrees with this comment. VISTAS used the original 2028 emissions inventory to perform the PSAT modeling, and the original PSAT results were linearly scaled to reflect the updated 2028 emissions. Although linear scaling introduces some uncertainty to the final PSAT results, EPA agrees with VISTAS and South Carolina that adjusting the results to account for VISTAS’ updated 2028 emissions inventory using linear scaling is a reasonable approach to account for VISTAS’ updated 2028 emissions projections and is a better approach than relying on the original PSAT modeling.

Linear scaling of photochemical modeling results to account for changes in emissions is, in most cases, reasonable and is an accepted practice by EPA. For example, EPA guidance

recommends using EPA’s Modeled Emission Rates for Precursors (MERPs) for evaluating the impacts of secondary particulate matter of 2.5 micrometers or less in diameter (PM_{2.5}) in Prevention of Significant Deterioration (PSD) modeling analyses and allows for and recommends scaling of photochemical modeling results based on emissions.⁴⁴ This guidance recommends an approach where the PM_{2.5} impacts are estimated using an archived national-scale photochemical modeling analysis, performed using CAMx and Community Multiscale Air Quality (CMAQ)⁴⁵ photochemical models, that uses hypothetical emissions sources, and then linearly scaling the photochemical modeling results using the ratio of the PSD project-specific source emissions to the modeled emissions from the hypothetical source (see Equation 1 on page 3 of the referenced April 30, 2024, MERPs memorandum). This approach is widely used and accepted by state air quality agencies and EPA to account for secondarily formed PM_{2.5} from precursor emissions (SO₂ and NO_x) for PSD modeling analyses. Since the regional haze modeling uses linear scaling with CAMx and for the same PM_{2.5} precursors (SO₂ and NO_x) as the MERPs analyses, EPA finds the method of linear scaling of PM precursor emissions conducted by VISTAS to be an acceptable practice.

Comment 7.d: The Conservation Groups note that South Carolina relied on the PSAT modeling results for its multiple in-state sources that are located less than 50 kilometers (km) from Cape Romain and claim that PSAT modeling has been shown to be unreliable for sources that are within a short distance from a Class I area,⁴⁶ referencing Federal Land Manager (FLM)⁴⁷ guidance that addresses regional grid models. According to the Conservation Groups, this guidance shows that regional grid

models are not preferred for sources located close to Class I areas and that the grid size used by VISTAS is too small to produce accurate results for those sources.

Response 7.d: The Conservation Groups state that PSAT modeling has been shown to be unreliable for sources located less than 50 km from a Class I area. However, they do not provide any specific model performance information demonstrating that the CAMx model nor the PSAT source apportionment tool have poor model performance for evaluating visibility impacts from sources located within 50 km of any of the Class I areas located in South Carolina.

Instead, the Conservation Groups provide qualitative arguments to support their assertion. They assert that the FLMs’ Air Quality Related Values Work Group (FLAG) Guidance indicates that photochemical grid models are not the preferred model for evaluating visibility impacts from sources less than 50 km from Class I areas and reference the use of direct plume impact models. However, they are inappropriately citing the FLAG guidance and recommendations, which is not intended to apply to photochemical grid modeling or outside of the permitting context. The FLAG reference to direct plume models (e.g., Plume Visibility Model) is only for evaluating visibility impacts under the New Source Review (NSR)/PSD (NSR/PSD) permitting regulations and is not applicable to regional haze analyses. EPA’s regional haze regulations and guidance do not require evaluations of direct plume impacts separate from the photochemical modeling analyses used for regional haze visibility analyses. Therefore, the argument is not relevant for the visibility analyses for regional haze.

The Conservation Groups separately contend that South Carolina’s correlation analysis of the sulfate AoI versus PSAT presented in Section 7.6.3 of the Haze Plan is flawed. They point out the scatter in the AoI/PSAT ratio data for distances less than 100 km in Figure 7–29 of the Haze Plan and argue this makes the State’s correlation conclusions invalid. They also refer to the scatter in the sulfate fractional bias values in Figure 7–30 in the Haze Plan and argue the AoI versus PSAT correlation is invalid. EPA disagrees. While there is more scatter between the data points less than 100 km from the Class I area, there is clearly a trend that the AoI values are much larger than the PSAT values within 100 km compared to the ratios for further distances. There is logic to this result due to the way the

⁴⁴ See “Clarification on the Development of Modeled Emission Rates for Precursors (MERPs) as a Tier 1 Demonstration Tool for Ozone and PM_{2.5} under the PSD Permitting Program,” April 30, 2024, Memorandum from Tyler Fox to Regional Office Modeling Contacts is available at: https://www.epa.gov/sites/default/files/2020-09/documents/epa-454_r-19-003.pdf.

⁴⁵ See <https://www.epa.gov/cmaq> for further information on CMAQ.

⁴⁶ Citing to 2021 Gebhart North Carolina Report at 4.

⁴⁷ EPA’s regulations define “Federal Land Manager” as “the Secretary of the department with authority over the Federal Class I area (or the Secretary’s designee) or, with respect to Roosevelt-Campobello International Park, the Chairman of the Roosevelt-Campobello International Park Commission.” See 40 CFR 51.301. The U.S. National Park Service (NPS), U.S. Fish and Wildlife Service (FWS), and U.S. Forest Service (USFS) are collectively referred to as the “Federal Land Managers” or “FLMs” throughout this notice.

AoI metric is calculated using the Extinction Weighted Residence Times (EWRT) multiplied by the Emissions (Q) divided Distance (d) (EWRTxQ/d). The EWRT is calculated using the frequency that winds (represented by Hybrid Single-Particle Lagrangian Integrated Trajectory (HYSPLIT) back trajectories) pass over a specific geographic area (represented by a modeling grid cell) on the path to the Class I area.⁴⁸ For sources located less than 100 km from a Class I area, there is likely to be a higher frequency of the HYSPLIT back trajectories passing over the 12 km grid cell containing the source, thus the EWRT and AoI value will be larger. The CAMx PSAT modeling is a more refined photochemical modeling approach that calculates the atmospheric fate and transport of the PM precursors and their chemical reactions to form visibility impairing pollutants (e.g., ammonium sulfate). Therefore, compared to the AoI screening process, the refined PSAT technique is less likely to overestimate the visibility impacts for sources located within 100 km of the Class I area. Regarding the scatter of the data resulting in the AoI to PSAT fractional bias correlation, EPA acknowledges that there is scatter in the data which is reflected in the 0.72 coefficient of determination (R^2) value shown in Figure 7–30 in the Haze Plan. However, this level of correlation is not uncommon in these types of modeling data analyses, and the results are reasonable. For these reasons, South Carolina's correlation approach is valid.

The photochemical modeling employed by VISTAS and South Carolina is the most refined methodology available for evaluating regional haze visibility impacts. Moreover, South Carolina's AoI screening process identified sources located within 50 km of its Class I areas, including the WestRock-Charleston and Century facilities located 29 km and 39 km, respectively, from Cape Romain that met the PSAT source selection criteria and further underwent reasonable progress analysis. As discussed above, South Carolina demonstrated in Section 7.6.3 of the Haze Plan that the AoI screening technique tends to overestimate visibility impacts for sources located within 100 km of a Class I area. Based upon this AoI overestimation, in Section 7.6.4 of the Haze Plan, South Carolina explains why some sources located less than 100 km from its Class I areas were not tagged for PSAT modeling and thus were not selected for FFAs. South

Carolina's justification regarding why the other sources within 100 km were not selected for FFAs is reasonable.

Comment 7.e: The Conservation Groups claim that South Carolina's use of a percent-based threshold at the PSAT step biased the process against heavily polluted Class I areas. They explain that reliance on the percent-based threshold would require source impacts to be 80 times larger for the most visually impaired Class I areas versus the least visually impaired Class I areas to be selected.

Response 7.e: EPA disagrees with this comment. Section 7.6.4 of the Haze Plan explains the State's rationale for using a one percent PSAT threshold to select sources for a reasonable progress evaluation. Using a percentage-based threshold enabled the State to identify the sources that contribute most to visibility impairment at the Class I areas, regardless of the magnitude of visibility impairment at each Class I area. Therefore, South Carolina's targeting of sources with the largest visibility contributions to each Class I area regardless of magnitude of visibility impairment at a Class I area is reasonable. Use of a percentage-based threshold produced a relative ranking of impacts on visibility impairment, allowing the State to focus on the sources with the greatest visibility impacts on each individual Class I area. Regardless of whether a relative or absolute threshold was used, South Carolina's source contribution threshold identified the largest sources for evaluation of emissions measures. Therefore, the methodology is reasonable and was adequately documented in its Haze Plan.

Comment 7.f: The Conservation Groups claim that neither South Carolina nor EPA have provided adequate justification to support the source selection thresholds, and therefore, the source selection process is arbitrary and capricious. They state four ways in which South Carolina's justification misses the mark. First, they argue that South Carolina did not provide an explanation for why it set a different selection threshold for out-of-state sources, or with regard to that threshold, include a description of the criteria used to determine which sources or groups of sources it evaluated in violation of 40 CFR 51.308(f)(2)(i). Second, they argue that South Carolina effectively claims that the URP is a safe harbor in violation of the CAA, RHR, and EPA interpretation, and the State did not need to select additional sources because Cape Romain is projected to be below the URP in 2028 without any additional controls. Third, the

Conservation Groups assert that South Carolina inappropriately claims that emission reductions already achieved in the second planning period excuses the State from selecting additional sources. Lastly, the Conservation Groups maintain that South Carolina unreasonably set its selection thresholds to only select the largest sources for further analysis, pointing to EPA guidance. They note that the USFS explained that South Carolina's source selection process found the sources selected by South Carolina accounted for just 24 percent, 12 percent, 47 percent, and 38 percent of emissions that impact Linville Gorge National Wilderness Area (Linville Gorge), Shining Rock National Wilderness Area (Shining Rock), Joyce Kilmer-Slickrock (Joyce Kilmer), and Cohutta National Wilderness Area (Cohutta), respectively.

Response 7.f: EPA disagrees with the Conservation Groups' contention that South Carolina did not adequately justify its source selection thresholds.

First, regarding the out-of-state AoI threshold, no out-of-state sources exceeded South Carolina's in-state thresholds of two percent sulfate or three percent nitrate at Cape Romain; therefore, the higher out-of-state threshold had no impact on the outcome of the Haze Plan. As discussed in Response 7.a, South Carolina's source selection method is reasonable and adequately explained.

Second, EPA disagrees with the Conservation Groups' assertion that South Carolina effectively claims that the URP is a safe harbor, and the State did not need to select additional sources because Cape Romain is projected to be below the URP in 2028 without any additional controls. As discussed in Response 7.a, South Carolina did not claim the URP to be a safe harbor. South Carolina based its source selection on AoI and PSAT analyses, selected the sources with the largest visibility impacts to Class I areas impacted by South Carolina, and considered the four statutory factors.

Third, the comment that South Carolina "claims that already achieved emission reductions in the second planning period excuse it from selecting additional sources" is unclear. The Haze Plan contains no such statement. As discussed in Response 7.a, South Carolina's source selection methodology is reasonable and is adequately documented in its Haze Plan. The fact that sources were not selected for FFAs for either SO₂ or NO_x for this planning period is the result of the reasonable application of the State's source selection process and source selection thresholds.

⁴⁸ See Section 7.5 of the Haze Plan for additional detail.

Finally, EPA disagrees with the Conservation Groups assertion that South Carolina unreasonably set its selection thresholds to only select the largest sources for further analysis. As discussed further in Response 7.a, states have flexibility to adopt any source selection methodology so long as the methodology is reasonable and their choices are reasonably explained. A percentage threshold, rather than one using an absolute visibility threshold (Mm-1 or dv), allowed South Carolina—like every other VISTAS state—to select sources with the largest visibility contributions to each Class I area regardless of the magnitude of visibility impairment at a Class I area, which EPA agrees is reasonable. Regarding the four Class I areas identified in Comment 7.f, no South Carolina facility exceeded the State's AoI source selection thresholds.⁴⁹ As discussed in Response 7.a, EPA evaluated South Carolina's source selection process and determined it to be reasonable; thus, the facilities the State selected for further analysis were reasonable.

Comment 7.g: The Conservation Groups contend that EPA did not address “significant flaws” in the VISTAS modeling and source selection process and that EPA improperly concluded that South Carolina's selection of five in-state sources was reasonable because it enabled the identification of sources with the largest visibility impacts. They argue that this is contrary to EPA's guidance which states that a source selection threshold that captures only a small portion of a state's contribution to visibility impairment in Class I areas is more likely to be unreasonable and contrary to the CAA which does not authorize states or EPA to select only the largest contributors to visibility impairment. They assert that South Carolina should have used a different selection method with a lower threshold, such as a Q/d with a threshold of five or lower, to capture the meaningful portion of in-state sources.

Response 7.g: EPA disagrees with the assertion that South Carolina's selection of the five in-state sources contributing to visibility impairment at Class I areas is contrary to EPA's guidance. The PSAT modeling performed by VISTAS found that the five sources selected by South Carolina for further analysis have the largest contribution to visibility

impairment of any point sources in the State. As discussed in Response 7.a, the PSAT modeling results show that the total cumulative contribution to visibility impairment on the 20 percent most impaired days at South Carolina's Class I area from all SO₂ and NO_x emitting sources in the State is relatively small, at about 8.0 percent for Cape Romain based on Table 2, above.⁵⁰ Given state discretion in selecting sources to evaluate for emissions controls, and since the SO₂ and NO_x emissions from all point sources in South Carolina contribute a relatively small amount to the total visibility impairment at its Class I area, the State's selection of the five largest in-state sources that contribute to visibility impairment is reasonable.

Regarding the Conservation Groups' claim that the State should have adopted a different selection method (such as Q/d) with a lower threshold to select more sources in South Carolina, as discussed above, a state is not required to evaluate all sources of emissions in each planning period. Instead, a state may reasonably select a set of sources for an analysis of control measures. Selecting a set of sources for analysis of control measures in each planning period is also consistent with the RHR, which sets up an iterative planning process and anticipates that a state may not need to analyze control measures for all sources in a given SIP revision. Moreover, use of Q/d (which simply involves dividing the quantity of emissions by the distance to a Class I area) does not consider transport direction/pathway, dispersion and photochemical processes, or the particular days that have the most anthropogenic impairment due to all sources. Therefore, compared to photochemical modeling, using a simple Q/d technique, as the Conservation Groups suggest, would have resulted in a less accurate quantification of visibility impacts on Class I areas. As discussed in detail above, South Carolina's reliance on VISTAS modeling and the State's source selection methodology are well documented within the SIP submittal and reasonable.

Comment 7.h: The Conservation Groups state that EPA asserts in its proposal that South Carolina's source selection method is reasonable because: (1) visibility conditions at in-state Class I areas are projected to improve and have improved since the baseline period, (2) EPA's evaluation of the 2015–2019 IMPROVE data on the 20 percent most impaired days for Cape Romain confirmed that ammonium

sulfate is the dominant visibility impairing pollutant at this area during that time period, and (3) ammonium nitrate contributions to regional haze at the State's Class I area remain relatively low at eight percent of the total visibility impairment as compared to ammonium sulfate at 56 percent. They argue, however, that projected visibility condition improvement at South Carolina's Class I areas and the fact that those areas are below their respective URPs are not a valid basis to approve the State's flawed selection method. They state that despite EPA's URP policy, the URP is not a safe harbor and that states cannot avoid requiring sources to install reasonable controls merely because there have been emissions reductions due to ongoing air pollution controls since the first planning period or because visibility is projected to improve at Class I areas. The Conservation Groups state that even if Class I areas impacted by South Carolina sources are already on or below the glidepath, the CAA and RHR still require the State to engage in rigorous source selection and conduct FFAs to determine whether additional control measures are reasonable.

Response 7.h: EPA agrees that the URP is not a “safe harbor” to avoid evaluating and determining the emission reduction measures that are necessary to make reasonable progress by considering the four statutory factors. However, being below the URP is relevant to whether a state needs to perform a “robust demonstration” based on the requirements in 40 CFR 51.308(f)(3)(ii)(A) and 40 CFR 51.308(f)(3)(ii)(B).⁵¹ It is also relevant to EPA's application of the URP Policy. EPA's responses addressing the URP Policy are contained in Responses 1 through 5. EPA did not approve South Carolina's source selection methodology based on projected visibility improvement at any Class I area or the URP. See the NPRM and Response 7.a that projected visibility condition improvement at South Carolina's Class I areas and the fact that those areas are below their respective URPs. As discussed in Response 7.a, South Carolina based its source selection on AoI and PSAT analyses, not on the URP.

Comment 8: The Conservation Groups assert that EPA incorrectly endorses South Carolina's decision to exclude consideration of NO_x controls in any

⁴⁹ New-Indy Catawba Pulp and Paper Plant (New-Indy Plant) was the South Carolina facility with the largest impact to Linville Gorge (0.77 percent sulfate; 0.02 percent nitrate), Shining Rock (0.46 percent sulfate; 0.03 percent nitrate), Joyce Kilmer (0.19 percent sulfate; 0.00 percent nitrate), and Cohutta (0.34 percent sulfate; 0.04 percent nitrate).

⁵⁰ See footnote 40.

⁵¹ Emissions from South Carolina are not reasonably anticipated to contribute to visibility impairment in any Class I areas that are above the 2028 URP, which is relevant to whether a state needs to perform a “robust demonstration” based on the requirements in 40 CFR 51.308(f)(3)(ii)(A) and 40 CFR 51.308(f)(3)(ii)(B).

FFAs, and therefore, EPA ignores an important aspect of the problem. They contend that VISTAS’ modeling did not accurately reflect the shift in the 20 percent most impaired days and the corresponding increase in the contribution of nitrate to visibility impairment at Southeastern Class I areas. They state that more of the 20 percent most impaired days now occur in the winter, when nitrate plays a bigger role in visibility impairment; that South Carolina explained in its SIP that “nitrate concentrations are higher on winter days and are more important for the coastal sites where the 20% most impaired days occur during the winter months;” and that Cape Romain is a coastal Class I area.

The Conservation Groups claim that EPA, South Carolina, and the USFS have noted that nitrate’s contribution to visibility impairment has increased in recent years. They contend that South Carolina’s Haze Plan confirms that nitrate contributes to a substantial portion of light extinction at several Class I areas, and that on multiple of the 20 percent most impaired days, for impacted Class I areas during the 2015–2019 period, nitrate is the biggest contributor. Furthermore, they note that more recent IMPROVE data at Great Smoky Mountains shows the contribution of nitrate to light extension on the 20 percent most impaired days have increased. They also note EPA’s general expectation that states will, at a minimum, consider both SO₂ and NO_x in this planning period, and they assert that there are multiple sources of significant NO_x emissions that South

Carolina should have analyzed for NO_x controls.

Response 8: EPA disagrees with this comment. The RHR does not prescribe which visibility impairing pollutants must be evaluated in the FFAs. When selecting sources for analysis of control measures, a state may focus on the PM species that dominate visibility impairment at the Class I areas affected by emissions from the state and then select only sources with emissions of those dominant pollutants and their precursors. EPA has recommended that states that do not evaluate SO₂ and NO_x in both source selection and control evaluations show why consideration of these pollutants would be unreasonable, especially if the state considered both of these pollutants in the first planning period.⁵²

South Carolina followed these recommended approaches here. South Carolina considered both SO₂ emissions (via sulfates visibility impacts) and NO_x emissions (via nitrates visibility impacts) in the source selection process. As part of the Haze Plan, South Carolina presented the results of PSAT modeling conducted by VISTAS to estimate the projected impact of statewide SO₂ and NO_x emissions across all emissions sectors in 2028 on total light extinction for the 20 percent most impaired days in all Class I areas in the VISTAS modeling domain. The result of this process was that while sources were selected for SO₂ control analysis determinations, no sources in South Carolina met the State’s nitrate source selection thresholds. Therefore, South Carolina did not select any sources for a NO_x emissions control evaluation.

Contrary to the Conservation Groups’ assertion that South Carolina made a “decision” not to consider NO_x controls in any FFAs, it was South Carolina’s application of its source selection process, in combination with data and modeling showing that SO₂ is the dominant visibility impairing pollutant, that resulted in South Carolina only selecting sources for SO₂ emissions control analyses and not NO_x emissions control analyses.

Additionally, to better understand the trends in PM species contributions to visibility impairment, South Carolina examined more recent IMPROVE monitoring data. More recent IMPROVE monitoring data shows that ammonium sulfate remains the dominant visibility impairing pollutant at Cape Romain and neighboring Class I areas as discussed in Section 2.5.2 of the Haze Plan (particularly Figures 2–4 through 2–6 for the 2009–2013 period) and in Section 2.6.2 (particularly Figures 2–7 through 2–9 for the 2014–2018 period). The 2015–2019 IMPROVE monitoring data (the most recent data available at the time) from the IMPROVE website identifies the relative contributions of PM species contributing to the total visibility impairment at Cape Romain, which is shown in Table 4, below. In spite of increased nitrate contributions on the 20 percent most impaired days (as the Conservation Groups note, often on winter days), as indicated in that table, ammonium nitrate contributions to regional haze at Cape Romain remain relatively low at around eight percent of the total visibility impairment as compared to ammonium sulfate at 56 percent.

TABLE 4—2015–2019 SPECIATED IMPROVE MONITORING DATA (PERCENT) FOR CAPE ROMAIN⁵³

	Ammonium sulfate	Ammonium nitrate	Organic carbon	Elemental carbon	Fine soil	Coarse mass	Fine sea salt
Cape Romain	56	8	19	5	1	7	3

Furthermore, in Table 7–14 of the Haze Plan, the State provided a calculation of the sulfate and nitrate EWRT used in the AoI analysis for Cape Romain for the 20 percent most impaired days, demonstrating that the sulfate EWRT are significantly higher than the nitrate EWRT. This further supports the importance of focusing on SO₂ emissions reductions for this planning period. The State’s rationale

for focusing on SO₂ controls in the FFAs is summarized in South Carolina’s SIP submittal and the NPRM.⁵⁴

With respect to the Conservation Groups’ assertion that nitrate is the biggest contributor to light extinction on multiple of the 20 percent of most impaired days for Cape Romain during the 2015–2019 period (especially on winter days), as described above, the average nitrate contribution across the

20 percent most impaired days is still relatively small. Thus, while nitrate impairment may be relatively high on a particular day, the data that states are required to use for regional haze as specified in 40 CFR 51.301 and 40 CFR 51.308(f)(1) show ammonium nitrate only contributed around eight percent the total visibility impairment (during the 2015–2019 period). Regarding the comment on the contribution of nitrates

⁵² South Carolina considered SO₂ for FFAs conducted in the first planning period. See 82 FR 39079.

⁵³ See the spreadsheet containing the 2015–2019 speciated IMPROVE monitoring data for South Carolina’s Class I area included in the docket for this rulemaking.

⁵⁴ See Haze Plan, Section 2, particularly Figure 2–4, Section 7 (particularly Figures 7–14 through 7–18), and Section 10 (particularly Figures 10–1); 90 FR 36012.

to visibility impairment at Great Smoky Mountains, it is unclear why the Conservation Groups are referencing nitrate impacts at this Class I area in this rulemaking. Using the data available at the time, the VISTAS PSAT modeling analyses projects that the cumulative nitrate visibility impact at Great Smoky Mountains from all NO_x emissions sources in South Carolina is 0.4 percent (all South Carolina sources modeled nitrate at Great Smoky Mountains (0.014 Mm⁻¹) divided by total modeled nitrate impact at Great Smoky Mountains (3.382 Mm⁻¹) = 0.0041 × 100 = 0.4 percent)).⁵⁵ Regardless, the NPS chart referenced by the Conservation Groups shows that sulfates continue to be the dominant visibility impairing pollutant at Great Smoky Mountains on the most impaired days.⁵⁶

For these reasons, South Carolina's justification for not evaluating sources selected for SO₂ emission control analyses for a separate NO_x emission control analysis is reasonable for this planning period. The trends in PM species' contributions to visibility impairment will continue to be evaluated in future planning periods. If the data warrants consideration of NO_x controls in future planning periods, EPA expects that South Carolina will address potential NO_x controls in future regional haze SIP revisions.

Comment 9: The Conservation Groups assert that EPA ignores that South Carolina unreasonably excluded significant sources from FFAs. They state that to correct errors in the source selection method, EPA must require South Carolina to assess additional sources identified by NPS and NPCA [Williams Generating Station (Williams Station), Wateree Generating Station (Wateree Station), Cope Generating Station (Cope Station), Sylvamo Eastover Mill (Sylvamo Mill, formerly International Paper—Eastover), Argos Harleyville Cement Plant (Argos Plant), Holcim Holly Hill Plant (Holcim Plant), New-Indy Plant (formerly Resolute FP US INC), WestRock Florence Paper Mill (WestRock-Florence)] which have emissions that likely contribute to impairment in Class I area. Furthermore, the Conservation Groups assert that EPA must find that the State arbitrarily refused to consider cost-effective control upgrades or measures improving efficiency of existing controls at these sources and Winyah. Additionally, they claim that South Carolina's analysis

unlawfully relied on unenforceable, speculative emission reductions to avoid conducting control analyses for several of those facilities, and the State arbitrarily and unlawfully refused to conduct FFAs for several EGUs that contribute to visibility impairment in Class I areas. The comments regarding specific sources identified by the Conservation Groups are addressed in Comments 9.a, 10, and 10.a–10.c, below.

Response 9: As explained in Response 7.a and in the NPRM, the RHR does not require states to select and consider controls for all sources, all source categories, or any or all sources in a particular source category. Nor does the RHR expressly specify criteria for minimum source selection thresholds. States have discretion to choose reasonable source selection criteria, and sources that meet the state's criteria are selected for an evaluation of potential control options for specific visibility impairing pollutants by considering the four statutory factors in CAA section 169A(g)(1).

South Carolina did not select Williams Station, Wateree Station, Cope Station, Sylvamo Mill, Argos Plant, Holcim Plant, New-Indy Plant, or WestRock-Florence for FFAs because these facilities did not exceed the State's source selection thresholds. As discussed in Response 7.a, South Carolina's source selection methodology is reasonable and is adequately documented in its Haze Plan. Winyah exceeded the State's source selection threshold for SO₂, and as discussed in Responses 10 and 10.a–10.c, below, EPA has determined that South Carolina's effective controls demonstration for Winyah is reasonable. As discussed in Response 8, NO_x impacts were considered by the State, but no sources were selected for a NO_x control evaluation because visibility impacts for NO_x did not exceed the State's source selection threshold. See Responses 7.a (source selection), 8 (nitrates/NO_x controls), and 10 (Winyah) for further discussion.

Regarding the claim that South Carolina's analysis unlawfully relied on unenforceable, speculative emission reductions to avoid conducting control analyses for several of those facilities, EPA disagrees that a SIP enforceable mechanism must be put in place for those sources. Williams Station, Wateree Station, Cope Station, Sylvamo Mill, Argos Plant, Holcim Plant, New-Indy Plant, and WestRock-Florence were not selected for control evaluation because they did not exceed the State's source selection thresholds, and therefore, no measures are necessary at these facilities for reasonable progress.

As discussed in Response 7.a, South Carolina's source selection methodology is reasonable and is adequately documented in its Haze Plan. The fact that these sources were not selected for FFAs for either SO₂ or NO_x for this planning period is the result of the reasonable application of the State's source selection process and source selection thresholds. Although Winyah exceeded the State's source selection threshold for SO₂, EPA has determined that South Carolina's effective controls demonstration for Winyah is reasonable. See Response 10 for further discussion. South Carolina did not identify any measures at Winyah as necessary for reasonable progress. Because no measures are necessary for reasonable progress at these nine facilities, the CAA and RHR do not require South Carolina to include enforceable measures for these facilities in its LTS.

Comment 9.a: The Conservation Groups assert that VISTAS' modeling and source selection process was arbitrary and capricious and unreasonably excluded the following eight "significant" sources that "likely contribute to impairment at one or more Class I areas with a [cumulative] Q/d of 5 or more"—Williams Station (Q/d of 209.65), Wateree Station (Q/d of 8.98), Cope Station (Q/d of 6.99), Sylvamo Mill (Q/d of 191.18), Argos Plant (Q/d of 54.87),⁵⁷ Holcim Plant (Q/d of 132.82), New-Indy Plant (Q/d of 115.29) and WestRock-Florence (Q/d of 84.8). They state that EPA's proposal does not evaluate emissions from any of these eight sources and that there are likely reasonable and cost-effective controls available for these sources that would be necessary to make reasonable progress.

The Conservation Groups further assert that Williams Station is very close to Cape Romain and the scrubber and selective catalytic reduction (SCR) systems can likely be cost-effectively optimized or upgraded. For Sylvamo Mill, they contend that South Carolina excluded the source because it discontinued burning coal in one of its boilers even though there are no restrictions on any of the boilers that prohibit the use of coal. For the New-Indy Plant, the Conservation Groups state that according to the USFS, the plant is the largest source in South Carolina contributing to visibility

⁵⁵ See "ATTACHMENT_A_PSAT_TAG_RESULTS_adjusted_09-02-2020.xls" spreadsheet included in the docket for this rulemaking.

⁵⁶ See Exhibit 38 to the Conservation Groups' September 29, 2025, comment letter.

⁵⁷ The comment appears to erroneously use the cumulative Q/d value from the "Argos Cement" facility in Shelby County, Alabama. According to the NPCA's Regional Haze Interactive Map (2024), the Q/d for Argos Plant (labeled as "Harleyville Cement Plant" on the map) should be 54.87, instead of the 5.49 originally stated in the comment. See <https://experience.arcgis.com/experience/46dd650b65284b64bf38ccba0e90af8b/?org=npca>.

impairment at multiple Class I areas in North Carolina and Georgia. They claim that the plant contributes over 38 percent of South Carolina's emissions that impact Linville Gorge, over 26 percent of South Carolina's emissions that impact Shining Rock, over 19 percent of South Carolina's emissions that impact Cohutta, and nearly 13 percent of South Carolina's emissions that impact Joyce Kilmer.

Response 9.a: EPA disagrees that the Agency must require South Carolina to conduct FFAs for Williams Station, Wateree Station, Cope Station, Sylvamo Mill, Argos Plant, Holcim Plant, New-Indy Plant, and WestRock-Florence. These sources did not exceed South Carolina's source selection thresholds, and EPA has determined that the State's source selection methodology is reasonable. See Responses 7.a and 8 for further discussion.

The assertion that the Q/d values for these eight sources are greater than five appears to be the overarching basis for the Conservation Groups' argument that South Carolina unreasonably excluded these sources from FFAs. However, as discussed in Response 7.g, the use of Q/d (which simply involves dividing the quantity of emissions by the distance to a Class I area) does not consider transport direction/pathway, dispersion and photochemical processes, or the particular days that have the most anthropogenic impairment due to all sources. When compared to photochemical modeling, using a simple Q/d technique would have resulted in a less accurate quantification of visibility impacts on Class I areas. EPA has determined that the State's source selection methodology is reasonable for the reasons discussed in the NPRM and this notice of final rulemaking (NFRM). See Responses 7.a and 8 for further discussion.

Regarding the specific comments about Williams Station, Sylvamo Mill, and New-Indy Plant, again, these sources were not selected for further analysis, and EPA agrees with the State's source selection methodology. See Response 9.

Comment 10: The Conservation Groups assert that South Carolina unreasonably refused to conduct an FFA for Winyah on the basis that it is effectively controlled. The Conservation Groups argue that the plain language of the CAA and RHR do not allow EPA or the State to eliminate sources from analysis based on the assertion that sources are "effectively controlled." Instead, they comment that the CAA and RHR require states to consider the four statutory factors for any existing source that is reasonably anticipated to

cause or contribute to any impairment of visibility in any Class I area and determine the emission reduction measures necessary to make reasonable progress. They state that the RHR and CAA require South Carolina to develop a LTS "that addresses regional haze visibility impairment" for each affected Class I area, and that flexibility in recent EPA guidance does not override the CAA and the RHR. They contend that South Carolina failed to conduct FFAs for EGUs such as Winyah despite their contribution to visibility impairment. They assert that although Winyah exceeded source selection thresholds, the State exempted the facility from an FFA by claiming it had "effective controls" in place. The Conservation Groups claim that the State therefore attempted to "re-write" the CAA and the RHR to include an exemption from the required FFA that does not exist anywhere in the plain text, defeating the requirement to eliminate all anthropogenic visibility pollution and failing to reasonably conduct or reasonably explain the source selection process.

The Conservation Groups continue by stating that the CAA makes clear that Congress intended states to analyze all potentially available control measures to reduce emissions contributing to impairment. They argue that, beyond the four statutory factors, the CAA does not provide any other bright line requirement for how much pollution a control must potentially reduce before it must be considered. The Conservation Groups maintain that once a state is "subject to" the requirements of the regional haze program, an FFA must be conducted to identify all potentially available controls for that source to make reasonable progress. They also claim that, in any event, the State failed to show that Winyah is effectively controlled and that EPA relied on the State's December 12, 2024, letter that attempts to withdraw all permit conditions from the 2022 SIP revision.

The Conservation Groups note that the concept of "effectively controlled" sources only appears in EPA's 2019 Guidance and 2021 Clarification Memo, which they assert cannot override the plain language of the CAA and RHR. They also assert that EPA has repeatedly explained that states cannot categorically exclude sources from an FFA simply because the source has existing controls and must provide source-specific explanations as to why their decisions for excluding sources from FFAs are reasonable.

Finally, the Conservation Groups argue that there are likely feasible and cost-effective controls available for

Winyah that are reasonable and therefore necessary for reasonable progress. The Conservation Groups' specific comments on these controls are addressed in Comments 10.a through 10.c, below.

Response 10: EPA disagrees with these comments. CAA section 169A(b)(2) does not discuss which sources, types of sources, or groups of sources must be considered to determine reasonable progress. Reasonable progress is addressed in CAA section 169A(g)(1) in that States must "take into consideration" (1) the costs of compliance; (2) the time necessary for compliance; (3) the energy and non-air quality environmental impacts; and (4) the remaining useful life of "any existing source subject to such requirements." The RHR does not require states to consider controls for all sources, all source categories, or any or all sources in a particular source category or provide minimum source selection criteria. The RHR requires that "[t]he State should consider evaluating major and minor stationary sources or groups of sources, mobile sources, and area sources. The State must include in its implementation plan a description of the criteria it used to determine which sources or groups of sources it evaluated and how the four factors were taken into consideration in selecting the measures for inclusion in its long-term strategy." See 40 CFR 51.308(f)(2)(i). In addition, the technical basis for source selection must also be documented, as required by 40 CFR 51.308(f)(2)(iii). Thus, States must utilize a reasonable source selection methodology, and whatever choices States make regarding source selection should be reasonably explained. Therefore, EPA disagrees with the notion that CAA sections 169A(b)(2) and (g)(1) and the RHR prohibit states from forgoing a full FFA based on a state's determination that a source is effectively controlled.

EPA likewise disagrees that forgoing an FFA on an effectively controlled source defeats the requirements in the CAA and RHR to eliminate all anthropogenic visibility pollution. As outlined in the 2017 RHR, "EPA has consistently interpreted the CAA to provide States with the flexibility to conduct four-factor analyses for specific sources, groups of sources or even entire source categories, depending on State policy preferences and the specific circumstances of each State."⁵⁸ However, within the bounds of the flexibility afforded to states, EPA also stated that states must "exercise reasoned judgment when choosing

⁵⁸ See 82 FR 3088 (January 10, 2017).

which sources, groups of sources or source categories to analyze.”⁵⁹

While states have the option to analyze all sources, the 2019 Guidance explains that “an analysis of control measures is not required for every source in each implementation period,” and that “[s]electing a set of sources for analysis of control measures in each implementation period is . . . consistent with the Regional Haze Rule, which sets up an iterative planning process and anticipates that a State may not need to analyze control measures for all its sources in a given SIP revision.”⁶⁰ EPA therefore recognizes, consistent with the RHR, that analyses regarding reasonable progress are state-specific and based on the individual circumstances for each state and source.

In the 2019 Guidance, EPA recognized that a State may reasonably decide not to select sources that have recently installed effective controls.⁶¹ EPA notes that if a source’s emissions are already well-controlled, it is unlikely that further cost-effective reductions are available. In such a scenario, the state should explain why it is reasonable to assume that a full FFA would likely result in the conclusion that no further controls are necessary.⁶²

EPA agrees that guidance cannot override the plain language of the CAA and RHR. However, EPA’s citations to guidance documents in the NPRM were simply intended to provide further context on what is generally considered to be a reasonable approach to fulfill the statutory and regulatory requirements addressing regional haze for the second planning period. EPA acknowledges that the suggestions in those guidance documents are not binding but are generally assumed to be reasonable. States can deviate from the suggestions within EPA guidance documents.

EPA disagrees that EPA and South Carolina failed to show that Winyah is effectively controlled, or that EPA fails to defend the conclusion that no other controls are likely available or cost effective for this facility. In this case, South Carolina evaluated Units 1–4, including permit limitations, control efficiencies, regulations, actual emissions, past emission trends, and projected 2028 emissions to demonstrate that the existing high level of control makes it reasonable to conclude that the controls are effective and that a full FFA would likely result in the conclusion that no further controls are necessary. EPA reviewed

this evaluation and determined that South Carolina’s consideration of effective controls is reasonable and consistent with the RHR. Scrubber systems are widely considered the best control technology for reducing SO₂ emissions, as they can achieve very high removal efficiencies, making them highly effective at capturing SO₂ from industrial flue gases.⁶³ For the purpose of SO₂ control measures, an EGU that has add-on flue gas desulfurization (FGD)⁶⁴ and that meets the applicable alternative SO₂ emission limit of the Mercury and Air Toxics Standards (MATS) Rule for power plants is one example of a scenario in which it may be reasonable for a state not to select a particular source for further analysis because the two limits in the rule [0.20 pounds per million British thermal units (lb/MMBtu) for coal-fired EGUs or 0.30 lb/MMBtu for EGUs fired with oil-derived solid fuel] are low enough that it is unlikely that an analysis of control measures for a source already equipped with a scrubber and meeting one of these limits would conclude that even more stringent control of SO₂ is necessary to make reasonable progress.⁶⁵ EPA analyzed the controls and confirmed that Winyah Units 1 through 4 are equipped with wet scrubber systems that routinely achieve a high SO₂ control effectiveness (with recent yearly averages fluctuating between 96.9 to 97.2 percent) that has been and is meeting the MATS SO₂ emission limit.⁶⁶ The typical SO₂ removal efficiency range for wet scrubbers ranges from 90 to 98 percent.⁶⁷ Thus, it is unlikely that an FFA would result in the conclusion that further SO₂ emissions control measures are necessary for reasonable progress in the second planning period. Therefore, EPA finds South Carolina’s effective controls demonstration for Winyah to be reasonable.

Regarding the comment concerning reliance on the State’s December 12, 2024, letter, that letter only addresses Century. EPA proposed to approve the Haze Plan without the permit conditions, as requested by South

Carolina in its June 4, 2025, letter, based on the new URP policy. South Carolina considered the four statutory factors for Century, IP-Georgetown, Cross, and Winyah in technical analyses. Subsequently, South Carolina clarified in its June 4, 2025, letter that it is not necessary to include in the SIP any final permit conditions for these evaluated facilities and that statements appearing in South Carolina’s submittal concerning existing or additional measures are no longer applicable. In addition, South Carolina confirmed in its June 4, 2025, letter that it does not intend to submit or include final permit conditions for these facilities for incorporation into the regulatory portion of the South Carolina SIP. As discussed in the NPRM, because South Carolina considered the four statutory factors for these facilities and visibility conditions at all Class I areas to which South Carolina contributes are below the URP, South Carolina has demonstrated that it has made reasonable progress for the second planning period without any measures in the regulatory portion of the SIP for these facilities.

Comment 10.a: The Conservation Groups assert that there are likely feasible and cost-effective controls available to reduce emissions from Winyah based on their assertion that South Carolina used an incorrect distance for Winyah to Cape Romain in its source selection process. They note that South Carolina used a distance of 51.4 km but argue that South Carolina should have used a distance of 24.5 km, the distance between Winyah and the northeast edge of Cape Romain. Furthermore, the Conservation Groups assert that this distance is more than double the distance that should have been utilized in PSAT modeling and that this error was further compounded by the unreliability of PSAT modeling at such close distances, resulting in incorrect projections of visibility impairment from Winyah at Cape Romain. The Conservation Groups assert that the State failed to correct this error in its response to comments and ignored the comment.

Response 10.a: It is unclear how the distance from Winyah to Cape Romain used in the State’s source selection process is relevant to the Conservation Groups’ argument that there are likely feasible and cost-effective controls to reduce emissions at Winyah. South Carolina selected Winyah for further analysis because it exceeded the State’s source selection thresholds. The State then concluded that the source is effectively controlled, and EPA agrees with that decision for the reasons

⁵⁹ *Id.*

⁶⁰ See 2019 Guidance at 9.

⁶¹ See *id.* at 22–25.

⁶² See *id.* at 23.

⁶³ See Section 5, Chapter 1, of EPA’s “Air Pollution Cost Control Manual” (CCM), available at <https://www.epa.gov/economic-and-cost-analysis-air-pollution-regulations/cost-reports-and-guidance-air-pollution>.

⁶⁴ FGD is a type of scrubber system.

⁶⁵ See 2019 Guidance at 23.

⁶⁶ See 90 FR 36012 and EPA’s analysis of EGUs in South Carolina found in the spreadsheet file called “SC EGU scrubber efficiency analysis 2017–2023” (hereinafter “EGU scrubber efficiency spreadsheet”), included in the docket for this rulemaking.

⁶⁷ See Table 1.1 on page 1–3, Section 5, Chapter 1 of the CCM.

discussed in the NPRM and Response 10. The distance used in South Carolina's source selection process has no relevance to the feasibility and cost-effectiveness of controls for Winyah.

For the reasons discussed in Response 7.a., South Carolina's source selection methodology is reasonable and resulted in the selection of a reasonable set of sources contributing to visibility impairment at Class I areas affected by South Carolina's sources. Furthermore, EPA disagrees with the Conservation Groups' claim that PSAT modeling at such close distances results in incorrect projections of visibility impairment. *See* Response 7.d for discussion regarding PSAT modeling of facilities close to Class I areas. EPA disagrees with the assertion that South Carolina failed to correct this error and ignored the comment. EPA finds that South Carolina's Haze Plan provided adequate documentation regarding use of the 51.4 km distance and that South Carolina's source selection process was appropriate and well supported.

Comment 10.b: The Conservation Groups assert that South Carolina failed to conduct the required FFA at Winyah for the four EGUs, which are all equipped with wet scrubber and SCR systems, that would demonstrate that SO₂ and NO_x emissions control systems can be optimized or upgraded. They also state that South Carolina's claim that the wet scrubber efficiency is 90 percent and the facility is meeting maximum achievable control technology (MACT) emission limits does not constitute an FFA or show that the four EGUs at Winyah are effectively controlled. Furthermore, the Conservation Groups assert that the scrubbers and SCR systems at Winyah have demonstrated the capability to operate at a significantly lower emission rate and the emission control systems are capable of better performance. With respect to this claim, the Conservation Groups cite to historical monthly SO₂ emissions data and state that this data reflects "the lax title V permit requirements." The Conservation Groups assert that modern wet scrubber systems are capable of performing at an efficiency of 98 percent, whereas Winyah's title V permit requires the scrubber systems on Units 1 and 2 to achieve a 30-day average efficiency of 95 percent and Units 3 and 4 to achieve an efficiency of 90 percent.

Furthermore, the Conservation Groups also assert that historical monthly NO_x emissions data are erratic, show that the SCR systems are underperforming, and are a reflection of the "lax title V requirements for the SCR systems." The Conservation Groups

state that none of Winyah's four SCR systems achieve emission rates that a modern SCR is capable of achieving, which they cite from the 2021 Kordzi Report is a monthly average of 0.05 lb/MMBtu. The Conservation Groups also state that because these systems are already installed, it is likely that substantial gains can be achieved very cost-effectively with little to no capital costs by simply running the SCR systems more efficiently all year and/or using more reagent.

Response 10.b: Regarding the comments concerning SO₂ emissions and SO₂ control efficiencies, EPA agrees with South Carolina's determination that it is unlikely that an FFA would result in the conclusion that further SO₂ emissions control measures at Winyah are necessary for reasonable progress in the second planning period, and therefore, EPA finds South Carolina's effective controls demonstration for Winyah to be reasonable. *See* Response 10 for further discussion. As detailed in that response, the units are equipped with wet scrubber systems that routinely achieve high SO₂ control effectiveness, scrubber systems are widely considered the best control technology for reducing SO₂ emissions, and the units are subject to the MATS Rule SO₂ emission limit of 0.20 lb/MMBtu.

Regarding the comments concerning NO_x emissions and NO_x control efficiencies, EPA has determined that South Carolina's decision to not evaluate sources selected for SO₂ emission control analyses for a separate NO_x emission control analysis is reasonable for this planning period. *See* Response 8.

Comment 10.c: The Conservation Groups assert that EPA improperly proposes to grant South Carolina's request to remove necessary permit provisions for Winyah from the 2022 SIP Revision that the State determined are necessary to make reasonable progress and prevent future impairment. They state that South Carolina reaffirmed that determination in its 2025 SIP supplement which proposed to incorporate updated permit provisions for Winyah into the SIP. The Conservation Groups assert that South Carolina and EPA entirely rely on the new URP policy to remove these measures from the SIP and that the new policy violates both the CAA and the RHR. Furthermore, the Conservation Groups argue that South Carolina failed to follow the CAA's procedural requirements to hold a public notice and comment process before removing the existing permit provisions for Winyah from the SIP. Lastly, the

Conservation Groups note that they raised practical enforceability issues on Winyah's draft permit modification and that EPA must require South Carolina to correct errors in the updated permit provisions before incorporating those provisions into the SIP.

Response 10.c: EPA disagrees with this comment. As discussed in the NPRM and this NFRM, South Carolina has demonstrated reasonable progress without the need for additional measures in the LTS under the URP policy, and the URP policy is consistent with the CAA and RHR. *See* Responses 1–4. Because EPA is not approving any permit conditions into the SIP, nor does it have any enforceable permit conditions to incorporate, the comments regarding the practical enforceability of the Winyah permit conditions are irrelevant. Furthermore, as discussed in Response 11.e, the State did not submit its 2025 SIP supplement to EPA and it is not necessary to re-notice the Haze Plan at the state level.

Comment 11: The Conservation Groups assert that EPA shirks its duty to review South Carolina's source-specific FFAs. They state that EPA proposes to "rubber stamp" the SIP submission without engaging in any meaningful and independent analysis of South Carolina's FFAs to ensure they comply with the CAA and the RHR. The Conservation Groups claim EPA merely restated what South Carolina did and that EPA entirely failed to grapple with the record before it and thus shirked its duties under the Act. They note that EPA stated in its 2021 Clarification Memo that EPA expects states to "undertake rigorous reasonable progress analyses that identify further opportunities to advance the national visibility goal" and that if FFAs "evaluate a reasonable range of potential control options, we anticipate that in many cases states will find that new (*i.e.*, additional) measures are necessary to make reasonable progress." The Conservation Groups state that "South Carolina did not require any of the sources to adopt additional control measures to make reasonable progress" and that EPA accepts the State's analysis to ignore and reject available, feasible, and likely cost-effective controls "without question" which they contend violates the CAA and RHR. Furthermore, the Conservation Groups assert that the State relied on the URP to justify what the Conservation Groups characterize as "flawed Four-Factor Analyses and reasonable progress determinations," which they allege violates the CAA and RHR. The Conservation Groups' specific

comments on the FFAs are addressed in Comments 11.a through 11.e, below.

Response 11: EPA disagrees with these comments. EPA's approval of the Haze Plan is a proper exercise of EPA's authority under the CAA. Congress crafted the CAA to provide for states to take the lead in developing implementation plans but balanced that decision by requiring EPA to review the plans to determine whether a SIP meets the requirements of the CAA. When reviewing SIPs, EPA must consider not only whether the state considered the appropriate factors in making decisions, but also whether it acted reasonably in doing so. In undertaking such a review, EPA does not usurp the state's authority but ensures that such authority is reasonably exercised.

Contrary to the comment that the Agency "shirks" its CAA obligations, EPA has performed its duties with diligence. EPA carefully evaluated the Haze Plan and the associated record and engaged in a thorough analysis of each control option, including each of the underlying cost assumptions used in the calculations. South Carolina conducted extensive technical work in support of its SIP submittal, and EPA independently evaluated each FFA, including costs, and compared each FFA's control determination against EPA's CCM. These FFAs are discussed in more detail in Responses 11.a through 11.d. As discussed in the NPRM and this NFRM, South Carolina has demonstrated that it has made reasonable progress for the second planning period without the need for any additional measures, including measures at the facilities that underwent FFAs, because South Carolina considered the four statutory factors and visibility conditions at all Class I areas to which South Carolina contributes are below the URP. Regarding the Conservation Groups' assertion that the URP policy violates the CAA and RHR, see Responses 1, 1.a through 1.d, and 2.

Comment 11.a: The Conservation Groups assert that South Carolina's cost-effectiveness analyses are arbitrary, the State did not provide an objective metric for assessing the cost-effectiveness of controls analyzed, and the State improperly rejected controls that its own FFAs showed are reasonable and cost effective, particularly when compared to the thresholds adopted by other states in the second planning period, instead relying on exiting measures. The Conservation Groups provide examples for Century and IP-Georgetown. They state that although the CAA does not require the State to "use a bright line rule" for determining cost-effectiveness, South

Carolina is required to explain why the State has exercised its discretion in a given manner. The Conservation Groups assert that South Carolina was required to provide a reasoned basis for its decisions by establishing a cost-effectiveness threshold or explaining and justifying some other objective measure for determining cost-effectiveness and applying that threshold consistently across the FFAs. Furthermore, they claim that South Carolina did not meet its duty to document the technical basis supporting its source-specific analyses, including modeling, monitoring, cost, engineering, and emissions information. The Conservation Groups also comment on the escalation of the dollar-year control cost analyses using the Chemical Engineering Plant Cost Index (CEPCI) and assert that access to the CEPCI annual index is necessary for the public to be able to meaningfully review the cost analyses and determine whether those analyses are reasonable, reliable, and well-supported.

Lastly, the Conservation Groups assert that the State adopted unsupported and unreliable cost information in its FFAs and asserts that South Carolina's lack of basic documentation precludes any independent review from verifying control analyses which is contrary to the CAA and the RHR. Specifically, the Conservation Groups refer to the FFA for Cross and note that the State identified three possible controls and subsequently determined that only one was reasonable and only conducted a cost analysis on the single option. The Conservation Groups state that if a source prepares a flawed, incomplete, or undocumented FFA, EPA must require that the State either require the source to make the necessary corrections or make the corrections itself to ensure that the FFAs are fully supported. They assert that the State must provide and make publicly available all required documentation to ensure that the FFAs are fully supported, including the underlying cost inputs and cost-effectiveness calculations. They also assert that the lack of critical information and documentation not only precludes South Carolina and any independent review from verifying control analyses but is contrary to the CAA and the RHR.

Response 11.a: EPA disagrees with these comments. With respect to cost effectiveness determinations for regional haze in the second planning period, the CAA and RHR do not provide a specific cost effectiveness threshold or any requirement for states to establish bright line cost effectiveness thresholds when evaluating control costs in FFAs. The

CAA and the RHR instead require states to evaluate the costs of compliance, and EPA's 2019 Guidance recommends that states follow the recommendations in EPA's CCM to facilitate apples-to-apples comparisons of different controls options for the same source and comparisons across different sources.⁶⁸ Therefore, each state has discretion to provide a justification for the outcome of an FFA, including how the cost of compliance factor and any selected cost threshold impacted the state's decision-making.

The preamble to the RHR speaks to the flexibility afforded to states when considering the cost of compliance factor.⁶⁹ Inherent in this flexibility is the possibility that some states may choose bright-line cost effectiveness thresholds, and others may instead choose to adopt a different methodology to determine whether controls are cost effective. For states that choose to use bright-line cost-effectiveness thresholds, those thresholds may differ from state to state. Different states may take different approaches to comply with the RHR, and various methods of complying with the RHR may be reasonable depending on a number of varying circumstances (e.g., number and type of sources in the state; magnitude of emissions of visibility impairing pollutants from sources in the state; visibility impairment at impacted Class I areas). Given this flexibility, EPA disagrees that cost effectiveness thresholds in one state should be determinative of whether controls are cost-effective in another State. The Conservation Groups effectively suggest that EPA's determinations regarding the approvability of bright-line cost-effectiveness thresholds in the states, such as Colorado, Nevada, and New Mexico, should serve to set a nationwide cost-effectiveness floor. South Carolina was not required by the CAA or RHR to adopt a similar bright-line cost effectiveness threshold and the Conservation Groups themselves do not suggest a specific bright-line threshold, let alone provide rationale to support such a threshold.

Given that a state is not required to set a bright-line cost threshold by the RHR, the discretion afforded to the State to

⁶⁸ See 2019 Guidance at 31.

⁶⁹ See, e.g., 82 FR 3078, 3088 (January 10, 2017) ("While these final revisions to the RHR continue to provide States with considerable flexibility in evaluating the four reasonable-progress factors, we expect States to exercise reasoned judgment when choosing which sources, groups of sources or source categories to analyze."); 2019 Guidance at 4 ("States have discretion to balance these factors and considerations in determining what control measures are necessary to make reasonable progress.").

determine whether costs are reasonable, and the justification provided by South Carolina to determine whether control costs were reasonable for the second planning period as discussed in Responses 11.b, 11.c, and 11.d, EPA concludes that South Carolina's FFA determinations for Century, IP-Georgetown, and Cross were reasonable.⁷⁰ As discussed in the NPRM and this NFRM, South Carolina has demonstrated that it has made reasonable progress for the second planning period without the need for any additional measures, including measures at the facilities that underwent FFAs, because South Carolina considered the four statutory factors and visibility conditions at all Class I areas to which South Carolina contributes are below the URP.

EPA disagrees with the comments regarding the State's use of CEPCI for escalating costs. The CEPCI is published monthly by the magazine Chemical Engineering and has been used for decades in regulatory cost effectiveness analyses, and it is one of the tools that allows for a comparison to be made between cost effectiveness analyses at different facilities over various years. EPA's CCM cost-effectiveness spreadsheet allows for the use of CEPCI, and other well-known cost indices, to escalate costs.⁷¹ EPA agrees that as of September 2024, accessing this cost index is now a paid subscription. However, in the Haze Plan, each facility that used a CEPCI index value to escalate costs, cited to the specific year and CEPCI index value used. Furthermore, EPA independently evaluated the each of the FFAs, including the costs and methodology and EPA determined the State's use of CEPCI indices to be reasonable and appropriate.

EPA disagrees with the assertion that the FFA for Cross was inadequate and flawed because the source only conducted an FFA on a single control option and did not identify any cost-effective control measures for its EGUs. In Appendix G-2 of Haze Plan, the source adequately justified why an FFA was not performed on the other three control options identified. Cross noted that Units 1-4 are already controlled by wet FGD, which provides the greatest SO₂ reduction of the available add-on controls, thus retrofitting with a

different add-on control technology was not further evaluated. *See* Response 11.d. As such, EPA agrees that South Carolina's decision to only conduct a cost analysis for fuel switching option is reasonable.

EPA finds the assumptions used in the cost-effectiveness calculations submitted in the Haze Plan to be appropriately documented and reasonable. The State included all relevant information, justifications used, and support for each cost provided in the cost calculation within Appendix G-2 for EPA to independently review the cost analyses. EPA finds that South Carolina has sufficiently documented and provided costs, methodology, vendor estimates, and emissions information for EPA to make an independent determination that South Carolina's FFAs satisfies the CAA and the RHR.

Comment 11.b: The Conservation Groups assert that South Carolina's FFA for Century improperly inflates the cost of controls. They claim that Century provided outdated and incomplete emissions data by providing SO₂ emissions apportionment data across various processes from its 2004 title V permit renewal application. They assert that Century assigns SO₂ emissions to its bake oven and potlines using a combined total and must instead provide emissions data on a unit-by-unit basis for NO_x, SO₂, and PM for the last five years. They further assert that Century erroneously omitted a significant source of emissions from its FFA by excluding its bake oven from its SO₂ FFA because it accounts for 7.35 percent (334 tons) of the total SO₂ from the facility in 2028. They claim that this is not an insignificant amount of SO₂ emissions and must be included in the FFA. In addition, the Conservation Groups allege the following errors in Century's FFA that EPA must require the State to correct.

First, they state that the wet and dry scrubber efficiencies utilized are too low in comparison to the efficiencies in EPA's CCM and that documentation is insufficient to support the facility's deviation from the CCM's recommended control efficiency.

Second, they state that Century failed to provide vendor information to South Carolina, contrary to the requirements of the RHR, and that EPA must require South Carolina to obtain, review, and provide its analysis of the vendor information.

Third, they reference EPA's CCM and state that use of a 20-year equipment life, instead of a 30-year equipment life, for the dry scrubber is incorrect.

Fourth, they state that Century's URP safe harbor argument is not allowed under the CAA or RHR.

Fifth, they state that Century's argument to avoid controls because of emission reductions from another source category is misplaced and not supported by the RHR which does not provide the State with discretion to exclude a source selected for the FFA because sources in another category are reducing emissions.

Sixth, they state that Century erroneously included sales tax in its cost analysis, as pollution control equipment is exempted from sales tax in South Carolina.

Seventh, they state that Century erroneously combined the costs of controls by identifying the bake oven and potlines as individual emission units to solicit separate bids: one for the bake oven and a second for the potrooms. The Conservation Groups state that the effect of combining the costs of control for two distinct emission units resulted in a higher cost per ton amount. The Conservation Groups state that EPA rejected a similar approach from Texas and must also reject South Carolina's reliance on Century's combined approach and calculate the cost effectiveness for the bake oven and potlines separately.

Eighth, they claim that Century's annual cost for its dry scrubber contains significant errors and that when the "correct" calculation method is followed, the total annual cost using the figures Century provides in its analysis is nearly three times lower (\$10,772,422 rather than \$34,878,587). The Conservation Groups also state that "Century's capital cost of \$109,760,060 is similarly in error, as from its own figures this cost should be \$25,242,560."

The Conservation Groups state that the 2021 Kordzi Report corrects these errors and provides a revised FFA which shows that dry scrubbers are cost-effective. Using the updated values, the Conservation Groups revised the dry scrubber cost-effectiveness calculations for the potlines and the bake oven, each, showing a revised cost-effectiveness value of \$7,748/ton (in comparison to the \$9,105/ton value provided by Century), for the bake oven dry scrubber and \$2,223/ton (in comparison to the \$2,611/ton provided by Century) for the potlines dry scrubber. As a result, the Conservation Groups state that the revised analysis for the dry scrubbers for the bake oven and potlines are cost-effective and that EPA must require South Carolina include emission limitations in the SIP commensurate with a dry scrubber for the Century

⁷⁰ WestRock-Charleston permanently shut down after South Carolina submitted its Haze Plan; therefore, the State's FFA for this source is no longer relevant. The April 14, 2024, permit rescission letter is in the docket for this rulemaking.

⁷¹ Available at: https://www.epa.gov/sites/default/files/2019-05/sncrcostmanualspreadsheetv_f_april_2019.xlsx.

potlines and a dry scrubber for the bake oven.

With respect to the wet scrubber FFA, the Conservation Groups allege the following errors that EPA must require the State to correct. First, they state that Century failed to provide any explanation or justification for the more than seven-fold increase in the contingency cost between Century's initial contingency cost calculation (\$929,410) for the wet scrubber and the subsequently revised cost (\$6,722,732). The Conservation Groups state that South Carolina must require that Century fully explain and justify the \$6,722,732 figure or remove it from the analysis.

Second, they state that Century's wet scrubber cost-effectiveness calculation contains numerous unsupported figures that must be supported, including: (1) capital costs of approximately \$26 million for a wastewater pretreatment and piping system; (2) indirect annual costs of approximately \$2 million for various engineering and permitting items; and (3) direct annual costs of approximately \$3.5 million for various annual operating cost items. Furthermore, the Conservation Groups assert that the wet scrubber costs do not follow the procedure outlined in the CCM, from where Century obtains other cost items. They identify other costs of concern—(1) a “very unreasonable” labor charge of \$1,547,366 in comparison to the CCM methodology; (2) charges for various chemicals and failing to document and justify their use (e.g., hydrochloric acid, an unidentified polymer, an unidentified organosulfide, ferric chloride and sodium hydroxide); and (3) undocumented and unjustified charges of \$846 million and \$681 million for filter cake sludge and reverse osmosis brine reject disposal costs. Additionally, the Conservation Groups assert that there is no way for the public to separate out and independently construct the bake oven and potline scrubbers in the wet scrubber cost-effectiveness calculation.

Third, they assert that EPA must require South Carolina to either provide support for all calculations or follow EPA's CCM, in addition to revising the costs so that there are separate calculations for the bake oven and potlines.

Citing to the RHR and EPA guidance, the Conservation Groups contend that EPA cannot approve South Carolina's request to remove existing permit provisions for Century from the 2022 SIP Revision that are necessary to make reasonable progress and prevent future impairment. They claim that state-issued permits cannot conflict with SIP

requirements and that EPA and South Carolina “violated these requirements” in two ways. First, they argue that the State has proposed to modify Century's construction permit in a way that conflicts with the Haze Plan. The Conservation Groups assert that the 2022 SIP Revision identified permit Condition C.15 from Permit No. TV-0420-0015 as one of the existing measures that is necessary to make reasonable progress. That permit provision provides that the monthly average sulfur content limit for coke used at Century “shall not exceed 2.22% by weight” with a permitted exception to use coke with a sulfur content of three percent under a reduced operating scenario. However, South Carolina issued a draft permit modification in 2024 that would allow Century to increase the sulfur content limit for coke to three percent, regardless of the level of facility operations. The Conservation Groups state that the draft permit does not explain the discrepancy between the coke sulfur limit in the draft permit and that identified as necessary in the SIP. The Conservation Groups assert that EPA must therefore require South Carolina to either (1) retain the 2.22 percent coke sulfur limit in Century's final modified permit for incorporation into the regulatory portion of the SIP, or (2) conduct a new FFA for Century assuming compliance with the revised three percent coke sulfur limit in the draft permit.

Second, the Conservation Groups assert that EPA proposes to improperly approve the State's request to entirely remove existing permit provisions for Century from the Haze Plan. They state that the State's December 12, 2024, letter to EPA withdrawing these provisions does not explain or provide any analysis of how the 2.22 percent content limit is no longer necessary to make reasonable progress and that EPA's reliance on this letter to disregard a limit previously determined to be necessary for Century is arbitrary, capricious, and contrary to law. They also argue that EPA cannot rely on the URP policy to ignore South Carolina's determinations on measures necessary for reasonable progress and that EPA's statement in the NPRM that the State's request to incorporate permit conditions into the SIP is moot under the new policy is arbitrary and capricious.

Response 11.b: The Conservation Groups claim that Century assigns SO₂ emissions to its bake oven and potlines in a combined total and should instead provide emissions data on a unit-by-unit basis for NO_x, SO₂, and PM for the last five years. EPA disagrees with this

comment. Table 7–21 of the South Carolina Haze Plan provides the SO₂ emissions for Century on a unit-by-unit basis, for the modeled baseline (2011), and 2028 projected future emissions. EPA finds the emissions data provided to be appropriate as there is no requirement to provide data for each of the last five years. Furthermore, EPA notes that emissions from the prior five years would not be a valid representation of emissions because two of the four potrooms were not operated in those years but are expected to resume operation by 2028. With respect to PM and NO_x, the RHR does not prescribe which visibility impairing pollutants must be evaluated in FFAs. EPA's 2019 Guidance on page 11 states “[w]hen selecting sources for analysis of control measures, a state may focus on the PM species that dominate visibility impairment at the Class I areas affected by emissions from the state and then select only sources with emissions of those dominant pollutants and their precursors.” EPA agrees with South Carolina's focus on SO₂ emissions from its selected sources during the second planning period. *See* Response 8 for further discussion.

The Conservation Groups also claim that Century provided outdated and incomplete emissions data by providing SO₂ emissions apportionment data across various processes from its 2004 title V permit renewal application. Although the emission data used is from an older title V permit renewal application, EPA finds the use to be reasonable for the purpose of Century's FFA because it apportioned the 2028 annual SO₂ emissions from the VISTAS modeling study by using the 2004 title V permit emission limits for the Bake Oven and each potroom to pro-rate and estimate individual emissions for 2028 (363 tpy for Bake Oven and 930 tpy for each potroom).⁷² As 2028 annual SO₂ emissions were calculated by applying allotted (and active) permit limits to emissions projections that were modeled only a year before submission of the Haze Plan, EPA finds that the emissions data provided is neither outdated or incomplete.

The Conservation Groups erroneously contend that Century omitted its bake oven from its FFA. The Haze Plan states “[b]ased on the above information, this four-factor analysis is focused on the Bake Oven and the Potline Potrooms as these sources constitute 99.95 percent of Century's permitted SO₂ emissions.”⁷³

⁷² See Section 3.0 of Appendix G–2 of the Haze Plan Submittal.

⁷³ *Id.*

The Conservation Groups assert that the wet and dry scrubber efficiencies utilized in the cost analyses are too low in comparison to the efficiencies in EPA's CCM and that there is no justification for this deviation. However, the CCM states that wet scrubbers have an SO₂ control efficiency "between 90 and 98% with new designs achieving 99% removal,"⁷⁴ and that dry sorbent injection (DSI) scrubbers have efficiencies ranging from 50 to 70 percent.⁷⁵ As the Century FFA uses a wet scrubber SO₂ control efficiency of 93 percent⁷⁶ and a DSI efficiency of 90 percent,⁷⁷ EPA finds that the efficiencies used were within CCM guidance.

The Conservation Groups claim that Century failed to provide vendor information to South Carolina, contrary to the requirements of the RHR requirement, and that EPA must require the State to obtain, review, and provide its analysis of the vendor information. EPA disagrees. The RHR does not mandate the level of detail that must be provided for the cost calculations or require States to provide vendor information,⁷⁸ and vendor information was provided in Appendix G–2 of the Haze Plan.

Regarding Century's utilization of a 20-year equipment life for the dry scrubber, EPA evaluated the cost analysis used by Century for the DSI scrubber and found that the change from a 20-year useful life to the 30-year useful life would only reduce the cost-effectiveness from \$10,323 to \$9,347. South Carolina received this comment during the state-level comment period on the draft Haze Plan and responded to it.⁷⁹ The State did not alter its plan as a result of this comment, and EPA finds that conclusion to be reasonable.

The Conservation Groups state that Century's URP safe harbor argument is not allowed under the CAA or RHR and is utilized unlawfully. EPA disagrees that Century and South Carolina relied on the URP as a safe harbor. Although Century discusses the URP in its FFA, Century considered the four factors and performed a full FFA, independent of the URP, calculated cost-effectiveness values of \$10,323/ton for dry scrubber controls and \$7,485/ton⁸⁰ for wet scrubber controls, and determined that there are no cost-effective SO₂ control measures for the facility. EPA agrees that the URP is not a "safe harbor" to avoid requiring additional reasonable progress measures. *See* Response 7.h for further discussion.

The Conservation Groups state that Century's argument to avoid controls because of emission reductions from another source category is misplaced and not supported by the RHR which does not provide the State with discretion to exclude a source selected for the FFA because sources in another category are reducing emissions. EPA disagrees that Century is avoiding controls by relying on emission reductions from another source category as Century performed a full FFA which determined that there are no cost-effective SO₂ control measures for the facility.

EPA agrees with the Conservation Groups that a sales tax charge should not have been included in the cost analyses due to South Carolina's Sales and Use Tax Exemption for pollution abatement equipment.⁸¹ However, removing the sales tax from the cost analysis for the wet scrubber only accounts for approximately 1.6 percent of the total direct cost, which would not appreciably change the overall cost/ton identified by the FFA.

The Conservation Groups erroneously assert that Century's annual cost for its dry scrubber contains significant errors and that when the correct calculation method is followed, the Total Annual Cost is more than three times lower (\$10,772,422 rather than \$34,878,587). The Total Annual Cost figure accounts for the Total Annual Cost of all four DSI potroom scrubbers (\$8,035,388 each) and the Total Annual Cost for the singular DSI bake oven scrubber

(\$2,737,034), which correctly amounts to \$34,878,587. The Conservation Groups are similarly incorrect regarding the "capital cost" figure of \$109,760,060, as this figure provides the Total Capital Cost which accounts for the Total Capital Investment (TCI) for all four DSI potroom scrubbers (\$25,242,560 each) and the TCI for the singular DSI bake oven scrubber (\$8,789,820), which correctly amounts to \$109,760,060.

EPA disagrees with the comment about erroneously combining the costs of controls for the bake oven and potrooms. Appendix G–2 of the Haze Plan states that "in addition to the control equipment, Century's direct capital and operating costs would include constructing and operating a wastewater collection, conveyance, and pretreatment system for wet scrubber blowdown from five scrubbers under the wet scrubber control option scenario." As Century's direct capital and operating costs would also include constructing and operating a potable water piping network to supply all five wet scrubbers with makeup water, EPA finds Century's combined cost analysis for all five wet scrubbers to be reasonable. Regarding the alleged similarities between the Century approach and the Texas approach that was disapproved in 2016, EPA disagrees with the comparison. As stated in the NFRM on the Texas action, "Texas employed a large, superficially refined control set consisting of a mix of large and small sources from a number of different source categories located within varying distances of Class I areas."⁸² This approach is distinguishable from the Century approach that combined cost analyses for two types of sources at the same facility.

There is no requirement in the CAA or the RHR for states to establish bright line cost effectiveness thresholds when evaluating control costs in FFAs. *See* Response 11.a. The CAA and the RHR require states to evaluate the costs of compliance. EPA evaluated South Carolina's conclusion that the units at Century are well controlled for SO₂ and additional controls are not needed for the purpose of remedying any existing anthropogenic visibility impairment at Cape Romain and find it to be reasonable.

To explain the increase in the contingency cost provided in the revised FFA from the original FFA, Century revised this cost to incorporate a change in the method of calculation for Contingency costs from the 6th

⁷⁴ See Section 5 of the CCM, *Table 1.1: Comparison of Wet and Dry Scrubbers*.

⁷⁵ See Section 5 of the CCM, Section 1.2.1.3: *Other Designs*.

⁷⁶ Century matched the target efficiency used for a wet scrubber retrofit installation in South Carolina for a source in a similar industry (electrode production), as well as RACT/BACT/LAER Clearinghouse (RBLC) data from EPA which indicated that a smelter in Kentucky operates a scrubber with a design control efficiency of 93 percent. *See* Section 5.0 of Appendix G–2 of the Haze Plan Submittal.

⁷⁷ The Century FFA uses a DSI efficiency of 90 percent based on vendor information. *See* Section 5.0 of Appendix G–2 of the Haze Plan Submittal.

⁷⁸ 40 CFR 51.308(f)(2)(iii) states that, "[t]he State must document the technical basis, including modeling, monitoring, cost, engineering, and emissions information, on which the State is relying to determine the emission reduction measures that are necessary to make reasonable progress in each mandatory Class I Federal area it affects."

⁷⁹ *See* Haze Plan, Appendix H–3 at 47 (pdf numbering) and H–4 at 9 (pdf numbering).

⁸⁰ *See* spreadsheet included in the docket for this rulemaking titled "Century revised cost analysis.xlsx." The revised cost analysis at an assumed 99 percent control efficiency for wet scrubbers with a five percent interest rate and 30-year life determined the cost effectiveness calculated to be \$7,486 per ton of SO₂ reduction. The difference in costs is due to rounding. *See* Haze Plan at 165.

⁸¹ *See* South Carolina Code § 12–36–2120(17).

⁸² *See* 81 FR 296, 313–314 (January 5, 2016).

edition CCM (published 1995) to the 7th edition CCM (published 2021). The 6th edition of the CCM stated that the contingency cost may be calculated as three percent of the Purchased Equipment Cost,⁸³ while the 7th edition states that the cost may be calculated by multiplying the total direct and indirect costs by a contingency factor⁸⁴ (Century utilized a contingency factor of 0.10). The equations used to calculate the Contingency cost are documented in the 'Notes' section of both the original and revised FFA cost analyses.⁸⁵ As Century revised the Contingency cost to utilize an updated method of calculation, EPA finds the increased value to be justified.

Regarding the claim that there is no support or documentation for numerous costs, EPA finds the costs used in the Century FFA to be appropriately documented and reasonable. The State included all relevant information, justifications used, and support for each cost provided in the cost calculation within Appendix G–2. As discussed above, the RHR does not mandate the level of detail that must be provided for the cost calculations. Additionally, the figures pointed out by the Conservation Groups in Century's FFA each represent costs for not one but five wet scrubbers and were analogous to costs presented by other wet scrubber cost analyses⁸⁶ in Region 4, or provided costs for unique systems, from vendors, using facility-specific parameters.

The Conservation Groups claim that Century does not follow the procedure outlined in the wet packed tower absorber example in the CCM. While EPA's 2019 Regional Haze Guidance recommends that the CCM be used for determining costs, the RHR does not mandate it. EPA's Guidance allows for alternative approaches to cost calculations.

The Conservation Groups assert that undocumented and unjustified costs of concern include: (1) a labor charge of \$1,547,366; (2) charges for various chemicals; and (3) charges of \$846 million and \$681 million for filter cake sludge disposal (FCSD) and reverse osmosis brine reject disposal (ROBRD) costs. EPA carefully evaluated the Haze Plan and the associated record and engaged in a thorough analysis of each

control option, including the underlying cost assumptions used in the calculations for Century. In Table 1 of Appendix G–2 of the Haze Plan, Century documents each line-item of the cost analysis. In this table, Century documents: (1) the labor charge as a Direct Annual Cost of operating the 'Water Supply/Wastewater Collection, Conveyance, and Pretreatment' system; (2) the various chemicals listed by the Conservation Groups as chemicals used to manage the wet scrubber water supply, wastewater collection, conveyance, and pretreatment system, while specifically defining the organosulfide as TMT–15⁸⁷ and describing the polymer as having 40 percent active content; and (3) the FCSD and ROBRD as Annual Disposal Costs. The Conservation Groups also stated that Century failed to justify the use of these chemicals, however all the chemicals listed in the FFA (Lime, Hydrochloric Acid, Polymer, Organosulfide, Ferric Chloride, and Sodium Hydroxide) have valid uses in the treatment of wastewater. Chemicals such as sodium hydroxide and lime are used in order to raise the pH of the wastewater in order to optimize precipitation of metal compounds, while acids, such as hydrochloric acid, are used in conjunction with ferric chloride for chemical precipitation.⁸⁸ Organosulfide chemicals such as TMT are also used to precipitate and remove heavy metals.⁸⁹ Polymers are utilized as a flocculent to aid in the settling process during which precipitated metals are removed from solution.⁹⁰ EPA notes that the \$846 million and \$681 million costs listed by the Conservation Groups for the FCSD and ROBRD, is incorrect as the Table lists these costs as \$845,796, and \$680,952, respectively. EPA's assessment of the wet scrubber found that removal of the \$1,547,366 labor charge, FCSD, and ROBRD costs, and Annual Chemicals costs, only

⁸⁷ TMT–15 refers to the trade name for a 15 percent aqueous solution of sodium trimercaptotriazine.

⁸⁸ See EPA's "Development Document for Final Effluent Limitations Guidelines and Standards for Commercial Hazardous Waste Combustors Chemicals," available at: https://www.epa.gov/sites/default/files/2015-11/documents/chwc-eg_dd_2000.pdf.

⁸⁹ See EPA's "Technical Development Document for Proposed Supplemental Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category," available at: https://www.epa.gov/system/files/documents/2023-03/steam-electric-tdd_proposed_feb-2023_0.pdf.

⁹⁰ See EPA's "Development Document for Final Effluent Limitations Guidelines and Standards for Commercial Hazardous Waste Combustors Chemicals," available at https://www.epa.gov/sites/default/files/2015-11/documents/chwc-eg_dd_2000.pdf.

reduced the cost-effectiveness from \$7,485/ton⁹¹ to \$6,526/ton. South Carolina received these comments regarding "undocumented and unjustified costs" during the state-level comment period on the draft Haze Plan and responded to them.⁹² The State did not alter its plan as a result of these comments, and EPA finds that conclusion to be reasonable.

Concerning the Conservation Groups' assertion that EPA must require South Carolina to either provide support for all calculations or follow EPA's CCM, in addition to revising the costs so that there are separate calculations for the bake oven and potlines, EPA disagrees. South Carolina provides support for all calculations through the information provided in Appendix G–2 of the Haze Plan. As discussed above, while EPA's 2019 Guidance recommends that the CCM be used for determining costs, the RHR does not mandate it. EPA's 2019 Guidance also allows for alternative approaches to cost calculations.

Concerning South Carolina's request to remove existing permit provisions for Century, EPA proposed to approve the Haze Plan without permit conditions for Century, as requested by South Carolina in its June 4, 2025, letter, based on the new URP policy. South Carolina considered the four statutory factors for Century in technical analyses. Subsequently, South Carolina clarified in its June 4, 2025, letter that it is not necessary to include in the SIP any final permit conditions for Century and that statements appearing in its submittal concerning existing or additional measures are no longer applicable. In addition, South Carolina confirmed that it does not intend to submit or include final permit conditions for Century for incorporation into the regulatory portion of the South Carolina SIP. As discussed in the NPRM, because South Carolina considered the four statutory factors for Century and visibility conditions at all Class I areas to which South Carolina contributes are below the URP, South Carolina has demonstrated that it has made reasonable progress for the second planning period without any measures in the regulatory portion of the SIP for Century. For these reasons, EPA's statement that the State's request to incorporate permit conditions into the SIP for Century is moot is not arbitrary

⁹¹ The revised cost analysis at an assumed 99 percent control efficiency for wet scrubbers with a five percent interest rate and 30-year life determined the cost effectiveness calculated to be \$7,485 per ton of SO₂ reduction. See Haze Plan at 165.

⁹² See Haze Plan, Appendix H–3 at 51 (pdf numbering) and H–4 at 9 (pdf numbering).

⁸³ See Section 5 of the 6th Edition CCM, December 1995, Table 1.3 Capital Cost Factors for Gas Absorbers.

⁸⁴ See Section 5 of the 7th Edition CCM, April 2021, Section 1.3.3.2 Installation Cost.

⁸⁵ See the original and revised cost analyses in Appendix G–2 of the Haze Plan.

⁸⁶ See WestRock Fernandina Beach Mill Wet Scrubber Costs in Appendix G–2 of the Florida Department of Environment's 2021 submittal addressing regional haze for the second planning period.

and capricious, nor is EPA's reliance on the State's letters.

Comment 11.c: The Conservation Groups assert that South Carolina's reasonable progress FFA for Cross is inadequate and flawed. First, the Conservation Groups state that Cross did not consider any additional improvements or upgrades to its existing scrubber systems and instead focused its analysis solely on separate add-on control systems. The Conservation Groups state that the justification provided by South Carolina for not considering additional add-on SO₂ controls is a red herring. The Conservation Groups justify their position stating that EPA has long indicated that upgrades to existing FGD (and SCR) systems are likely cost-effective and should be investigated through an FFA. The Conservation Groups assert that scrubber upgrades and/or optimizations for Unit 2 should have been investigated and included as part of the FFA and also assert that the existing scrubber on Unit 2 has not been operating consistently since 2012. They state that the scrubber is required by permit to maintain an 87 percent SO₂ removal efficiency, substantially lower than the 98 percent efficiency that a modern wet scrubber is capable of attaining.

Second, the Conservation Groups assert that Cross, South Carolina, and EPA mistakenly relied on the fact that all four EGUs are equipped with wet FGDs and are meeting the MATS SO₂ emission limits to exclude them from an FFA. The Conservation Groups state that Cross and South Carolina misinterpreted the "effectively controlled" language in the 2019 Guidance, and thus, the source should have evaluated control optimizations for these units in the FFA.

Third, the Conservation Groups assert that Cross failed to consider any NO_x controls as part of the FFA and that the NO_x emission limits for Units 1, 2, and 4 are above the 0.05 lb/MMBtu monthly limit that modern SCR systems can attain. The Conservation Groups state that South Carolina should have required that the SCR systems be evaluated for optimization and/or upgrade. They state that this is especially important since "nitrate concentrations are higher on winter days and are more important for coastal sites [such as Cape Romain] where the 20 percent most impaired days occur during the winter months" and that data from the second planning period demonstrates large nitrate impacts at Cape Romain associated with anthropogenic emissions. Based on this information, the Conservation Groups

state that South Carolina should have made the nitrate threshold lower than the SO₂ threshold because the AoI threshold used by South Carolina requires that nitrate impacts be proportionately larger than SO₂ impacts in order to be selected for PSAT tagging. As such, no sources were tagged for nitrates.

Fourth, the Conservation Groups assert that the only control considered is a switch to a low sulfur coal and that this switch cannot be independently assessed because it depends on confidential data concerning the costs of Cross' current and lower sulfur replacement coals.

The Conservation Groups state that, as a result, South Carolina neglected to require reasonable, cost-effective controls on Cross and that EPA must require South Carolina to conduct an appropriate FFA for Cross, including assessing available reasonable control measures (e.g., permit limits, optimization of equipment efficiency, and equipment upgrades, etc). They state that it is likely to achieve substantial gains very cost-effectively with little to no capital costs by running the existing controls efficiency, using more reagent, and/or setting lower emissions rates.

The Conservation Groups also state that EPA ignored South Carolina's determinations on the measures necessary for reasonable progress, including enforceable permit conditions for Cross, and that EPA's identification of these measures as moot under the new policy without addressing the State's findings or providing a rational explanation is arbitrary and capricious. The Conservation Groups also contend that before EPA incorporates necessary existing permit conditions for Cross into the SIP, EPA must require the State correct the errors in those permit provisions. They claim that the permit conditions in the 2025 SIP supplement significantly differ from those in Cross's updated permit finalized on December 31, 2024. The Conservation Groups also raised issues regarding the practical enforceability of the revised permit provisions for Cross at the state level. Specifically, the Conservation Groups note that South Carolina inappropriately included illegal exemptions from the relevant haze emission limits during periods of start-up, shutdown, and malfunction. The Conservation Groups contend that South Carolina must correctly identify the permit provisions proposed for inclusion in South Carolina's regional haze SIP for Cross.

Response 11.c: EPA disagrees with the Conservation Groups' assertion that South Carolina's FFA for Cross is

inadequate and flawed. Units 1–4 are equipped with wet FGDs and are permitted to comply with the MATS SO₂ emission limit of 0.20 lb/MMBtu. Units 1, 3, and 4 are permitted and required under a consent decree to achieve a 30-day rolling average removal efficiency for SO₂ of at least 95 percent, and Unit 2 is required to achieve a 30-day rolling average removal efficiency for SO₂ of at least 87 percent.^{93,94} The consent decree also required Cross to upgrade the wet FGDs on Units 1 and 2 to increase removal efficiency through upgrades of existing FGD modules in order to meet the SO₂ emission limits specified in the consent decree. EPA analyzed the controls and confirmed that Cross Units 1–4 are equipped with wet scrubber systems that routinely achieve a high SO₂ control effectiveness. From 2017 through 2023, the average yearly SO₂ removal efficiencies were between 96.8 percent and 98.1 percent (Unit 1), between 91.6 percent and 95.5 percent (Unit 2), between 97.2 percent and 98.3 percent (Unit 3), and between 97.6 percent and 98.3 percent (Unit 4).⁹⁵ The typical SO₂ removal efficiency range for wet scrubbers ranges from 90 to 98 percent.⁹⁶ Thus, it is unlikely that an FFA would result in the conclusion that further SO₂ emissions control measures are necessary for reasonable progress in the second planning period. Therefore, EPA finds South Carolina's effective controls demonstration for Cross to be reasonable.

Regarding the comment that Unit 2 has not been operating consistently since 2012, EPA reviewed the recent historical scrubber efficiency data for Unit 2 between 2017 and 2023 and found that the typical average yearly SO₂ removal efficiencies fluctuate between 91.6 percent and 95.5 percent, well above the required control efficiency required by consent decree. While new wet FGD scrubbers can achieve greater than 98 percent SO₂ removal efficiency, Unit 2's wet FGD was installed in 1984, upgraded in 2005 to maintain the 87 percent removal efficiency by June 30, 2006, and designed to meet a limit of a control

⁹³ See Consent Decree, *U.S. v. S.C. Public Service Authority*, Civil Action No. 2:04cv822 (D.S.C., Charleston Division) (filed June 24, 2004) at Paragraphs 64–66. This consent decree is included in the docket for this rulemaking.

⁹⁴ See Cross' title V Permit No. TV-0420-0030, Condition 5.E.18 for the 30-day rolling average removal efficiency for SO₂ for Units 1 through 4. This permit is included in the docket for this rulemaking.

⁹⁵ See footnote 66 regarding EGU scrubber efficiency spreadsheet.

⁹⁶ See Table 1.1 on pages 1–3, Section 5, Chapter 1 of the CCM.

efficiency of up to 91 percent (as required by the consent decree).

EPA disagrees with the assertion that South Carolina misinterpreted the “effectively controlled” language in the 2019 Guidance. As mentioned above, EPA’s analysis confirms that the units are “not uncontrolled or lightly controlled.” Furthermore, these units are subject to the MATS Rule and are each equipped with wet FGDs that routinely achieve high SO₂ control efficiencies. Thus, it is unlikely that an FFA would result in the conclusion that further SO₂ emissions controls (including emissions control measures) are necessary for reasonable progress in the second planning period. EPA also notes that there is no statutory or regulatory requirement to consider all technically feasible measures or any particular measures.⁹⁷ As such, EPA finds that South Carolina’s decision to only conduct a cost analysis for fuel switching to be reasonable.

Regarding the comments concerning NO_x controls and nitrate impacts, EPA has determined that South Carolina’s decision to not evaluate sources selected for SO₂ emission control analyses for a separate NO_x emission control analysis is reasonable for this planning period. See Response 8.

EPA disagrees with the Conservation Groups that the cost information for switching to a low sulfur fuel cannot be independently assessed because it contains confidential data concerning the costs of Cross’ current and lower sulfur replacement coals. Although the specific costs for the current and lower sulfur coal were not explicitly provided in the cost analysis, the overall difference in cost is reasonable and within the values provided in EPA’s “New Coal-Fired Power Plant Performance and Cost Estimates”⁹⁸ as well as within the range based on the recent average coal prices from various locations in the U.S.⁹⁹

EPA disagrees with the Conservation Groups that EPA ignored South Carolina’s determination on the measures necessary for reasonable progress for Cross. EPA proposed to approve the Haze Plan without permit conditions for Cross, as requested by South Carolina in its June 4, 2025, letter, based on the new URP policy. South Carolina considered the four statutory

factors for Cross in technical analyses. Subsequently, South Carolina clarified in its June 4, 2025, letter that it is not necessary to include in the SIP any final permit conditions for Cross and that statements appearing in its submittal concerning existing or additional measures are no longer applicable. In addition, South Carolina never submitted its 2025 SIP Supplement, and it confirmed in its June 4, 2025, letter that it does not intend to submit or include final permit conditions for Cross for incorporation into the regulatory portion of the South Carolina SIP. As discussed in the NPRM, because South Carolina considered the four statutory factors for Cross and visibility conditions at all Class I areas to which South Carolina contributes are below the URP, South Carolina has demonstrated that it has made reasonable progress for the second planning period without any measures in the regulatory portion of the SIP for Cross. For these reasons, EPA’s statement that the State’s request to incorporate permit conditions into the SIP for Century is moot is not arbitrary and capricious.

Comment 11.d: The Conservation Groups assert that South Carolina’s FFA for IP-Georgetown was highly flawed, and therefore, EPA must require the State to correct several alleged errors and cannot finalize approval of the Haze Plan. They claim that EPA must require a NO_x FFA and include emission limitations commensurate with reasonable NO_x controls in the SIP; include emissions limitations in the SIP that cover operational fuel use changes; and require an FFA for the No. 2 Recovery Boiler because the assertions that the unit is effectively controlled are misplaced. They also argue that EPA must require corrections to the “grossly inflated” cost analyses for the power boilers, specifically raising concerns with the use of EPA’s EGUs cost algorithms for wet and dry scrubbers that are limited to EGUs, as IP-Georgetown is not an EGU, and instead use worksheets for industrial boilers. In addition, the Conservation Groups state that EPA should not allow the use of EPA’s spray dryer absorber (SDA) worksheet, as this worksheet is intended for EGUs.

Furthermore, the Conservation Groups assert EPA must not allow for the use of an unjustified retrofit factor and that South Carolina must either require actual documentation that demonstrates the problems the facility would encounter in installing the controls are in fact unusual or revise the FFA using retrofit factors of 1.0. They also state that EPA must require IP-

Georgetown to explain how the boiler’s heat rating was converted from million British thermal units per hour (MMBtu/hr) to megawatts (MW), as this may result in additional corrections that must be made to the scrubber cost-effectiveness calculation. They further allege that EPA must require the removal of the allowance for funds used during construction (AFUDC) costs from IP-Georgetown’s wet and dry scrubber cost-effectiveness calculations, which is not allowed under EPA’s CCM overnight method (citing to *Oklahoma v. EPA*, 723 F.3d 1201, 1212 (10th Cir. 2013), where the court found EPA had reasonable basis for rejecting Oklahoma’s cost estimates that included the AFUDC costs), and the removal of the “additional undocumented very large fee” for an engineering procurement construction (EPC) contract, citing to EPA’s CCM default approach. The Conservation Groups assert that IP-Georgetown can use the “multiple lump sum” contracts that include Engineering and Construction Management Costs without adding the large fee associated with an EPC contract. Lastly, the Conservation Groups assert that EPA must require the use of unit-specific NO_x, SO₂, and PM emissions because the cost-effectiveness calculation is inaccurate and cannot be verified.

The Conservation Groups cite to the 2021 Kordzi Report which provided revised cost analyses using revised inputs (reduced retrofit factor from 1.5 to 1.0, deselected the EPC Contract option, removed the owner’s cost and AFUDC, and revised the Capital Recovery Factor from 0.069 based on a 30-year life and an interest rate of 5.5 percent to 0.053 based on a 30-year life and an interest rate of 3.25 percent). According to the Conservation Groups, the revised cost analysis shows that the wet scrubbers on IP-Georgetown’s power boilers would be cost-effective at \$4,380/ton.

Furthermore, the Conservation Groups assert that EPA improperly proposes to approve South Carolina’s request to remove existing permit measures that are “necessary to make reasonable progress” and prevent future impairment for IP-Georgetown. They argue that EPA’s conclusory statement that incorporation of permit conditions into the SIP is “moot” under the new URP policy is arbitrary and capricious because the 2025 SIP Supplement included finalized permit conditions and proposed to incorporate them into the SIP; the State proposed the 2025 SIP Supplement because it determined that the permit conditions were necessary for reasonable progress, nothing in the record demonstrates that this

⁹⁷ See 2019 Guidance at 29.

⁹⁸ EPA document titled “New Coal-Fired Power Plant Performance and Cost Estimates,” prepared by Sargent & Lundy, (August 27, 2009). This document is included in the docket for this rulemaking.

⁹⁹ “Coal Markets” report issued on October 27, 2025. This document is included in the docket for this rulemaking and also available at <https://www.eia.gov/coal/markets>.

determination is no longer valid, South Carolina and EPA purport to eliminate measures that the State previously deemed necessary to make reasonable progress; the URP policy does not automatically “moot” measures deemed necessary for reasonable progress; and the policy contradicts the CAA and the RHR.

Response 11.d: EPA disagrees with the assertion that South Carolina’s FFA was highly flawed. Regarding the comments concerning a NO_x FFA, EPA has determined that South Carolina’s decision to not evaluate sources selected for SO₂ emission control analyses for a separate NO_x emission control analysis is reasonable for this planning period. See Response 8. With respect to the claim that International Paper-Savannah grossly inflated the power boilers’ cost analyses by incorrectly using EPA’s Retrofit Cost Analyzer (RCA)¹⁰⁰ because this spreadsheet is limited to EGUs and IP-Georgetown is not an EGU, EPA disagrees. EPA’s RCA spreadsheet uses the same equations and methodology as EPA’s CCM, Section 5, Chapter 1, “Wet and Dry Scrubbers for Acid Control.” Furthermore, the spreadsheet also indicates that it “allows users to estimate the capital and annualized costs for installing and operating scrubbers for reducing sulfur dioxide [. . .] from fossil-fuel combustion units and other industrial sources of acid gases.” With that same rationale, EPA disagrees with the Conservation Groups’ claim that EPA’s RCA spreadsheet is only suited for EGUs. The Conservation Groups also assert that this spreadsheet is not viable for emission units with emissions below 0.06 lb/MMBtu. EPA disagrees and notes that in the IPM Model document for “SDA FGD Cost Development Methodology,” this is a recommended value.¹⁰¹ In addition, a value below the floor rate results in a conservatively higher cost-estimate further supporting IP-Georgetown’s decision that an SDA or FGD on the power boilers is not cost-effective.

EPA also disagrees with the Conservation Groups that the use of a retrofit factor of 1.5 was not justified. The FFA for IP-Georgetown states that the costs associated with the increased retrofit factor take into account the challenges associated with the installs such as limited space around the power boilers. Whether the exact retrofit factor was appropriately justified, the wet FGD and the SDA controls were not found by

the State to be cost-effective. Using a retrofit factor of 1.0 would produce a lower cost-effectiveness value (roughly \$13,900 for the SDA and \$8,000 for the wet FGD).¹⁰² South Carolina received this comment during the state-level comment period on the draft Haze Plan and responded to it.¹⁰³ The State did not alter its plan as a result of these comments, and EPA finds that conclusion to be reasonable.

Although the calculations for converting the boiler’s heat rating from MMBtu/hr to MW were not included in EPA’s RCA worksheet, IP-Georgetown provided the information needed to convert the heat input from the heat output given in MMBtu/hr for the power boilers. Each power boiler is rated at 592 MMBtu/hr. The Conservation Groups reference the 2021 Kordzi Report, which state that if the boiler’s heat rating is expressed in terms of heat output, the equivalent conversion is 1 megawatt hour (MWh) is equivalent to 3.413 MMBtu. Using this conversion factor results in a power output of 173.5 MW. The heat input in MW is calculated using the boiler’s efficiency. American Forest & Paper Association’s (AFPA’s) emission control study¹⁰⁴ states that a boiler’s efficiency can be assumed to be 85 percent, except for wood-fired boilers, which can be assumed to have a 65 percent efficiency. In Appendix G–2c of the Haze Plan, IP-Georgetown indicates that the power boilers burn coal, wood/bark, and tire-derived fuel (TDF) and state that “[w]ood/bark and TDF continue to provide about 85% of the heat input to the power boilers.” Using the two efficiencies provided by AFPA and the actual proportion of fuel burned in the power boilers, EPA calculated the weighted average efficiency of the boiler to be 68 percent. This calculated weighted efficiency was multiplied by the power output of 173.5 MW, resulting in 118 MW of power, which is approximately equal to the value used by IP-Georgetown in the cost-effectiveness spreadsheet (118.4 MW).¹⁰⁵ EPA finds IP-Georgetown’s MW value used in the cost analyses to be reasonable and does not agree with the assertion that this may bear additional corrections to the cost-

effective calculations. Furthermore, as discussed above, the RHR does not mandate the level of detail that must be provided in the cost calculations.

EPA agrees with the assertion that AFUDC costs should not be included in IP-Georgetown’s cost-effectiveness calculations for the wet and dry scrubber and that these costs are not allowed under the CCM’s overnight method. South Carolina received and responded to this comment during the state-level comment period on the draft Haze Plan.¹⁰⁶ The State did not alter its plan as a result of these comments, and EPA finds that conclusion to be reasonable.

EPA disagrees with the assertion that South Carolina should remove the fees for using an EPC contract and instead use multiple lump sum contracts that include the Engineering and Construction Management costs. EPA’s CCM does not identify multiple lump sum contracts as a “default” methodology, but instead identifies both options as viable methods to estimate the capital and annual costs. EPA finds that IP-Georgetown’s inclusion of 15 percent EPC fees is reasonable because EPA’s CCM states that costs for turnkey contracts, such as an EPC contract, may be 10 to 15 percent higher than those calculated using a multiple lump sum contract; EPA’s template RCA spreadsheets for EPC projects include a 15 percent EPC fee; and when the “EPC Project” box is unchecked the cost calculations do not include the 15 percent EPC fee.

Additionally, EPA disagrees with the assertion that the cost-effectiveness value is inaccurate because IP-Georgetown did not include unit-specific NO_x, SO₂, and PM emissions. EPA agrees with South Carolina’s focus on SO₂ emissions from its selected sources during this period. See Response 8.

With respect to the assertion that cost-effectiveness was improperly calculated using the total annual cost of the control evaluated (wet FGD and dry FGD) and dividing by the combined tons of SO₂ emissions removed for both power boilers, EPA finds this approach to be reasonable because the total annual cost used includes the estimated cost for one wet FGD or one dry FGD, and if the cost-effectiveness calculations were recalculated to be unit specific rather than combined, the resulting cost-effectiveness value would be significantly higher, further justifying the State’s determination that the costs are not cost-effective.

¹⁰⁰ EPA’s Retrofit Cost Analyzer, see <https://www.epa.gov/power-sector-modeling/retrofit-cost-analyzer>.

¹⁰¹ See https://www.epa.gov/system/files/documents/2024-05/13527-002-sda-fgd-cost-methodology_final_march-2024.pdf.

¹⁰² See spreadsheet titled “IP-Georgetown revised costs.xlsx,” in the docket for this rulemaking. Minor differences in the cost compared to what was submitted by IP-Georgetown in Appendix G–2g of the Haze Plan can be attributed to rounding.

¹⁰³ See Haze Plan, Appendix H–3 at 52 (pdf numbering) and H–4 at 10 (pdf numbering).

¹⁰⁴ AFPA’s emission control study is included in Appendix G–2 of the Haze Plan.

¹⁰⁵ See Table B–1 of Appendix G–2c of the Haze Plan at 258 (pdf numbering).

¹⁰⁶ See Appendix H–3 at 52–53 (pdf numbering) and H–4 at 10 (pdf numbering) to the Haze Plan.

For the above reasons, EPA thus disagrees that adopting wet scrubbers for the power boilers would result in the wet scrubbers being cost-effective at \$4,380/ton. EPA evaluated each assumption used in the cost analyses as part of the pre-hearing process and throughout the Haze Plan development process.

Based on the aforementioned responses to each of the Conservation Groups' comments, EPA agrees with the State's conclusions that no measures for IP-Georgetown are necessary for reasonable progress.

EPA disagrees with the Conservation Groups that EPA is improperly proposing to approve South Carolina's request to remove the measures identified as necessary make reasonable progress and prevent future impairment for IP-Georgetown from South Carolina's regional haze SIP. EPA proposed to approve the Haze Plan without permit conditions for IP-Georgetown, as requested by South Carolina in its June 4, 2025, letter, based on the new URP policy. South Carolina considered the four statutory factors for IP-Georgetown in technical analyses. Subsequently, South Carolina clarified in its June 4, 2025, letter that it is not necessary to include in the SIP any final permit conditions for IP-Georgetown and that statements appearing in its submittal concerning existing or additional measures are no longer applicable. In addition, South Carolina never submitted its 2025 SIP Supplement, and it confirmed in its June 4, 2025, letter that it does not intend to submit or include final permit conditions for IP-Georgetown for incorporation into the regulatory portion of the South Carolina SIP. As discussed in the NPRM, because South Carolina considered the four statutory factors for IP-Georgetown and visibility conditions at all Class I areas to which South Carolina contributes are below the URP, South Carolina has demonstrated that it has made reasonable progress for the second planning period without any measures in the regulatory portion of the SIP for IP-Georgetown. For these reasons, EPA's statement that the State's request to incorporate permit conditions into the SIP for IP-Georgetown is moot is not arbitrary and capricious.

Comment 11.e: The Conservation Groups argue that approval of the Haze Plan without any of the permit provisions that the State determined are necessary to make reasonable progress is arbitrary, capricious, and an abuse of authority because South Carolina substantively revised the Haze Plan via letters dated December 2024 and June 2025, EPA's NPRM is based on the new

policy, and the new policy violates the CAA and the RHR. In so doing, the Conservation Groups assert that South Carolina and EPA failed to follow the public notice requirements for SIP rulemakings under the CAA. They state that EPA's final rule must only reflect the SIP revision package that was subject to the CAA's rulemaking procedures.

Regarding the alleged violation of the substantive requirements of the CAA and RHR based on the new URP policy, the Conservation Groups claim that EPA has repeatedly explained, including in its NPRM, that measures determined to be necessary to make reasonable progress toward remedying existing impairment and preventing future impairment must be included as federally enforceable measures in the regulatory portion of the State's SIP. They assert that the 2022 Plan explains that existing permit measures for Century, IP-Georgetown, Cross, and Winyah were all necessary to make reasonable progress and prevent future impairment, and so, the State proposed to incorporate those measures into the regulatory portion of the SIP as required by the CAA and RHR. They also state that South Carolina did not provide any analysis or claim that the permit conditions for Century, IP-Georgetown, Cross, or Winyah were no longer necessary for reasonable progress or to prevent future impairment in its December 2024 and June 2025 letters and that EPA did not provide such an analysis in the NPRM.

Regarding public notice, the Conservation Groups contend that a SIP revision is only effective after the state adopts the revision following reasonable notice and public hearings and EPA adopts the plan via its rulemaking procedure which involves public notice and comment. They then argue that states do not have an independent power of amendment, citing to *Nat. Res. Def. Council, Inc., Project on Clean Air v. EPA*, 478 F.2d 875, 883 (1st Cir. 1973), supplemented 484 F.2d 1331. The Conservation Groups assert that South Carolina improperly removed permit measures that are necessary to make reasonable progress from the Haze Plan without providing an opportunity for notice and comment and that EPA did not include any of the existing permit measures that the State determined were necessary to make reasonable progress and prevent future impairment for Century, IP-Georgetown, Cross, and Winyah. The Conservation Groups claim that South Carolina substantively revised the Haze Plan via one letter withdrawing the permit provisions for Century and another

letter withdrawing the permit provisions for IP-Georgetown, Cross, and Winyah without the opportunity for public comment at the state level. They also state that rather than providing comment on a proposal to remove permit provisions from the Haze Plan, South Carolina provided an opportunity for public comment on a proposed 2025 SIP Supplement to incorporate updated permit provisions for IP-Georgetown, Cross, and Winyah into the regulatory portion of the SIP and that the Conservation Groups submitted multiple public comments on that proposal.

Response 11.e: EPA disagrees with the Conservation Groups' assertion that approval of the Haze Plan under the new URP policy without any of the permit provisions is arbitrary, capricious, and an abuse of authority and does not comply with the substantive requirements of the CAA and RHR. EPA proposed to approve the Haze Plan without permit conditions, as requested by South Carolina in its June 4, 2025, letter, based on the new URP policy. South Carolina considered the four statutory factors for Century, IP-Georgetown, Cross, and Winyah in technical analyses. Subsequently, South Carolina clarified in its June 4, 2025, letter that it is not necessary to include in the SIP any final permit conditions for these evaluated facilities and that statements appearing in its submittal concerning existing or additional measures are no longer applicable. In addition, South Carolina confirmed that it does not intend to submit or include final permit conditions for these facilities for incorporation into the regulatory portion of the South Carolina SIP. As discussed in the NPRM, because South Carolina considered the four statutory factors for these facilities and visibility conditions at all Class I areas to which South Carolina contributes are below the URP, South Carolina has demonstrated that it has made reasonable progress for the second planning period without any measures in the regulatory portion of the SIP for these facilities.

EPA also disagrees with Conservation Groups' assertion that South Carolina failed to follow the public notice requirements for SIP rulemakings under the CAA and that South Carolina must re-notice the Haze Plan. South Carolina provided a 40-day public comment period on the Haze Plan, and EPA provided a 60-day public comment period on its NPRM. South Carolina sufficiently and fairly apprised the public of the issues involved which encompassed whether any measures were necessary for reasonable progress,

whether enforceable measures such as permit conditions should be incorporated into the SIP for any source, and the content of those permit conditions. In fact, the Conservation Groups submitted multiple public comments on permit conditions in both South Carolina's and EPA's public comment periods. Thus, whether any permit conditions should be incorporated into the SIP at all, and the content of those permit conditions, was at issue during the state-level public comment period.

Consequently, the Conservation Groups are not prejudiced by South Carolina's alleged failure to provide a second round of notice and comment at the state level. The Conservation Groups already provided a 90-page comment letter to the State with multiple technical exhibits advocating for their desired Haze Plan and addressing the enforceability of the permit conditions. Regarding public participation on the new policy, EPA developed this policy, not South Carolina, and the instant federal rulemaking provided a sufficient forum for public participation on the application of that new policy to the Haze Plan. EPA, as the author of the policy, is in the best position to address comments on it, and the Agency has responded to the approximately 16 pages of adverse comment on the new policy submitted by the Conservation Groups.

The relevance of the comment concerning the State's proposed 2025 SIP supplement is unclear. South Carolina never submitted a final supplement with enforceable permit conditions to EPA because the State later requested that the Agency approve its SIP revision under the new policy. As discussed in the NPRM and NFRM, under the new policy, South Carolina has demonstrated reasonable progress without the need for additional measures in the LTS.

EPA also disagrees that South Carolina and EPA violated the substantive requirements of the CAA and RHR. South Carolina clarified in its June 4, 2025, letter that it is not necessary to include in the SIP any final permit conditions for the evaluated facilities and that statements appearing in South Carolina's submittal concerning existing or additional measures are no longer applicable. EPA is approving the Haze Plan under the new policy, and that policy is consistent with the CAA and RHR for the reasons discussed in the NPRM and in Responses 1–4, above.

Comment 12: The Conservation Groups state that the CAA and RHR require states to consult with the FLMs

that oversee the Class I areas impacted by a state's sources, SIP revisions must meet certain procedural and consultation requirements, and consultation must be early enough for state officials to meaningfully consider the views expressed by the FLMs. They contend that the RHR further requires states to provide for continuing consultation between the states and the FLMs and to meaningfully address the FLMs' comments in the proposed SIP. They further contend that consultation is not a box checking exercise; it is a mandatory, iterative process requiring the state to meaningfully consider and incorporate into the SIP the concerns of the agencies responsible for managing the Class I areas' resources impacted by pollution from the state.

The Conservation Groups allege that South Carolina improperly failed to engage in FLM consultation on its decision not to submit the 2025 SIP Supplement to EPA and to instead request that EPA remove from the Haze Plan existing permit provisions that the State had determined were necessary to make reasonable progress and prevent future impairment. They claim that this alleged failure is contrary to the CAA and RHR's consultation requirements and that the State's decision was a significant revision to the Haze Plan. They state that “[a]lthough South Carolina engaged in formal consultation with FLMs on its proposed 2025 SIP Supplement, nothing in the record suggests that South Carolina consulted with the FLMs regarding its decision to withdraw these permit conditions or its broader decision not to submit the 2025 SIP Supplement, as required by the RHR.”

Response 12: EPA disagrees with this comment. As discussed in the NPRM, South Carolina provided its draft Haze Plan to the FLMs on July 27, 2021, prior to the start of the public comment period which opened on November 26, 2021, and included a summary of the conclusions and recommendations of the FLMs in the proposed plans issued for public review, thereby satisfying the consultation requirements of CAA section 169A(d) and 40 CFR 51.308(i)(2) for the second planning period.

As discussed in Response 11.e, EPA proposed to approve the Haze Plan without permit conditions based on the new URP policy, as requested by South Carolina in its June 4, 2025, letter. South Carolina sufficiently and fairly apprised the FLMs of the issues involved, and thus, whether any measures were necessary for reasonable progress, whether enforceable measures such as permit conditions should be incorporated into the SIP for any source,

and the content of those permit conditions, was at issue during FLM consultation. Furthermore, pursuant to 40 CFR 51.308(i)(2), South Carolina's consultation process provided the opportunity for the FLMs to discuss their assessment of impairment of visibility in any mandatory Class I area and recommendations on the development and implementation of strategies to address visibility impairment.

Consequently, the FLMs are not prejudiced by South Carolina's alleged failure to provide a second round of consultation. The FLMs already provided comments to the State advocating for their desired Haze Plan. Regarding public participation on the new policy, EPA developed this policy, not South Carolina, and the instant federal rulemaking provided a sufficient forum for public participation on the application of that new policy to the Haze Plan. EPA, as the author of the policy, is in the best position to address comments on it. For these reasons, no further FLM consultation was required on the Haze Plan. *See* Response 11.e regarding the irrelevance of the State's proposed 2025 SIP supplement.

Comment 13: The Conservation Groups state that EPA did not analyze how haze-forming emissions from in-state sources impact communities surrounding these facilities. They maintain that regional haze plans have significant potential to achieve co-benefits for people and that pollution reductions required by the regional haze program could reduce disproportionate air pollution burdens in the surrounding communities.

Additionally, the Conservation Groups state that the same pollutants that travel hundreds of miles to obscure scenic views at National Parks also contribute to disparate health impacts for people living closest to polluting facilities. They also state that these polluting facilities are often located in low-income communities and communities of color. They further state that “[s]tudies have also found that those living in communities of color and low-income communities tend to experience higher levels of PM and NO_x pollution than other communities. These adverse health effects are particularly problematic for disproportionately impacted communities, as residents in these communities tend to have less access to quality health care to treat the health impacts of environmental pollution when they arise.” Finally, the Conservation Groups state that EPA has explained that states can consider these community impacts in their FFAs under

the statutory “non-air quality environmental impacts” factor and that EPA “should consider the impacts from the South Carolina facilities discussed above and explain how a strong Regional Haze Plan can mitigate harm to communities.”

Response 13: EPA disagrees with this comment. Neither the CAA or the RHR requires states or EPA to consider the impacts of pollution on communities near potentially affected facilities when developing or reviewing a regional haze plan.

Comment 14: EPA received comments from the MANE-VU, disagreeing with “EPA’s use of the URP as a factor in finding a state has “presumptively demonstrated” reasonable progress in its haze SIP.”¹⁰⁷ First, MANE-VU states that section 169A(g)(1) of the CAA sets forth the four factors a state must apply in evaluating potential emission reductions from sources within its borders. They then note that “EPA now invokes an extra-statutory fifth factor, the URP” which “[a]s framed by the EPA, . . . can override a statutory four factor analysis finding that while additional requirements placed on visibility-impairing sources constitute ‘reasonable progress,’ these can be dismissed because the impacted Class I area is below the URP.” MANE-VU notes that “[b]ecause the URP is a regulatory creation outside the CAA section 169A(g)(1) definition of determining reasonable progress, . . . the URP as a factor to supersede a statutory four factor analysis is not permissible.” MANE-VU states that “CAA section 169A(g)(1) explicitly defines how to determine reasonable progress, and the EPA has received no authority from Congress to impose an additional overriding regulatory criterion that goes beyond the statutory factors [see, e.g., *Loper Bright Enterprises, et al. v. Raimondo, et al.* 603 U.S. 369 (2024)].”

Similarly, MANE-VU states that “EPA ‘believes’ that its change in policy to use the URP as a metric ‘aligns with the purpose of the statute and RHR, which is achieving ‘reasonable’ progress, not maximal progress, toward Congress’ natural visibility goal.’” See 90 FR 36017. Based on this understanding, MANE-VU claims that “EPA could

dismiss requirements to achieve progress below the URP because it would be considered “maximal progress” even if “reasonable progress” as determined using the four Clean Air Act statutory factors would result in greater progress than the URP,” saying that, “[t]he URP metric is . . . an impermissible reframing of “reasonable progress” from what Congress intended.”

Additionally, MANE-VU remarks how the URP is not a “safe harbor” from reducing further emissions but is rather a straight-line tracking metric from the 2000–2004 baseline to the 2064 natural visibility goal set by EPA in regulation. They say that the RPG, according to the CAA and the RHR at 40 CFR 51.308(d)(1), are established by states to improve visibility on most impaired days and ensure no degradation in visibility on clearest days. They insist that the established RPGs are set to achieve incremental improvement in visibility to meet the 2064 goal and that the URP “is merely an “upper bound” measuring stick to indicate whether the rate of improvement remains on track.” MANE-VU states that EPA now invokes the URP as the determinative metric rather than the state-determined RPGs for their Class I areas. MANE-VU acknowledge that the neither the URP, nor the RPGs are enforceable metrics, and they assert that, “it seems incongruous the EPA it seems incongruous that EPA would opt for a URP untethered from the CAA and ignore the extensive work of the states.”

Response 14: For the reasons discussed in Responses 1–4 regarding the URP policy, EPA disagrees with MANE-VU’s comments.

Comment 15: EPA received comments from the Augusta Aiken Audubon Society, the Coalition to Protect America’s National Parks, NPCA, the South Carolina Environmental Law Project, and the Waccamaw Audubon Society in opposition to EPA’s proposed approval of South Carolina’s Haze Plan. These Commenters claim that the Haze Plan would allow for more than 40,000 tons of uncontrolled haze-causing pollutants to continue to be released each year. They assert that due to a “flawed methodology that ignored” NO_x and PM emissions and “exempted multiple large polluting facilities from review,” South Carolina improperly concluded that “almost no new reductions in pollution are warranted.”

These Commenters further assert that the Haze Plan does not comply with the CAA and EPA is incorrectly approving it. Moreover, they insist that EPA’s reliance on a “new policy” is also a violation of the CAA. They also allege

that the new policy violates the CAA, reverses EPA’s longstanding position that the URP is not a safe harbor, and is inconsistent with existing EPA policy and actions across other EPA regions.

Lastly, these Commenters note that South Carolina did not finalize a SIP supplement that included permit provisions for multiple facilities and that instead of submitting the supplement to EPA, the State requested that the Agency approve its Haze Plan under the new policy without permit conditions. They claim that EPA is letting South Carolina off the hook for making reasonable progress because the Agency is approving the Haze Plan without permit conditions that the State had previously concluded were necessary to make reasonable progress.

Response 15: EPA disagrees with these comments. The Commenters do not provide any explanation as to how the Haze Plan would allow for more than 40,000 tons of uncontrolled haze pollutants to be released each year; why the State’s methodology is flawed; why the plan does not comply with the CAA; and why the URP policy is inconsistent with the CAA, existing policy, and actions across other regions. Nonetheless, EPA refers the commenters to the responses in this NFRM including Response 7.a regarding the State’s source selection methodology and Response 8 regarding the focus on SO₂ controls; Responses 1–4 regarding the URP policy; and Response 11.e regarding permit conditions.

III. Final Action

EPA is approving South Carolina’s March 3, 2022, SIP revision as satisfying the regional haze requirements for the second planning period contained in 40 CFR 51.308(f).

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 CAA 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 that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);

¹⁰⁷ MANE-VU is a RPO that consists of representatives from Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Penobscot Nation, Rhode Island, Saint Regis Mohawk Tribe, and Vermont. RPOs coordinate efforts and resources to evaluate technical information and develop air quality plans across tribes and states. However, the September 29, 2025, letter represents only the opinions from the non-federal and non-tribal partners.

- Is not subject to Executive Order 14192 (90 FR 9065, February 6, 2025) because SIP actions are exempt from review under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

Because this Haze Plan merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law, this Haze Plan for the State of South Carolina does not

have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). Therefore, this action will not impose substantial direct costs on Tribal governments or preempt Tribal law. The Catawba Indian Nation (CIN) Reservation is located within the boundary of York County, South Carolina. Pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120 (Settlement Act), “all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and Reservation and are fully enforceable by all relevant state and local agencies and authorities.” The CIN also retains authority to impose regulations applying higher environmental standards to the Reservation than those imposed by state law or local governing bodies, in accordance with the Settlement Act.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 9, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and

shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

Dated: December 2, 2025.

Kevin McOmber,
Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart PP—South Carolina

■ 2. In § 52.2120(e), amend the table by adding an entry for “Regional Haze Plan—Second Planning Period” at the end of the table to read as follows:

§ 52.2120 Identification of plan.

*	*	*	*	*
(e)	*	*	*	*

Provision	State effective date	EPA approval date	Explanation
* * *	*	*	*
Regional Haze Plan—Second Planning Period	3/3/2022	12/11/2025, 90 FR [Insert Federal Register page where the document begins].	

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